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臨床研究ならびに医療における手術・手技にかかる国内外の規制の調査研究

手術・手技にかかる諸外国の法規制等の研究

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研究要旨

目的：手術・手技に関する先進諸国の規制の現状を把握し、わが国の法制度への示唆を得ること。

方法：文献および関係機関のヒアリングを行い、イギリス、フランス、ドイツ、米国における手術・手技にかかる研究および診療の規制の状況について調査した。

結果：いずれの国においても、医薬品および医療機器を用いた手術・手技の研究については法的規制が整備されていたが、これらを用いない場合の研究は法的規制の対象とならない場合が多かった。診療として実施される場合、保険償還上規制対象となる事例、医療機関単位での管理目的で審査・承認が行われる事例がみられたが、研究と診療の明確な区分は困難であり、効果・安全性が十分に確認されない状況で新規手術・手技が用いられる可能性があることが明らかになった。その一方で、英国 NICE/NHS による新規侵襲的治療プログラムや、米国大学における（累積）症例報告の研究としての扱い規定など、これらの課題への解決に向けた試みも見られた。また、新規手術・手技の導入および研究・長期評価を行うプロセスが開発・提案され EU を含む一部公的機関においても利用が開始されていた。

結論：研究と臨床的導入（治療）を明確に区分し、監視対象とすることは困難であるが、手術・手技の特性を考慮しつつ、診療上導入された新規医療技術の評価を行い、その結果を評価、さらには共有・公開する手順・制度の構築が望まれており、海外ではいくつかの先駆的な試みが見られた。臨床導入の初期の段階からの登録と継続的な評価体制の構築、また診療・研究の評価を行い知識化していくための課題整理は、安全かつ効果的な新規手術・手技の導入において有効であると考えられ、わが国の制度設計を行う場合に参考にすべきと考えられた。

A. 研究目的

手術・手技の研究および診療における監視・規制については、医薬品、医療機器等のそれらと比較して明確でない場合が多い。手術・手技に関する先進諸国の監視・規制の現状を把握し、わが国の今後の法制度の整備への示唆を得ることを目的とした。

B. 研究方法

文献調査と関係機関のヒアリングにより調査を実施した。調査対象はわが国と医療・研究レベルが近くまた診療・学術上の交流も多い国であること、また医薬品・医療機器の開発研究・臨床試験の監視制度を整備すると共に、手術・手技に関する監視・規制についての議論が近年もたれていることが過去の調査より把握されている米国、英国、フランス、ドイツを対象とした。

1. 文献調査

Medline 等のデータベース、欧米諸国の規制当局および主要外科系学会のウェブサイト等を検索し、手術手技の実施、実施者、実施施設に関する法令および指針。以下の資料を収集した。
手術手技に関連する臨床研究の規制および指針（被験者保護、質の標準化、監視の観点から）

2. 関係機関のヒアリング

わが国と医療・研究レベルが近くまた診療・学術上の交流も多い国であること、また医薬

品・医療機器の開発研究・臨床試験の監視制度を整備すると共に、手術・手技に関する監視・規制についての議論が近年もたれていることが過去の調査より把握されている米国、英国、フランス、ドイツを対象とした。実施期間は 2019 年 1 月から 3 月で、必要に応じてメールによるフローアップを行なった。

国・地域	機関名
ドイツ	連邦保健省（BMG） 連邦合同委員会（G-BA） 連邦教育・研究省（BMBF） 連邦医薬品医療機器庁（BfARM） 臨床研究コーディネーションセンターネットワーク（KKSN） ベルリン大学（シャリテ病院） ハイデルベルグ大学
フランス	高等保健機構（HAS） フランス保健省（DGS・DGOS） フランス医薬品安全庁（ANSM） パリ大学（デカルト）・ジョルジュポンピドー欧州病院 パリ政治学院（SciencesPo）
英国	国立健康研究所（NIHR） 国民保健サービス（NHS） 国立医療技術評価機構（NICE） 医療研究機構（HRA） ブリストル大学 オックスフォード大学（IDEAL Collaboration） サウザンプトン大学 インペリアル・カレッジ・ロンドン レスター大学
米国	国立衛生研究所（NIH） 米国食品医薬品局（FDA） 連邦被験者保護局（OHRP） 米国外科学会（ACS） ハーバード大学 コーネル大学 ペンシルベニア大学 ジョンスホプキンス大学 デューク大学

表 1　調査対象国・機関

3. 調査項目

- 手術手技の実施、実施者、実施施設に関する法令および指針
- 手術手技に関連する臨床研究の規制および指針（被験者保護、質の標準化、監視の観点から）
- 手術手技に関する臨床研究の国別の実施状況（国際共同研究を含む）と介入の類型化（機器、術式、管理体制など）
- 手術手技に関連した被験者保護および生命倫理、研究倫理の観点から問題となった事例
- 間接的に手術手技を規制する規制法令、指針等

（倫理面への配慮）

本研究では、個人データ等を扱っていないので倫理面への配慮は必要ない。

C. 研究結果

1. イギリス（イングランド）

1）一般的な研究規制の概要

医薬品および医療機器を扱う研究は、それぞれ臨床試験規則（Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004), (Amendment) (EU Exit) Regulations 2019 No. 744）、医療機器規則（Medical Devices Regulations (2002), Medical Devices (Amendment) Regulations 2008 No 2936）の各法令により規定される。手術・手技を含む医薬品または医療機器を用いない研究については法的規制の対象外である。

新規手術・手技を研究として導入する場合は、医療研究機構（Health Research Authority, HRA）の規定を遵守し、倫理委員会（Research Ethics Committee）の審査・承認を得る必要がある。当該行為が研究（Research）に該当するか否かは HRA により定義が定められており、Research 以外（Service Evaluation、Audit、Usual care）に分類される場合は、倫理委員会による事前の承認は不要である。

法令以外の規定として、General Medical Council (GMC)による Good Medical Practice および Good Practice in Research に研究に関する規定

が定められている。また、王立外科学会（Royal College of Surgeons）の Good Surgical Practice にも研究に関する規定がある。

２）研究登録

イギリスには WHO の Primary Registry は設置されていない。医薬品、医療機器の研究についてはそれぞれ EU-CTR、EUDAMED に登録されるが、手術・手技の研究については登録義務はない。

３）手術・手技の導入に関する規制

手術・手技を対象とした法令や指針は定められていない。

４）新規手術・手技の定義および診療と研究の類型化

新規手術・手技に関する明確な定義はない。当該行為が研究（Research）に該当するか否かは HRA により定義が定められており、Research 以外（Service Evaluation、Audit、Usual care）に分類される場合は、倫理委員会による事前の承認は不要である。既存治療の改変や手術・手技を研究の一部として行うか否かについては、医師の裁量に委ねられている部分が大きい。

研究の枠組以外で新規手術・手技が導入される場合については、National Institute for Health and Care Excellence (NICE)により、Intervention procedures guidance が策定されており、一部の NHS Trust（NHS の医療機関の経営単位）では、このガイダンスのもとに新規手術・手技の評価委員会（New Interventions Procedure Committee などと呼ばれる）を設置し、導入の可否の判断および導入後の事後評価を行っている。この場合の新規性は NHS トラスト・施設単位で定められ、既存の手術・手技を当該施設で初めて実施する場合なども含まれる。また、申請すべき手術・手技に関する規定はなく、申請するか否かは医師の判断に委ねられている。

NHS トラストによっては、手術・手技を含め新規医療（あるいは既存治療の改変）の事前審査を求め、またその治療結果について委員会への報告を求める規則を有する。委員会は、その評価に基づいて、当該医療をトラスト内で継続して実施することの許認可を行うものである。

５）手術・手技の研究に関する近年の動向

オックスフォード大学を中心とした IDEAL Collaboration は、より効果的かつ安全な新規手術・手技の導入に向けた臨床研究のための枠組と推奨（IDEAL Framework and Recommendations）を示し、手術・手技の研究推進への基盤整備を進めている。例えば、

National Institute of Healthcare Research （NIHR）の Surgical Technology Evaluation Portal は、医療機器製造者等と NHS の外科医（研究者）をマッチングして、新規医療機器・医療技術の研究開発を推進するプログラムだが、研究推進のプロセスで IDEAL Framework を利用している。

2. フランス

１）一般的な研究規制の概要

人を対象とする臨床研究は、医薬品、医療機器に限らず、手術・手技を対象とした研究や観察研究を含めて Code de Santé publique（CSP）による規制対象となる（2012 年の改正法 loi n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine、通称ジャルデ法。l’ordonnance n° 2016-800 du 16 juin 2016 により修正の後施行）。これにより、研究はリスクに応じて以下の３区分に分類され、段階的な規制が定めれらている（Code de la Sante Public（CSP）L.1121-1）。

1. 通常の医療では正当化できない介入を伴う介入研究
2. 軽微なリスクおよび拘束しか伴わない介入研究（具体的なリストは保健大臣がデクレ（命令）により定める）
3. 実施する行為および使用する製品がすべて通常の使用の範囲内で行われ、リスクや拘束を伴わない非介入研究

上記１に該当する研究は、研究開始に先立って倫理委員会に相当する人保護委員会（Comités de Protection des Personnes, CPP ）の好意的な意見（favorable opinion）と規制当局である国立医薬品・医療用品安全管理機構（Agence Nationalede Sécurité du Médicament et des Produits de Santé, ANSM）の承認が必要となる。これに対して、上記２または３に該当する研究は、CPP の好意的な意見を得られれば、規制当局への申請を行わずに研究を開始することができる（CSP L.1121-4）。なお、データベース等を

用いる観察研究については CPP の審査は不要であり、保健医療分野の研究と評価の専門委員会（Comité d'Expertise pour les Recherches, les Etudes et les Evaluations dans le domaine de la Santé, CEREES）の意見を得た上で、情報処理と自由に関する国家委員会（Commission Nationale de l'Informatique et des Libertés, CNIL）の承認を得ることで実施することができる（loi du 26 janvier 2016 de modernisation de notre système de santé prévoit により規定)。

法令による規制の他、フランス医師会（Conseil National de l'Ordre des Médecins）による医療倫理規定（Le code de déontologie médicale）があり、第 15 条に人を対象とした研究に関する倫理規定が定められている。

２）研究登録

フランスには WHO の Primary Registry は存在せず、臨床研究の登録も義務付けられていない。

３）手術・手技の導入に関する規制

社会保険制度による国民皆保険であり、保険が適用される診療行為については高等保健機構（Haute Autorite de Sante, HAS）が効果と安全性、医療技術評価をおこなった上で支払い対象とするか判断する（CSP, L1151-1～L1151-3)。支払い対象として承認された後、保健製品経済委員会(Comite Economique de Produits de Sante, CEPS)が関連企業との協議のもとで価格を設定し、疾病保険金庫全国連合(Union National des Caisses d'Assurance Maladie, UNCAM)が支払い率を定める。

保健省が保険診療の対象となる医薬品および医療機器のリスト、UNCAM が診療行為のリスト（いずれもポジティブリスト）を作成し、確定する。支払い対象可とされた場合でも、長期的な予後などについては不明な場合も少なくないが、そのような場合は、post-registration study を行う（Code de la Sécurité Sociale (CSS), L163-18)。

４）新規手術・手技の定義および診療と研究の類型化

保険診療としての導入に際しては上記の規制があるが、自由診療として実施される場合には法令上の監視規則は存しない。また、ある手術手技が、新規・革新的なものであるか既存手術・手技の枠内（支払対象としての範囲内とも解される）にあるものかに関する明確な規定・判断基準はなく、この観点から言えば、新規の手術・手技の導入にかかる直接的な法的規制はない。医師の倫理指針を遵守した行動が求められるのみである。

医療における技術革新（innovation）の推進目的で、近年いくつかの例外的な制度が設けられている。DGOS は innovation を「初めて普及、販売、商品化された診断、治療、スクリーニングの技術であり、臨床研究により効果と安全性が検証されたものであり、医薬品及び医療機器に関しては製造販売許可が得られたもの」と定義している(Instruction n° DGOS/PF4/2014/33 du 28 janvier 2014)。なお、技術的なものだけでなく、診療体制などの組織的なものも、イノベーションの対象とみなされる。

DGOS によると、医療または手術・手技のイノベーションは以下の要件を満たすものとされる。

- 単なる技術の進歩以上の新たな特徴を示すもの
- 普及の前段階にあること
- 患者及び医療従事者の使用に関連したリスクが研究により評価されていること
- 臨床的なベネフィットが大きく、現状では満たされていない医療ニーズに答えるものであること、または医療費を大幅な削減を可能にする臨床的ベネフィットがあること

新規手術・手技を保険による償還対象とするか否かの決定は、HAS の審査・判断により行われる。償還対象となった診療行為のうち、長期的な予後などについて十分な知見が得られていない場合は、臨床導入後も継続評価が行われる。

一定の要件を満たす革新的な医療機器または手術・手技のうち、臨床的ベネフィットの評価が不十分だが、潜在的な効果が期待されると判断された場合は、期間限定で試験的な臨床導入が許可され、公的助成により臨床的ベネフィットの継続評価の対象となる（Forfait Innovation と呼ばれ、英語では innovation package と訳される)。また、革新的な医療機器や手術・手技のうち、技術的、経済的な理由等により適用範囲を限定すべきと判断された場合

は、提供可能な医療機関、医師を限定して償還対象とする枠組みもある（CSP L1151-1）。

3. ドイツ

１）一般的な研究規制の概要

医薬品および医療機器を扱う研究は、それぞれ医薬品法（Arzneimittelgesetz, AMG）、医療機器法（Medizinproduktegesetz, MPG）の各法令により規定され、各法令は該当の EU 規則に対応している。手術・手技を含む医薬品または医療機器を用いない研究については法的規制の対象外である。

法令以外の規制として、ドイツ連邦医師会による「医師の職業規定」（(Muster-)Berufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte (Stand 2018)。連邦レベルの基本モデルをもとに州単位で作成される）の 15 条に研究に関する規定が定められている。同条は 1)人または特定できる人由来の試料・データを用いる研究に対する事前の倫理委員会による審査の義務付け、2)研究結果出版時の利益相反の開示、3)ヘルシンキ宣言（人間を対象とする医学研究の倫理的原則）の遵守、の３項からなる。

２）研究登録

WHO の Primary Registry として German Clinical Trials Register (Deutschen Register Klinischer Studien, DRKS)が設置されている。臨床試験の DRKS への登録について法的な定めはない。しかし、研究助成機関（MBMF や DFG など）により登録が求められる場合がある。主要な助成機関である連邦教育・研究省（Bundesministerium für Bildung und Forschung, BMBF）、ドイツ研究振興協会（Deutsche Forschungsgemeinschaft, DFG）などの規定により登録が求められる場合がある（なお、ドイツでは連邦保健省（Bundesministerium für Gesundheit, BMG）は研究助成を行なっていない）。

３）手術・手技の導入に関する規制

手術・手技を対象とした法令や指針は定められていない。

４）新規手術・手技の定義および診療と研究の類型化

新規手術・手技に関する明確な定義はない。研究と診療の区分についても明確な区分はなく、医師等の判断による。当該手術・手技を研究として行う場合、医薬品または医療機器を扱う場合は上述の法令による規制対象となるが、例えば、CE マーク認証取得済みの医療機器を用いた研究で、当該医療機器を認証対象の目的で使用し、かつ侵襲や負荷の大きい実験でない場合は、法令による規制対象外となり（MPG §23b）、法令上は、倫理委員会による審査および認証機関への届出の対象外となる。医薬品、医療機器のいずれも用いない手術・手技に関する研究についても法令上の規制はない。しかし上述の「医師の職業規定」にある通り、規範上は研究実施に先立って倫理委員会の審査・承認を得て実施することが求められる。

新規手術・手技を公的医療保険 Gesetzliche Krankenversicherung（GKV）による償還対象とするか否かについては、最高意思決定機関であるドイツ連邦合同委員会（Gemeinsame Bundesausschuss, G-BA）の審査・判断の結果を受けて保健省が決定する。外来診療では G-BA に承認された診療行為のみが実施可能とされるが、入院診療についてはその限りではなく、医師の判断で新規手術・手技の導入が可能である（この場合、標準診療の範囲内での償還対象となる）。新規手術・手技を含む新たな検査・治療法のうち、G-BA の審査過程で効果が期待されるものの検証が不十分と判断された場合、期間限定での条件付き償還対象（”Potential”と呼ばれる）となり、臨床導入後の症例の登録、評価が義務付けられ、この結果に基づき最終的な審査が行われる（社会法典第５編（Fünftes Buch Sozialgesetzbuch, SGB V）§137e）。

ドイツでは臨床試験（特にランダム化比較試験（RCT））の実施件数が、他の先進国に比較して少ないという指摘があり、2003 年、ドイツ外科学会（Deutsche Gesellschaft für Chirurgie, DGCH）にドイツ外科学会研究センター（Studienzentrum der Deutschen

Gesellschaft für Chirurgie, SDGC）が設置され、外科領域の多施設 RCT の推進が図られている。ドイツ国内においては、ハイデルベルグ大学が大きな推進力となった模様である。さらに、2006 年には臨床研究コーディネーションセンターネットワーク（Koordinierungszentren für Klinische Studien Netzwerk, KKSN）、および外科臨床試験ネットワーク(CHIR-*Net*)が BMBF の助成を受けて設置された。いずれもドイツ全国をカバーするネットワークであり、臨床研究（RCT、システマティック・レビュー、メタアナリシスなど）の計画、実施、評価について、専門職の派遣や若手外科研究者の育成などを行っており、上述の IDEAL Framework を活用した研究基盤が整備されつつある。

4. 米国

１）一般的な研究規制の概要

臨床研究に関する法令は、医薬品を扱う研究と医療機器を扱う研究により大きく分けられる。医薬品（生物製剤を含む）については、連邦規則集（Code of Federal Regulations, CFR）Title 21 Part 312 (21 CFR 312)において、新薬臨床試験許可申請（Investigational New Drug Applications）について規定されており、食品医薬品局（FDA の承認が得られていない生物製剤を含むすべての医薬品（先進医薬品も含まれる）および FDA の承認が得られた医薬品の適応外使用については、研究の実施にあたり FDA の許可が必要となる。医療機器については、FDA の市販承認の有無によらずあらゆる医療機器を用いた臨床研究が規制対象となるが、診断機器の研究については免除される（21 CFR 812.2）。FDA が管轄する医薬品や医療機器を扱わない臨床試験（例：手術・手技や認知行動療法などに関する臨床試験）は FDA による規制対象とはならないが、連邦政府の助成を受けた研究については、FDA の所管によらずコモン・ルール（45 CFR 46　サブパート A）による規制対象となり、倫理委員会（米国では Institutional Review Board, IRB）による審査が必須となる。

手術・手技に関する研究で、FDA が管轄する医薬品等も扱わず、連邦政府の助成も受けていない研究については、連邦レベルの規制対象とはならないが、州による規制の対象となることもある。ただし、連邦認証（Federal wide Assurance FWA）を得た機関については、連邦政府の助成を受けていない研究を含むすべての研究に対してもコモン・ルールを適用することが可能である。

２）研究登録

臨床試験の登録および結果情報の提出に関する規則（42 CFR 11.22）により、以下の項目をすべて満たす場合は、国立衛生研究所（National Institute of Health, NIH）の国立医学図書館（National Library of Medicine, NLM）が管理運営するレジストリ ClinicalTrials.gov に登録することが求められる。

1. 介入研究である
2. FDA により規制される医薬品、生物学的製剤または医療機器の評価を行う
3. 医薬品または生物学的製剤のフェーズ 1 試験ではない。または、医療機器のフィージビリティ研究ではない。
4. 以下のいずれかに該当する

– 少なくとも 1 つの研究施設が米国内（海外領土を含む）にある
– FDA の IND 申請または IDE により実施される
– 米国内（海外領土を含む）で製造され、米国外の国に研究目的で輸出された医薬品、生物学的製剤または医療機器の研究であるまた、当該研究が NIH の助成を部分的にでも受けている場合は、全ての介入研究（FDA の規制対象とならない手術・手技等を含む）で ClinicalTrials.gov への登録が必須となる（NIH Policy on the Dissemination of NIH-funded Clinical Trial Information）。

３）手術・手技の導入に関する規制

手術・手技を対象とした法令や指針は定められていない。

４）新規手術・手技の定義および診療と研究の類型化

新規手術・手技に関する明確な定義はない。上述のコモン・ルールでは、研究（research）

は一般化可能な知見（generalizable knowledge）の創出を目的とした系統的探究（systematic investigation）と定義されている(45 CFR 46.102(d))。新規手術・手技の導入を研究と捉えるか、診療の一環、あるいは品質改善活動（Quality Improvement Activities と呼ばれる）と捉えるかについては、連邦レベルの規定はなく、施設レベルあるいは個々の医師の判断に委ねられている。したがって、連邦助成を受けた研究の枠組みで導入される新規手術・手技については監視対象となるが、該当しない場合は少なくとも監視対象とならない。

診療目的で（研究意図を明示せず）行われる手術・手技について、これらが後日、症例報告として発表・論文化されるような場合、これを研究と見なすか否か、倫理審査委員会の審査対象とするか否かについては、施設により扱いが分かれている。しかし、報告症例数が複数に上る累積症例報告などについては研究として扱い、個人情報保護を含めて審査委員会にかけるべきとする大学附属病院も存している。一方、NIH など連邦予算により研究機関として運営されている施設で行われる診療行為は、それが初期に計画された研究（評価すべき介入手段）の一部とされていない場合でも、原則的に研究として扱われる。

Society of University Surgeons (SUS)は 2008 年の意見表明において、革新的な手術・手技を適正に監視する機能として、施設単位で surgical innovation committee（SIC）を設置することを推奨している。しかし米国外科学会の外科部門長会（Society of Surgical Chairs）を対象とした調査によると、2013 年時点で上記意見表明を把握していた対象者は半数に満たず、SIC または同等の委員会を設置していた施設は 23%で、審査もほとんど実施されていなかった。また、「通常診療のバリエーション」、「イノベーション」、「研究」の区分については 86%の施設で検討されていたが、公式な検討が行われていたのは 42%であった（McNair L. & Walter B. 2015 Ann Surg)。

D. 考察

対象としたいずれの国においても、医薬品および医療機器を用いた手術・手技の研究については法的規制が整備されていたが、これらを用いない場合の研究は法的規制の対象とならない場合が多く、実務上は医師会等による倫理指針、あるいは国際医学編集者会議（International Committee of Medical Journal Editors, ICMJE）による学術雑誌投稿規定による規定が運用されていた。

診療として実施される場合も、基本的には新規手術・手技の導入は特に医薬品、医療機器を用いない場合は、医師の裁量に委ねられる傾向がみられた。

ドイツ、フランスの例にあるように、保険償還上の規制もあるが、例えば標準診療の枠内の支払いで新規手術・手技を用いて治療を行う場合は、実施が可能であり、継続的に監視するシステムも存在していないため、有害事象等が発生するまで検知は不可能である。一方、英国の NHS トラストで実施される医療機関単位での新規手術・手技の審査・承認体制は、事前の審査が行われる点で、適切に運用されれば安全と効果を担保する機能が期待される。上述のように、NHS トラスト・医療施設によっては、新規の手術・手技の導入に関して事前の審査、事後の評価を要件化している例があり着目される。しかし現状では、申請の判断の実際面においては、医師の恣意的判断に任されている部分が大きく、確実な監視体制とはなっていない。

手術・手技について直接的な規制がないことについてはいくつかの理由が考えられる。Darrow は、１）外科医に対する間接的な規制で十分である、２）患者ごとに手術・手技は異なるため規制になじまない、３）介入の性質上 RCT の実施が困難である、４）大量生産される医薬品と異なり、手術・手技は様々な場所に分散した外科医により小規模な単位で実施されるため、個々の外科医にとって効果と安全性を確保してコストを削減することへのインセンティブが生じにくい、などの理由を挙げている（Darrow J. 2017 Cornell J. L. & Pub. Pol'y)。確かに医薬品や医療機器と比

較して、規制対象としにくい側面があるが、侵襲の程度などは必ずしも医薬品・医療機器に比べて小さいとは言えず、実際に有害事象も散見されることから、このまま規制対象としないという選択肢はないだろう。また、上記１）の理由とも関連するが、米国で SIC が普及しない理由として、手術・手技に対する監視の必要性に対する外科医の認識が低く、Mortality & Morbidity カンファレンス等による事後評価で十分という風潮が強いこと挙げられており、医師の意識変容のための教育も必要であるという意見もある。

外科医の専門団体により始められた IDEAL Collaboration の取り組みは、安全で効果的な手術・手技の導入を推進するという点で評価できる。しかし、EU における医療機器の評価プロセスなどで一部利用が始まっているとの由であるが、現時点ではまだ広く普及しているとはいえない。徐々に行われている公的機関の研究助成や技術開発プログラム等での利用の促進、また ICMJE による学術雑誌投稿への要件化などにより普及が推進するものと考えられる。さらに、長期的な評価、既存の標準診療の再評価を可能にするために、手術・手技に関する研究・診療の標準化されたデータベースの確立も必要だと考えられる。

E.結論

いずれの国でも、手術・手技を扱う研究に特化した法的規制は存在していない。しかし、英国 HRA や米国の連邦規則（コモンルール)、さらに（今回は調査対象としなかったが）オランダにおける研究規則のように、ヒトに対する介入研究をその目的・手段によらず一律に扱うことを原則とする制度が存在し、考慮に値するものと思われる。研究として行われない場合であっても、倫理委員会あるいは診療委員会の事前審査対象とする例、また事後の評価・報告を求める制度も参考となる。研究と臨床的導入（治療）を明確に区分し、監視対象とすることは困難であるが、英国 NICE/NHS の取り組み、また米国の一部施設に見られるように、研究と診療との概念区分を明確にした上でこれらの実際面での不可分性を考慮した経験の知識化、科学的根拠の創出に向けた制度設計が望まれる。

手術・手技の特性を十分に考慮しない制度はその実効性が乏しいものとなる危惧がある。ドイツ、フランスの試みや IDEAL Collaboration の取り組みにみられるような、臨床導入の初期の段階からの登録と継続的な評価体制の構築は、安全かつ効果的な新規手術・手技の導入において有効であると考えられる。

F. 健康危険情報

なし

G. 研究発表

1.　論文発表

なし

2.　学会発表

なし

H. 知的財産権の出願・登録状況

（予定を含む。）

1. 特許取得

特になし

2. 実用新案登録

特になし

3.その他

特になし

資料
佐藤元　2019

英国における新規医療技術監視

Department of Health/ NICE によるNew Interventional Procedures Programme

1 Department of Health:
Health Service Circular HSC2003/011

2 National Institute for Health and Care Excellence (NICE)
Interventional Procedures Programme

3 Oxford University Hospitals/ NHS Foundation Trust
Policy for Introducing New Technologies & Procedures
Technologies Advisory Group (TAG) Committee
Variation on existing technology/ procedure form
TAG Committee application form

4 Mersey Care/ NHS Trust (Liverpool)
Corporate policy and procedure for the introduction of all new interventions
(Duties, Process, Flow chart)

5 University Hospitals Bristol/ NHS Foundation Trust
Policy on introducing New Interventional Procedures into routine clinical practice
(normal/special arrangements for consent and for audit, responsibilities)

6 Portsmouth Hospitals/ NHS Trust
New clinical interventions and technologies introduction policy
(Proposal for the Introduction of a new procedure / technique, Equality Impact Screening)

7 Newcastle upon Tyne Hospitals/ NHS Foundation Trust
Introduction and Development of New Clinical Interventional Procedures
New Interventional Procedure Registration Form
Proctors for new surgical interventions/ Proctor's evaluation form

8 Solent/ NHS Trust
Policy for the Implementation of National Guidance
(Integrated Governance and Performance [IGAP] Committee)

9 Epsom and St. Heller University Hospitals/ NHS Trust
Clinical quality and assurance report

10 Notes

Health Service Circular

Series Number:	**HSC 2003/011**
Issue Date:	**13 November 2003**
Review Date:	**12 November 2005**
Category:	**Clinical Effectiveness**
Status:	**Action**
	sets out a specific action on the part of the recipient with a deadline where appropriate

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The Interventional Procedures Programme

Working with the National Institute for Clinical Excellence to promote safe clinical innovation

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For action by: NHS Trusts - Chief Executives

For information to: NHS Trusts – Chairman
Primary Care Trusts - Chief Executives
Medical Schools – Deans Medical Directors
Directors of Nursing
National Care Standards Commission
National Patient Safety Agency
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The Interventional Procedures Programme

Working with the National Institute for Clinical Excellence to promote safe clinical innovation

1. From 13 November 2003, medical practitioners planning to undertake new interventional procedures (see definition on page 4) should seek approval from their NHS Trust's Clinical Governance Committee before doing so. The Chair of the Clinical Governance Committee should notify the procedure to the Interventional Procedures Programme at the National Institute for Clinical Excellence (NICE) unless it is already listed there. In a case where the procedure has to be used in an emergency (see below) the procedure should be notified to the Clinical Governance Committee within 72 hours.

2. The only exception to the process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC).

Purpose of the Programme

3. NICE's Interventional Procedures Programme assesses the safety and efficacy of new interventional procedures. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

How the programme works

4. Medical practitioners intending to carry out a new interventional procedure should seek the approval of their NHS Trust's Clinical Governance Committee. If the procedure is not listed on NICE's website (www.nice.org.uk/ip), the Chair of the Committee should notify the procedure to NICE via the website. A new notification will initiate the following procedure:

   D NICE will prepare a brief overview of the evidence on the procedure's safety and efficacy and consult its Specialist Advisors

   D A NICE advisory committee will decide either to issue guidance on the procedure or to seek more information before doing so. As part of this process, NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with it

   D NICE consults publicly on all its guidance and its advisory committee will consider responses to consultation before guidance on any procedure is issued.

5. Patients, managers, commissioners and others can also notify procedures directly to NICE through its website.

What the NHS should do

6. The success of the Interventional Procedures Programme is dependent on appropriate engagement from the NHS.

7. Any doctor considering use in the NHS of a new interventional procedure which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Clinical Governance Committee.

If the procedure is the subject of NICE guidance, the Committee should consider whether the proposed use of the procedure complies with the guidance before approving it.

8. If no NICE guidance on the procedure is available, the Committee should only approve its use if:

- the doctor has met externally set standards of training
- all patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded. Patients need to understand that the procedure's safety and efficacy is uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment
- the Committee is satisfied that the proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure.

9. The Committee should also take account of the Clinical Negligence Scheme for Trusts standard 5.2.6.

10. It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new procedure in a clinical emergency so as not to place a patient at serious risk. If a doctor has performed a new interventional procedure in such circumstances he/she must inform the Clinical Governance Committee within 72 hours. The Committee will consider approval of the procedure for future use as above.

11. When NICE is collecting data under this Programme, doctors should supply the information requested on every patient undergoing the procedure. NHS Trusts are encouraged to support this to enable the NHS to have access more speedily to guidance on the procedure's safety and efficacy. The collection of data from patients will be governed by the Data Protection Act.

12. The only exception to the above process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). In this case, notification to NICE is not needed, as patients are protected by the REC's scrutiny. However, RECs should notify Trust Clinical Governance Committees when they approve a protocol involving an interventional procedure. Use outside the protocol should only occur after approval from the Clinical Governance Committee as set out above.

13. If an adverse incident occurs in association with a new interventional procedure, this should be reported to the National Patient Safety Agency in the normal way via the national reporting and learning system for adverse events to be implemented across the NHS in 2003.

14. CHI 's review teams assess how well clinical governance is working in Trusts by making enquiries about each of the seven components of clinical governance at corporate and directorate levels and in clinical teams. This involves collecting information systematically about review issues and will include how Trusts' Clinical Governance Committees introduce new interventional procedures.

Definitions

15. An *interventional procedure* is one used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

16. An interventional procedure should be considered *new* if a doctor no longer in a training post is using it for the first time in his or her NHS clinical practice.

Associated Documentation

17. Further information can be found on the NICE website www.nice.org.uk/ip and the Programme can be contacted via ip@nice.nhs.uk

This Circular has been issued by:
Professor Aidan Halligan Deputy
Chief Medical Officer

The National Institute for Health and Care Excellence (NICE)

Interventional Procedures Programme

Purpose of the Programme

1. NICE's Interventional Procedures Programme assesses the safety and efficacy of interventional procedures to determine whether they work well enough and are safe enough for use in the NHS. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

2. The process and methods of the Interventional Procedures Programme are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders, including patients, from across the UK.

Definitions and scope

3. An *interventional procedure* is one used for treatment or diagnosis that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

4. An interventional procedure may be assessed by the Interventional Procedures Programme if it is not yet generally considered established clinical practice in the NHS or UK independent sector, or if it is an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice.

Summary of requirements of medical practitioners and NHS or independent health care providers

5. Individual provider organisations will wish to have a process in place for the introduction of any new procedure into their organisation. Health care professionals planning to undertake in the NHS a new interventional procedures or an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice must, before doing so, obtain approval using the appropriate governance structures of the organisation in which the procedure is to be performed. The Medical Director (or nominated deputy) of the organisation should ensure any new procedure falling within the scope of the Interventional Procedures Programme at the National Institute for Health and Care Excellence (NICE) is notified to NICE.

6. The only exception to this process is when the procedure is being used solely within a protocol approved by a Research Ethics Committee (REC).

What the NHS should do

7. The safe introduction of procedures into the NHS is dependent on the effective engagement of all NHS organisations with the operation of the Interventional Procedures Programme.

8. All NHS providers of healthcare should ensure they have governance structures in place to review, authorise and monitor the introduction of new interventional procedures or the use of established clinical procedure, the efficacy or safety of which has been called into question by new information or advice. These structures should ensure that any health care professional considering using a new interventional procedure which he/she has not used before, or has only used outside the NHS, seeks prior approval to do so using the appropriate governance structures of the organisation in which the procedure is to be performed. This also applies to procedures which may be used in an emergency.

9. If the procedure is the subject of published NICE interventional procedures guidance, the organisation should consider whether the proposed use of the procedure complies with that guidance before allowing it to be undertaken in the organisation.

10. If the procedure is not the subject of published NICE interventional procedures guidance as listed on NICE's website but falls within the definition and scope of the Interventional Procedures Programme, the Medical Director of the organisation (or nominated deputy) should notify the procedure to NICE, if the health care professional has not already done so.

11. Health care professionals wishing to carry out a new interventional procedure or an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice must always obtain approval to do so using the appropriate governance structures within the organisation in which the procedure is to be performed.

12. If NICE is in the process of developing guidance on the procedure, the organisation should only approve its use if:

    a. The health care professional has appropriate experience and training.
    b. All patients offered the procedure are made aware of the special status of the procedure in the NHS. This should be done as part of the consent and shared decision-making process, and should be clearly recorded. Health care professional should ensure that patients understand that the procedure's safety and efficacy are uncertain. They should inform patients about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
    c. The organisation is satisfied that the proposed arrangements for clinical audit (which may include comparative or multicentre audit) are sound, and will capture data on clinical outcomes that will be used to review continued use of the procedure.

13. Once NICE has published its guidance on the procedure, the organisation should consider whether the proposed use of the procedure complies with the guidance before approving its continued use in their organisation, bearing in mind that NICE's final published guidance recommendations may need different arrangements to be put in place from those set out in section 12.

14. The organisation must ensure that any procedure on which there is interventional procedure guidance is coded using the coding provided by NICE in the published guidance.

15. When the recommendation about a procedure from NICE includes collecting data on outcomes and safety, health care organisations should ensure systems are in place to support health care professionals to supply the information requested on every patient undergoing the procedure. The data on the outcomes and safety of that procedure should be reviewed by the organisation. The individual undertaking the procedure should also be expected to discuss their outcomes as part of their annual appraisal to allow reflection, learning, and individual improvement.

16. The only exception to the above process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). Once the research is completed, the procedure should be notified to the NICE Interventional Procedures Programme in the normal way. If an adverse incident occurs in association with a new interventional procedure, this should be reported, investigated and escalated in line with local policies. Device- related incidents should be reported to the competent authority.

17. This process does not mandate commissioning of specific procedures. Cost- effectiveness evaluation is not within the scope of the NICE Interventional Procedures Programme.

18. An outline description of the programme is set out in the Annex to this document.

Date: March 2017

Annex

How the NICE Interventional Procedures Programme works

Any individual may notify a procedureto the NICE Interventional Procedures Programme by completing the online interventional procedures notification form. A new notification will initiate the following process: NICE will decide whether to develop guidance on the procedure, seeking more information from its specialist advisers and checking for a CE mark if needed.

The interventional procedures programme team will prepare a brief to initiate the assessment of the procedure. This is a short internal document covering key aspects of the procedure. The programme team seeks advice from appropriate specialist Committee members and the programme's specialist advisers when preparing the brief. Once the brief has been reviewed by the Committee, developing guidance on the procedure becomes part of the formal work of the programme.

NICE will prepare an overview of the evidence on the procedure's safety and efficacy. Specialist advice, patient commentary and evidence from device companies if available will elicited and taken into consideration as outlined in the IP programme manual.

The NICE interventional procedures advisory committee consisting of members who are independent of NICE will make draft recommendations on the efficacy and safe use of the procedure.

The NICE interventional procedures advisory committee may ask questions of Specialist Advisors and device companies before formulating its draft recommendations.

NICE publishes a consultation document consisting of the draft recommendations on the NICE website for four weeks.

At a further Committee meeting, the NICE interventional procedures advisory committee reviews the consultation document, and considers all the comments received during consultation, responds to them and makes any appropriate changes to the draft guidance.

Before guidance publication, there is a three week resolution stage. This process is a final quality assurance step where stakeholders who commented during the consultation period and who have completed a confidentiality statement are sent the final recommendations. NICE considers any requests for resolution and makes a formal response. The resolution process is not needed when no consultation comments are received or if stakeholders who provided consultation comments do not return their confidentiality statement.

Guidance is published on the NICE website once the resolution process is complete or sooner if there was no requirement for a resolution stage.

In some circumstances, NICE does not produce guidance on a procedure after receiving a notification. The most common reasons for this are that the procedure:

a. does not fit the programme's remit;
b. is not new;
c. involves a modification to an existing procedure whose safety and efficacy are sufficiently well understood;
d. relies on using a medical device but no device is available that has regulatory approval for the intended purpose.

Further information about the interventional procedures programme, including the programme manual can be found on the NICE website:

Oxford University Hospitals NHS
NHS Foundation Trust

Policy for introducing New Technologies &Procedures

Category:	Policy
Summary:	This policy describes the process for introducing new technologies and procedures for clinical use within the Oxford University Hospitals NHS Foundation Trust
Equality Impact Assessment undertaken:	September 2016
Valid From:	October 2017
Date of Next Review:	3 years from the approval date
Approval Date/ Via:	Clinical Policies Group 4 October 2016
Distribution:	Trust-wide
Related Documents:	Policy for Consent to Examination or Treatment
Author(s):	TAG Chair and Deputy Head of Clinical Governance
Further Information:	Deputy Head of Clinical Governance
This Document replaces:	Version 4.0

Lead Director: Medical Director

Issue Date: November 2018

Contents

Introduction

1. Oxford University Hospitals (OUH) NHS Foundation Trust supports the development of clinical practice to enhance patient care, experience and outcomes. This includes the introduction of new technologies and procedures into routine clinical practice or within an experimental medicine programme.

2. It is essential that patient safety is ensured when new technologies and procedures are introduced. The Trust will provide safeguards by evaluating all new technologies/ procedures in terms of appropriateness and effectiveness before they are introduced into routine clinical practice, and by ensuring clinicians are adequately trained to undertake them. Similar safeguards will be provided for all new technologies/ procedures being introduced within an experimental medicine programme.

3. This policy meets the recommendations set out within the Health Services Circular (HSC 2003/011) in relation to the introduction of new interventional procedures, and supports meeting the Care Quality Commission's regulatory standards and National Institute for Clinical Excellence (NICE) guidance.

Policy Statement

4. All new clinical technologies/procedures must be introduced into the Trust in line with the processes described within this policy in order to ensure patient safety.

5. All minor amendments to an existing clinical technology or procedure must be introduced in line with the processes described within this policy in order to ensure patient safety.

Scope

6. This document applies to all areas of the Trust, and all employees of the Trust and honorary contract holders, as well as individuals employed by a third party or external contractors, and voluntary workers, students, locums and agency staff.

Aim

7. The purpose of this Policy is to ensure that the Trust has robust processes in place which support clinicians to advance the delivery of clinical care to patients while maintaining patient safety at all times.

Definitions

8. The terms in use in this document are defined as follows:

8.1. **New technology/procedure** refers to any new device, instrument or intervention for diagnostic/therapeutic purposes that has not previously been used in the Trust, or a new combination of existing technologies/procedures currently in use in the Trust.

8.2. **Minor amendment** refers to a change in the way in which an existing technology/procedure is undertaken (including modifications to existing devices) and which does not require users to receive additional training or proctorship.

8.3. **Experimental medicine** refers to any new technology/procedure being introduced to *'demonstrate proof-of-concept evidence for the validity and importance of new discoveries or treatments'* (www.mrc.ac.uk), although any proposal that includes the use of a new medicine should also go to Management of Medicines and Therapeutics Committee (MMTC).

Responsibilities

9. The **Chief Executive** has overall responsibility for patient safety within the organisation.

10. The **Medical Director** has delegated authority for patient safety.

11. The **Medical Director** has delegated authority for the safe delivery of clinical technologies undertaken by medical and surgical practitioners.

12. The **Technologies Advisory Group (TAG) Committee** is responsible for conducting an objective and independent appraisal of all proposed new technologies/procedures (except for medicines, which are addressed in a separate forum). This committee reports to the Patient

Safety Committee on a minimum quarterly basis and provides an annual report. The Terms of Reference for this Committee are at Appendix 1.

13. The **TAG Chair** has authority to approve use of a new technology/procedure rapidly where there is an urgent clinical need and insufficient time to obtain approval through the usual processes.

14. **Divisional Directors** are responsible for ensuring that all medical staff in the Directorates within their Division are aware of, and comply with, this policy.

15. **Clinical Directors** are responsible for consulting within their Directorates about proposals to introduce a new technology/procedure within their specialty. They must also provide TAG with written confirmation that the application to introduce a new technology/procedure has their full support.

16. **Individual clinicians** are responsible for:

16.1. Introducing any new technology/procedure to their patients, including providing appropriate information and gaining appropriate consent.

16.2. Ensuring that, before any new technology/procedure is introduced, Trust approval is obtained in accordance with this policy.

16.3. Ensuring that the effectiveness and outcomes of any new technology/ procedure is audited.

16.4. Reporting the results of the audit to TAG.

17. **All staff** must be aware of this policy, and must raise any concerns relating to compliance with it to the TAG committee and, if appropriate, through the Trust's Risk Management incident reporting processes.

Process for introducing a New Technology/Procedure

18. Any clinician who is considering introducing a new technology/procedure must first have the written support of the relevant Clinical Director(s).

19. If the new technology/procedure is a variation on an existing technology/procedure (including modifications to existing devices) already being used in the Trust, this simply involves completing a short form (Appendix 2), which must be approved by the relevant Clinical Director(s) and sent to the TAG Committee.

20. For all other new technologies/procedures, the relevant Clinical Director(s) must ensure the proposal is discussed within the Directorate(s) and a decision made whether to support the application. This will include confirmation of funding to support the application and where necessary, the development of a business case for commissioning the new activity.

21. The lead clinician must then commence the application process:

21.1. In the first instance, this involves sending a short summary of the proposal to the TAG Committee Chair who will decide whether the application needs to be considered by the committee or can be approved by Chair's action.

21.2. Applicants must provide written confirmation that their relevant Divisional Management Team has allocated funding for the introduction of the technology or is in support of the development of a business case for funding the technology. Technology to be purchased through the development of a business case must not be purchased ahead of business case approval. Applications without financial information will not be considered.

21.3. If the TAG Committee has to consider the proposal, an application form must be completed (Appendix 3).

21.4. At the TAG Committee meeting, a presentation supporting the application (lasting no longer than 15 minutes) must be delivered, followed by 10-15 minutes of questions.

22. The TAG Committee will assess applications based on the following criteria:

22.1. Clinical effectiveness – evidence of risk: benefit analysis.

22.2. Technical suitability – evidence that the technology/procedure is safe and that the equipment meets appropriate safety standards before being offered to patients.

22.3. Evidence of competence – evidence that adequate training and competency evaluation will take place before the technology/procedure is introduced into routine clinical practice or within an experimental medicine programme.

22.4. Consent – the patient information and consent arrangements are appropriate and conform to the Trust consent policy (Policy for Consent to Examination or Treatment, version applicable at the time).

22.5. Funding - assurance about affordability and funding for each application must be provided by the authorised Divisional representative. Approval is conditional on financial information being provided. Approval will not be given to applications with no divisional financial information.

22.6. A u d i t – the plans for clinical audit of the new technology/procedure are satisfactory.

23. The TAG Committee will decide whether the proposal to introduce the new technology/procedure should be supported or not.

24. Decisions will be made by consensus and if there is disagreement the group will be asked to vote and everyone in the group will have the same vote weighting

25. Once a decision has been made, the TAG Committee will write to the applicant, and the relevant Directorate and Divisional Directors.

26. Where approval is given, the obligation to provide the Committee with an audit report 12 months after implementation will be made explicit. The requirement is to report all serious adverse incidents, including Serious Incidents Requiring Investigation (SIRIs) associated with the new technology/procedure in line with Trust Policy (Incident Reporting and Investigation Policy version applicable at the time), and to the Chair of the TAG Committee.

27. The status of any equipment that is the subject of an application, must be a fully CE- Marked Medical Device that is available on the market. Applications concerning equipment, that is itself under research, or as part of a research programme, are not appropriate from approval under TAG. Separate Research & Development governance arrangements exist for this.

Process for introducing a New Technology/Procedure in a clinical emergency

28. It is recognised that, in rare circumstances, where no other safe treatment options exist, there may be a need to use a new technology/procedure in a clinical emergency in the best interests of the patient.

29. In such circumstances, the clinician should contact the Chair of TAG Committee to discuss the use of the new technology/procedure.

30. The Chair may authorise a new technology/procedure in these circumstances based on the criteria described in point 20 above, and discussions with colleagues/experts in the Trust. In the Chair's absence, the Deputy Chair will be delegated this authority. Records will be kept of all such decisions made.

31. If neither the Chair nor Deputy Chair are available, or there is insufficient time to consult with them, the clinician should discuss the use of the new technology/procedure with the relevant Directorate or Divisional Clinical Directors, and/or the Medical Director, and then inform the Chair of the TAG Committee within 72 hours of undertaking the new technology/procedure.

32. Any new technology/procedure used in an emergency, which has not had prior approval for use by the TAG Committee, must have an application prepared for presentation at the next committee meeting.

Training

33. There is no mandatory training associated with this policy.

34. All consultant staff must be made aware of this policy at the time of Trust induction.

Monitoring Compliance

35. Compliance with the document will be monitored in the following ways.

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
All new technologies/ procedures will be introduced by following the processes set out in this policy	Incident Reporting	Clinical Risk Management Team will inform Deputy Head of Clinical Governance of any relevant incidents	Ongoing	Technologies Advisory Group (TAG) Committee
Clinicians responsible for a new technology/procedure that has been through the full TAG approval process will provide a report to the TAG Committee 12 months after implementation	TAG Committee database	Deputy Head of Clinical Governance	Annually	Patient Safety and Clinical Risk Committee

36. In addition to the monitoring arrangements described above, the Trust may undertake additional monitoring of this policy in response to any gaps being identified or as a result of identifying risks arising from the policy prompted by incident review, external reviews, or other sources of information and advice. Monitoring could include:

- Commissioned audits and reviews
- Detailed data analysis
- Other focused studies

The results will be reported to the nominated Committee.

Review

37. This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents, or sooner if national guidance or local arrangements change.

References

38. Health and Social Care Act 2008 (Regulated Activities) Regulations (2014) Care Quality Commission

39. Health Service Circular 2003/011. 'The Interventional Procedures Programme'. P1-4 (DOH)

40. Incident Reporting and Investigation Policy (v12) (2015) Oxford University Hospitals NHS Foundation Trust

41. Policy for Consent to Examination or Treatment (v4.0) (2016) Oxford University Hospitals NHS Foundation Trust

Equality Impact Assessment

42. As part of its development, this policy and its impact on equality has been reviewed. The purpose of the assessment is to minimise and, if possible, remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation or religious belief. No detriment was identified.

Terms of Reference for the Oxford University Hospitals NHS Foundation Trust Technologies Advisory Group (TAG) Committee

(V5.0) September 2016

Oxford University Hospitals NHS Foundation Trust
Technologies Appraisal Group

Terms of Reference

1. Authority

The Technologies Appraisal Group (TAG) is a standing committee of the Patient Safety and Clinical Risk Committee (PS&CRC). Its constitution and terms of reference shall be as follows, subject to amendment at future meetings of the PS&CRC

2. Purpose of Committee

The purpose of the TAG is to ensure that the clinical care provided to patients is safe by minimising any potential associated risks when new technologies and procedures are introduced into the Trust for routine clinical practice or within an experimental medicine programme. The status of any equipment that is the subject of an application, must be a fully CE-Marked Medical Device that is available on the market. Applications concerning equipment, that is itself under research, or as part of a research programme, are not appropriate from approval under TAG. Separate Research &Development governance arrangements exist for this.

3. Responsibilities and Duties

The TAG will:

- Receive applications for the introduction of all new technologies/procedures complete with authorised financial information
- Receive applications to introduce a minor amendment to an existing technology/procedure
- Approve or decline each application based on the criteria set out within the procedural document: Policy for Introducing New Technologies and Procedures
- Inform applicants (and their respective Clinical Directors) of the Committee's decision
- Require clinicians to:

  a) audit how the new technology/procedure has been implemented by monitoring staff training, patient outcomes and adverse effects, and
  b) provide the Committee with an audit report 12 months after implementation, or sooner at the Committee's discretion - the report will be passed to the relevant Division and to the PS&CRC

c) report all serious adverse incidents including Serious Incidents Requiring Investigation (SIRI) associated with the new technology/ procedure to the Chair of the group

- All TAG members, and all those bringing an application to TAG, must make a contemporaneous declaration of interest that includes any relationship with the manufacturer (personal support, personal payment, educational or research funding)

4. Membership

The membership of TAG shall be composed of the following core members:

Medical Director's Office representative
Consultant Radiologist
Consultant Surgeons x 2
Consultant Anaesthetist
Consultant in Intensive Care
Theatre Senior Nurse/Matron
Authorised Representative from each clinical Division (authorised by Divisional Director)
Clinical Engineering representative
Clinical Governance representative
Procurement representative
Medical Equipment Prioritisation Group representative
Oxfordshire Clinical Commissioning group representative
NHS England representative

The Medical Director will designate a representative to chair the meeting.

5. Attendance

It is expected that all members will attend 3 out of 4 committee meetings per financial year (or 75% of sequential meetings). If members are unable to attend a meeting they should identify a deputy who is authorised to represent their views/interests, or their direct reports.

6. Quorum

The quorum for any meeting of the Committee shall be attendance of a minimum of seven members of which three will be in clinical practice.

7. Meetings

Meetings of the TAG shall be scheduled monthly.

8. Notice of Meetings

Meetings of TAG shall be set at the start of the financial year. The agenda and supporting papers shall be forwarded to each member of the committee not less than five working days before the date of the meeting.

9. Reporting arrangements

The proceedings of each meeting of the Group shall be reported to the next meeting of the PS&CRC following production of the minutes. The Chairman of the meeting shall draw to the attention of the PS&CRC any issues that require escalation.

10. Administration

The TAG will be supported by the Medical Director who will ensure that the group is effectively supported by an appropriate administrative function.

The Deputy Head of Clinical Governance will provide oversight of the Group administration.

11. Review of Terms of Reference

The Terms of Reference of the Group shall be reviewed at least every three years and approved by the Patient Safety &Clinical Risk Committee.

October 2017

Variation on existing technology/procedure (including devices) form

Oxford University Hospitals NHS
NHS Foundation Trust

TAG Committee
newtechnologiesandprocedures@ouh.nhs.uk

Variation on existing technology/procedure (including devices)

If the new technology/procedure is a variation on an existing technology/procedure (including modifications to existing devices) already being used in the Trust, you are simply required to complete the short form below, which must be approved by the Clinical Director for the lead specialty and sent to newtechnologiesandprocedures@ouh.nhs.uk. The answers to the questions determine whether the variation is minor and, therefore, the introduction of the new technology/ procedure (including devices) does not require TAG approval.

Please complete and send a copy to: newtechnologiesandprocedures@ouh.nhs.uk

Name:	**Job Title:**
Directorate:	**Date:**

Please describe the existing technology/procedure and how the new technology/ procedure differs from the existing one (max. 200 words):

	Y	N
Was the existing technology/procedure approved by TAG?		
Is the existing technology/procedure being used routinely in the Trust?		
Will the variation be used in the same patient population?		
Will the variation be used for a new clinical indication?		
Will the variation require any additional training?		
Do you need a proctor to introduce the variation into clinical practice?		
Does the variation represent a change in clinical practice?		
Is this the first time the variation has been used in the UK?		

If the answers to any of the questions above are in the shaded boxes, then the application needs to be referred to TAG.

If all the answers are in the unshaded boxes, then TAG approval is not required. The Clinical Director for the lead specialty should simply sign the form below and submit it to newtechnologiesandprocedures@ouh.nhs.uk

Name:	
Signature:	
Directorate:	Date:

Appendix 3: TAG Committee application form

Oxford University Hospitals NHS
NHS Foundation Trust

TAG Committee
newtechnologiesandprocedures@ouh.nhs.uk

Application form and guidance for presenters

The Technologies Advisory Group (TAG) Committee was set up to review all proposals to introduce new technologies and procedures that could benefit patients and to the general delivery of the Trust's clinical services.

As a prerequisite to your application you must have the written support of the relevant Clinical Director(s) and your Division must have identified the source of funding or be in support of the development of an outline business case for commissioning the new activity.

Once your proposal is supported by the relevant Clinical Director(s) and funding process agreed by the Divisional Management Team, you may proceed with the application to TAG. Please complete the form below and answer all the questions. You will then be invited to give a presentation lasting no longer than 15 minutes, followed by 10-15 minutes of questions. Once your proposal has been reviewed the committee will write to you, and your Directorate and Divisional Directors. Outlined below, are the evaluation criteria and application process. For more information see the hospital intranet link below.
http://ouh.oxnet.nhs.uk/TAG/Pages/Default.aspx

TAG will consider each presentation against the following criteria:

- Clinical effectiveness – evidence of risk: benefit analysis.
- Technical suitability – evidence that the technology/procedure is safe and that the equipment meets appropriate safety standards before being offered to patients.
- Evidence of competence – evidence that adequate training and competency evaluation will take place before the technology/procedure is introduced into routine clinical practice or within an experimental medicine programme.
- Consent – the patient information and consent arrangements are appropriate and conform to the Trust consent policy (Policy for Consent to Examination or Treatment version applicable at the time).
- Audit – the plans for clinical audit of the new technology/procedure are satisfactory.

THE PROCESS

STAGE 1: Please, send a short overview of your proposal (no more than 3 paragraphs) a letter of support from the relevant Clinical Director(s),and confirmation from the Divisional Management Team confirming the funding arrangements of the technology to newtechnologiesandprocedures@ouh.nhs.uk. These will be reviewed by the Chair of TAG to determine whether your application needs to be presented to the Committee. Alternatively, you may receive Chair's approval to proceed.

STAGE 2: If a presentation is required you will be allocated the next available date and time. Please complete the application below and submit it electronically to newtechnologiesandprocedures@ouh.nhs.uk by the date requested. Please refer to the information required below and compose your paper so as to respond to all the questions. A

copy of this paper should also be sent to the relevant Clinical Director(s) before the date of your presentation.

STAGE 3: A presentation lasting no longer than 15 minutes is required, with a further 10-15 minutes allocated for questions. If your presentation is in PowerPoint format, please provide this in advance. The presentation must be given by the applicant: no company representatives should be present. If you have any questions about the process please call the TAG coordinator at extension 27794.

STAGE 4: Where approval is given, the applicant will be invited to provide the Committee an audit report 12 months after implementation or sooner at the Committee's discretion. The report will be passed to the relevant Division and to the Patient Safety &Clinical Risk Committee. The requirement is to report all serious adverse incidents, including Serious Incidents Requiring Investigation (SIRIs) associated with the new technology/procedure in line with Trust Policy (Incident Reporting and Investigation Policy version applicable at the time), and to the Chair of the TAG Committee.

Please complete and return to newtechnologiesandprocedures@ouh.nhs.uk

Applicants Details

Name:

Job Title:

Department/Directorate:

Presentation Title:

Date:

Funding

Will this procedure/technology have an impact on commissioned activity levels or expenditure within the Division?

If yes, please attach evidence of the Division's support to fund the procedure/ technology or to develop a business case?

1. Background

- An introduction to the technique
- Is this an innovation or a new indication for an existing technique?
- Is any equipment a fully CE-Marked Medical Device that is available on the market? (Applications concerning equipment, that is itself under research, or as part of a research programme, are not appropriate from approval under TAG. Separate Research &Development governance arrangements exist for this).

2. Current practice

- Is the technique currently being used in Oxfordshire, or in the UK and, if so, where?
- How many patients are being treated or expected to be treated?
- What are the current criteria for treatment?

3. Proposal for consideration

- Outline of proposed usage of technique
- Any staffing or service implications
- "Knock on" effects and implications for other services (i.e. critical care, nursing, diagnostics)
- Briefing on technique
- The implications if this technique is not introduced - are patients at risk?
- If yes, how?
- The implications if this technique is introduced – are patients at risk?
- If yes, how?
- What are the alternative treatments or procedures?

4. Training and competence

- Have you undertaken an accredited course for this technique? Details please.
- Has your competency been tested?
- Have you had animal experience?
- Have you proctored experience?
- Have you clinical experience? If so, how was it obtained and with whom?

5. Evidence of effectiveness

- Have NICE published, or are in the process of developing any interventional procedure guidance on the proposed new procedure? If yes, summarise the guidance.
- Data from research studies, clinical trials should be presented with reference list
- What are the proven benefits?
- What is the size of the benefit?

- How many patients will benefit? How will their quality of life improve?
- Do any sub-groups of patients benefit more than others?
- What evidence is there of risk?

6. Cost-effectiveness

- Data from economic evaluations should be presented list of references
- How does the treatment compare with those (of the same general type) in other clinical areas? (e.g. life-extending treatments from two different clinical areas)

7. Patient choice

- Is ethical review required?
- A patient information leaflet will be required as part of the application. Please bring this with you when you make your presentation to the committee.
- Do your consent arrangements conform to the Trust's patients consent policy?
- Do you have any views from individual patients?

8. Audit / Trials / Evaluation

- Are you already carrying out or planning any randomised trials?
- Please describe your plans to audit the introduction of this new technology/procedure, to be reported back to the committee at a later date to be agreed.

9. Are there any conflicts of interests? If yes, please give details

10. Clinical Director

Name:

Department/Directo

rate: Signature:

Date:

All enquiries and requests to present should be made through newtechnologiesandprocedures@ouh.nhs.uk

TRUST-WIDE CLINICAL POLICY DOCUMENT

CORPORATE POLICY AND PROCEDURE FOR THE INTRODUCTION OF ALL NEW INTERVENTIONS

Policy Number:	**SD16**
Scope of this Document:	**All Clinical Staff**
Recommending Committee:	**Drugs and Therapeutics Committee**
Approving Committee:	**Executive Committee**
Date Ratified:	**December 2015**
Next Review Date (by):	**December 2018**
Version Number:	**2015 – Version 1.4**
Lead Executive Director:	**Medical Director**
Lead Author(s):	**Chief Pharmacist**

2015 – Version 1.4

Quality, recovery and wellbeing at the heart of everything we do

1. PURPOSE AND RATIONALE

1.1 Mersey Care NHS Trust has an approach to delivering Perfect Care. This includes providing the most up to date and innovative therapies, medicines and interventions for service users. In order to do this, we need to ensure that when new therapies are introduced, it is done so within a framework that assures the quality of the practice. This is vital in order that service users receive the most effective care and that associated risks are managed effectively. This policy provides a framework that ensures due consideration is given those issues when new therapeutic interventions are introduced.

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

2.1 The aims of the document are as follows to demonstrate:

- Why the policy is necessary
- To whom it applies and where and when it should be applied
- The underlying principals upon which the policy is based
- The standards to be achieved
- How the policy standards will be met through working practices

2.2 The policy is applicable to any member of trust staff looking to introduce a new therapy or treatment in to the trust. The policy is not intend for use when a therapy or treatment is already established in one or more of the trust divisions and an additional area of the trust wishes to introduced the same therapy. In these circumstances the impact and effectiveness of the therapy must be discussed within the divisional management team.

2.3 This policy is an update to the original policy document SD-16; it should be read in conjunction with SD-12 - Handling of Medicine.

3. SCOPE

3.1 This policy applies to all Trust staff delivering any type of intervention to service users including as part of research. It also applies to non-Trust staff delivering interventions to service users within the care of the Trust as part of either research or contracted-out services.

3.2 The policy applies when a new type of intervention is introduced within a team where it has not been previously delivered or used. This may be traditional treatments such as medications; or psychological treatments such as talking therapies in group or individual sessions; or other types of treatments such as complimentary therapies, e.g. aromatherapy

4. DEFINITIONS

4.1 **New therapies -** Treatments that are introduced where they have not been provided previously used or utilised within the trust. These may be traditional treatments such as drugs; or psychological treatments such as talking therapies in group or individual sessions; or newer types of treatments such as complimentary therapies.

5. DUTIES

5.1 Trust Board - The trust board is responsible for ensuring that quality, safe and cost-effective treatments and therapies are used within the trust and that all staff working in the trust are aware of, and operate within the policy.

5.2 Drugs and Therapeutics Committee - The Drugs and Therapeutics Committee (DTC) works within the governance structures of the trust; it ensures that medicines and related treatments are managed in an effective manner across the organisation. The DTC reports directly to the trust Quality Assurance Committee (QAC).

5.3 Chief Pharmacist – The trust Chief Pharmacist is a member of the Pan-Mersey Area Prescribing Committee (APC) and also chairs the trust DTC. The Chief Pharmacist will ensure that there is appropriate dialogue between the two committees when considering new interventions. Pharmacy staff attend working sub-groups of the Pan-Mersey APC on a regular basis.

5.3 Divisional Associate Medical Director (AMD) - The Trust AMDs are responsible for ensuring that all managed staff members are aware of and operate within the policy.

5.4 Multidisciplinary team - It is an essential duty of the multidisciplinary team that potential new therapies and treatments are considered using an evidenced based approach.

5.5 Trust staff - should follow the algorithm overleaf when identifying a potential new treatment or therapy.

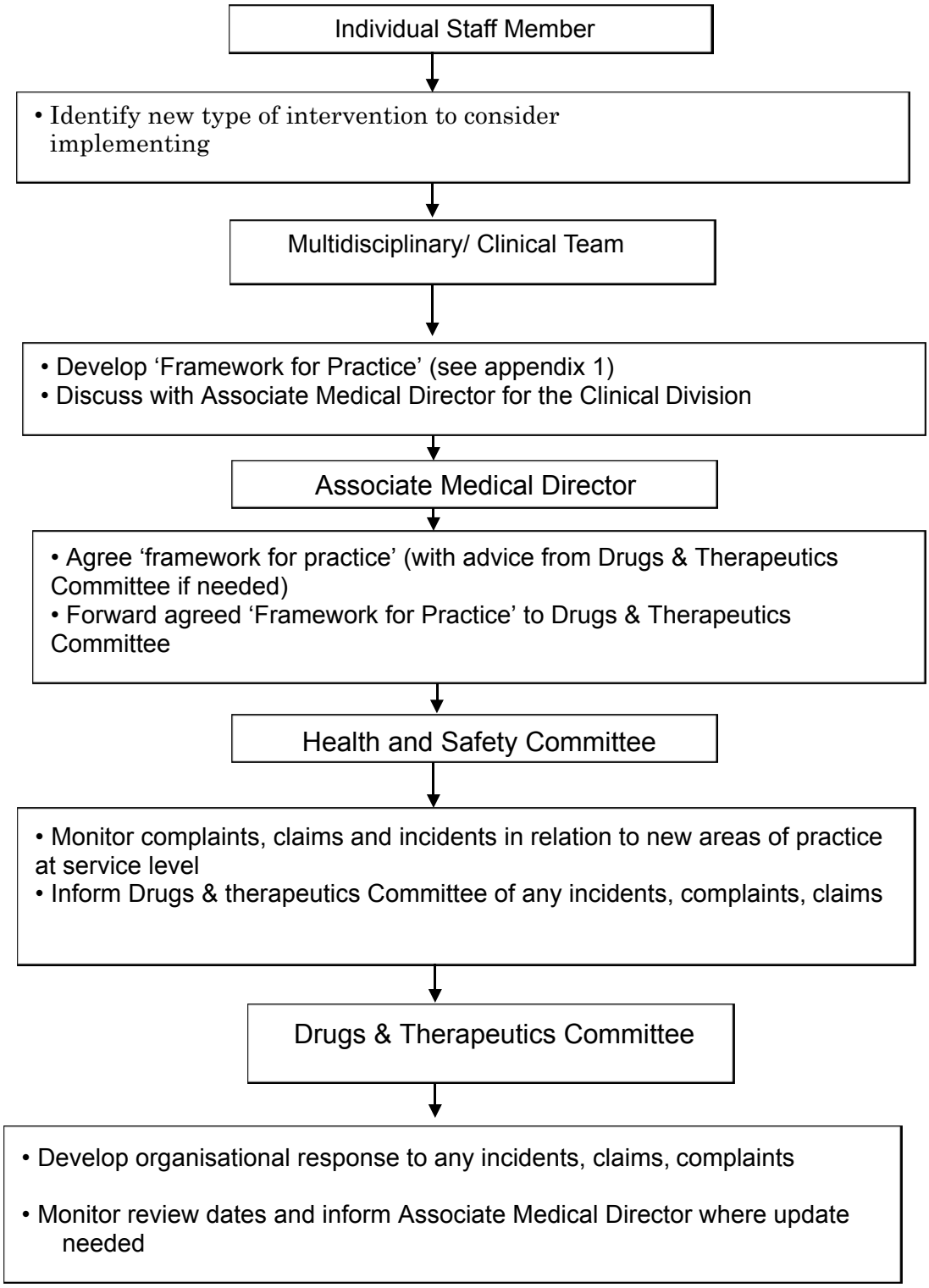
6. PROCESS

6.1 This is a corporate procedure for Mersey Care NHS Trust. Local procedures are not appropriate in relation to this Trust policy.

7. CONSULTATION

7.1 This procedure has been developed with the current and previous procedures that have been in place for Mersey Care NHS Trust and it's predecessors; in association with the trust's Drugs and Therapeutics Committee.

Figure 1 - Flow chart illustrating the corporate procedure for the introduction of new therapies



University Hospitals Bristol NHS
NHS Foundation Trust

Policy on introducing NEW INTERVENTIONAL PROCEDURES into routine clinical practice

Date:	May 2008
Author:	Clinical Effectiveness Coordinator (*James Osborne)*
Approved by:	UBHT Clinical Effectiveness Committee – May 19th 2008
Ratified by:	Governance & Risk Management Committee
Version:	3.0
Review Date:	May 2010

1 EXECUTIVE SUMMARY

1.1 This policy sets out the Trust's expectations for good governance in the introduction of new interventional procedures within the Trust.

2 DEFINITIONS

2.1 For the purposes of this policy, the term 'interventional procedure' refers to a clinical practice for diagnosis or treatment that involves one or more of the following;

- Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel
- Gaining access to a body cavity without cutting into the body - for example, inserted via the mouth
- Using electromagnetic radiation - for example, using a laser to treat eye problems.

3 SCOPE

3.1 The policy applies to interventional procedures offered by the Trust to NHS patients, irrespective of the location or staff involved, or if the procedure has been reviewed by the National Institute for Health and Clinical Excellence (NICE).

3.2 The policy does not apply to the private practice of Trust staff, where the interventional procedure is offered by an external provider to their private patients.

3.3 The policy does not apply where the interventional procedure is offered to patients within the context of a formal research study.

- In such circumstances, the Trust Research & Development Policy applies, which is available at the following URL: http://nww.avon.nhs.uk/dms/download.aspx?did=4158

4 UNDERLYING PRINCIPLES

4.1 The Trust aspires to be a leading centre of clinical excellence with an expectation that innovation in diagnosis and/or treatment is an ever-present cultural norm.

4.2 The Trust must be assured that clinical staff are competent in the activities that they undertake.

4.3 The Trust and its staff have a responsibility to ensure that all new clinical interventional procedures that are introduced into practice are safe and clinically effective, and in particular, in line with and in support of NICE Interventional Procedures requirements. (see also 6.2)

4.4 The key factors to be assessed in determining the clinical effectiveness of new interventional procedures include;

- reducing clinical morbidity and mortality
- increasing functional quality of life

- reducing patient length of hospital stay and overall recovery time
- reducing pain
- reducing adverse risks

4.5 The Trust is required to make best use of limited resources available, i.e. to balance both the clinical and the cost effectiveness of any interventional procedure and resultant overall diagnosis and/or treatment

4.6 Where a new interventional procedure replaces an existing procedure or treatment, the clinical effectiveness of the new procedure must be at least equivalent to the existing procedure or treatment.

5 APPLYING TO INTRODUCE A NEW INTERVENTIONAL PROCEDURE

5.1 The responsibility to inform the Trust and gain agreement before proceeding rests with the applying clinician.

5.2 The applying clinician has a responsibility to discuss their developing application with relevant colleagues and to demonstrate their broad clinical and managerial agreement in support of the application within the sponsoring clinical division.

5.3 The applying clinician must notify the Trust through the submission of a formal application to the Trust Clinical Effectiveness Committee.

- The interactive application form is available online on the Trust Intranet (*currently at* http://intranet/twg/clinical-effectiveness/new-procedures.htm)

- Submission is online. If technical assistance in completing the form is required, this is available from the Clinical Effectiveness Coordinator

5.4 The key elements of the application are as follows;

- Information about the applicant - *name, position, contract status, contact details, sponsoring clinical division*

- Information about the procedure - *name, brief description, disease, current procedure, patient selection, where else offered*

- Outline of the benefits and risks - *benefits to patients, benefits to the Trust, benefits to the wider NHS, likelihood of a learning curve, risks to patients, patient information leaflet for informed consent*

- Outline of the evidence base - *if reviewed by NICE or NHS Centre for Reviews & Dissemination and what they conclude, key peer-reviewed studies*

- The key finance implications - *likely financial impact, demonstrable divisional manager support, attached business case where appropriate, statement of any conflicts of interest*

- Information about relevant specialist training - *evidence of accredited training, any initial presence of visiting experts*

- Anticipated clinical audit - *whether current data is available for comparison, future audit criteria, audit timetable*

- Requested start date

5.5 The Clinical Effectiveness Coordinator will act as the named liaison between the Clinical Effectiveness Committee and the applicant.

5.6 The application will be considered at the next available meeting of the Clinical Effectiveness Committee, which typically meets monthly.

5.7 Where a new procedure is being considered **within an emergency** situation, the clinician is expected to consult with senior colleagues and if possible with the Medical Director. Following the event, the Chair of the Clinical Effectiveness Committee must be informed within 72 hours, and a formal application considered for future use.

6 REVIEWING A SUBMITTED APPLICATION

6.1 Where NICE have published interventional procedure guidance on the proposed new procedure, the Clinical Effectiveness Committee will reflect their guidance in its decisions;

- When NICE determine that the '*evidence on safety and efficacy of … is adequate to support the use of the procedure provided that **normal arrangements** are in place for consent and audit and clinical governance'*, the focus of the Committee in reviewing the application will be satisfactory submissions relating to the above caveats, and that the applicant clinician has met externally set standards of training. It is not expected in such circumstances that the Committee will repeat the detailed review of primary evidence, as this has already been conducted by NICE.

- When NICE determine that the *'evidence on the safety and efficacy of … does not appear adequate to support the routine use of this procedure without special arrangements **for consent and for audit or research'***, the Committee in reviewing the application will take into account any fresh supporting evidence provided, that there are satisfactory submissions relating to the above caveats, and that the clinician has met externally set standards of training.

- When NICE determine that the '*evidence on safety and efficacy of … does not appear adequate to support the routine use of this procedure. It is suitable for use **only within good-quality research studies approved by a research ethics committee and with explicit patient consent**'*, the default position of the Committee will be to refuse the application, and to redirect the applicant to considering the procedure within the context of a research study.

6.2 When it is known that NICE are developing guidance on the interventional procedure, the default position of the Clinical Effectiveness Committee will be to defer the application until the guidance is formally published.

- A list of published and 'in development' interventional procedure guidance is maintained by NICE at the following URL: http://guidance.nice.org.uk/page.aspx?o=ipsearch

6.3 If the procedure has not been notified to NICE, the Clinical Effectiveness Committee should only approve its use if the following conditions are met;

- Sufficient credible peer-reviewed evidence is provided as to the safety and efficacy of the procedure

- Documentary evidence that the clinician has met externally set standards of training, or that such training has been scheduled

- Patients are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded.

- Proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that can be used to review continued use of the procedure. Where possible, a pre-determined standard of acceptable clinical performance should be established, in order to allow the Trust to determine that anticipated clinical endpoints have been achieved.

- Where the submitted evidence is internally contradictory, an option open to the Committee is to refer the procedure for formal consideration by NICE. More information on this process is available at the following URL: http://www.nice.org.uk/page.aspx?o=ts.home

7 THE APPROVAL PROCESS

7.1 The applicant may be asked to attend the meeting of the Clinical Effectiveness Committee in person, in order to answer anticipated detailed questions arising from their application.

7.2 The decision of the Clinical Effectiveness Committee must be formally recorded in the minutes of the Committee

7.3 The decision of the Clinical Effectiveness Committee will be issued to the sponsoring clinical division in writing, signed by the Chair of the Clinical Effectiveness Committee.

7.4 In some circumstances, the approval may be conditional, for example on satisfactory performance as demonstrated by clinical audit.

8 APPEALING THE DECISION

8.1 Where an application is deferred or refused, the Chair of the Clinical Effectiveness Committee will provide a timely explanation in writing to the applicant and the sponsoring clinical division.

8.2 Where an application is deferred or refused, the applicant has the right of appeal and updated resubmission to the Chair of the Clinical Effectiveness Committee, and if further necessary, to the Trust Medical Director. There must be documented support for the appeal by the sponsoring Clinical Divisional Board.

9 ASSURING THE POLICY

9.1 The assurance framework for this policy is summarised in the following table;

9.2 A summary of approved procedures will be listed on the Trust Intranet

9.3 The Policy as a whole will be formally reviewed by the Clinical Effectiveness Committee every two years.

10 ROLES AND RESPONSIBILITIES

This section lists the key staff or group roles referred to in this policy, with a brief summary of their relevant responsibilities

10.1 Clinical lead (applicant)

- To seek authorisation from the Trust before introducing new interventional procedures
- To submit an application to the Clinical effectiveness Committee
- To prepare and agree a business case, where advised by the relevant divisional manager
- To develop/adapt an appropriate patient information leaflet
- To fully inform prospective patients of the benefits and risks associated with the procedure, compared to standard treatment, and to record this interaction within patient notes

10.2 Clinical Effectiveness Coordinator

- To liaise with clinical lead applicants to ensure that the submitted application form is fully completed
- To circulate completed applications to the Clinical effectiveness Committee
- To formally refer to NICE any new procedures apparently new to the NHS

10.3 Clinical Effectiveness Committee

- To review received applications carefully, and to make an assessment on the clinical effectiveness of the proposed procedure, taking into account known benefits/risks and proposed arrangements for training/supervision, informed consent, and clinical audit.
- In arriving at a decision, the Committee should take into account any relevant guidance issued by NICE or the NHS Centre for Reviews & Dissemination
- To request additional information from and personal attendance of the Clinical Lead Applicant, where there is uncertainty on any aspect of the proposed procedure

10.4 Clinical Audit Convenor & Facilitator

- To liaise with clinical lead applicants in scheduling appropriate clinical audit into the speciality forward programme
- To ensure that the audit is conducted and results presented locally, with appropriate action plans documented and signed off

Table summarising the assurance framework for this Policy

Monitoring	**What**	**When**	**Who By**
Consultant staff are aware of the need to seek authorisation	Consultant Information Packs on Induction Days and Away Days	Annual	Clinical Effectiveness Coordinator
Application forms are adequately completed	Submitted applications	Following online submission	Clinical Effectiveness Coordinator
Application forms are circulated to Clinical Effectiveness Committee	Committee agenda papers / emails	Annual	Clinical Effectiveness Coordinator
Clinical Effectiveness Committee reviews and decides on applications	Committee minutes	Annual	Clinical Effectiveness Coordinator
Process for ensuring that agreed clinical audit is scheduled	Registered Clinical Audit Project	Following approval by Clinical Effectiveness Committee	Clinical Lead (Applicant) Speciality Clinical Audit Convenor Speciality Clinical Audit Facilitator
Clinical audit results demonstrate expected clinical benefits	Speciality clinical audit meeting minutes and audit report	As stipulated in application form, no later than six months following commencement of procedure	Clinical Lead (Applicant) Clinical Effectiveness Coordinator
Agreed patient information is offered to patients	Documented in patient treatment notes as demonstrated by representative audit	Annual	Clinical Lead (Applicant) Speciality Clinical Audit Facilitator

Portsmouth Hospitals NHS
NHS Trust

NEW CLINICAL PROCEDURES, INTERVENTIONS AND TECHNIQUES INTRODUCTION POLICY

Version	5
Name of responsible (ratifying) committee	Operational Board
Date ratified	05 October 2016
Document Manager (job title)	Medical Director
Date issued	27 October 2016
Review date	26 October 2019
Electronic location	Clinical Policies
Related Procedural Documents	NICE Implementation Policy, Consent Policy, Patient Information Policy, Policy for the Management of Adverse Incidents and Near Misses, Policy for the Management of Serious Untoward Incidents
Key Words (to aid with searching)	New: Interventions; Procedures; Techniques; NICE; Clinical procedures; Clinical practice; Clinical guidelines; Medical staff; Forms; Clinical procedures; Clinical measurement; Professional advisory committees; Advisory committees; NHS structure; National Institute for Health and Clinical Excellence; National Institute for Clinical Excellence; Infection control; Risk assessment; Health and safety; Governance; Corporate governance; Business planning; Duties; Training; Protocols; Clinical guidelines

Version Tracking

Version	Date Ratified	Brief Summary of Changes	Author
5	05/10/16	No changes	Med Director
4	02/04/13	-	Med Director

INTRODUCTION

Portsmouth Hospitals NHS Trust (the Trust) recognises the need for innovation and views the introduction of new techniques and procedures as a vital part of practice to improve patient care and enhance the patient experience.

However, this must be balanced with the corporate responsibility for ensuring the safety of patients involved in the introduction of such techniques and procedures. The Trust must ensure that when new techniques and procedures are introduced they are appropriate, effective and that all staff undertaking or involved in the procedure are trained.

PURPOSE

This policy sets out the process for the introduction of new interventional techniques or procedures and is designed to enable clinicians to embrace those interventions whilst ensuring adequate controls are in place to protect patients and reduce risk.

SCOPE

This policy applies to:

- All clinicians working for the Trust but who are no longer in training, including locum and agency staff.
- The proposed introduction of any new clinical technique or procedure which has not previously been undertaken within the organisation.

This policy does not apply to:

- Any procedure which is part of a research study when the research governance procedures would apply;
- The introduction of new drugs as these are dealt with separately by the Formulary and Medicines Group.

Important Note

Incremental improvements to existing practice due to changes in technique proposed by professional bodies are not considered a new procedure. Any changes or improvement in technique must be fully supported by the relevant professional clinical organisations and NICE. A move from open surgery to endoscopic procedure would be new to the Trust and would require the completion of a new procedure proposal. Where any ambiguity exists with the proposed new procedure, clarification should be sought from the Specialty / CSC Governance Committee and if required with the Medical Director.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

DEFINITIONS

Interventional Procedure: a procedure used for diagnosis or treatment which involves the following

- Making a cut or hole to gain access to the inside of a patient's body. For example, when carrying out an operation or inserting a tube into a blood vessel;

or

- Gaining access to a body cavity, such as the digestive system, lungs or bladder, without cutting into the body. For example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth;

or

- Using electromagnetic radiation, including x-rays, lasers, gamma-rays and ultraviolet light. For example, using a laser to treat eye problems

New Clinical Procedure: any clinical intervention which involves new techniques which have not previously been undertaken by the Trust; it may also include the use of new equipment.

National Institute for Health and Clinical Excellence (NICE): NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.

DUTIES AND RESPONSIBILITIES

Chief Executive: The Chief Executive has overall responsibility for ensuring there are appropriate processes in place for the introduction of new techniques, but delegates this responsibility through the Medical Director.

Trust Board: The Trust Board has overall responsibility for ensuring that it receives appropriate updates from the Medical Director on the introduction of any new intervention or technique.

Medical Director: The Medical Director has responsibility for ensuring that appropriate processes are in place for the introduction of new techniques.

Operational Board: The Trust Operational Board has responsibility for final approval of the introduction of any new intervention or technique. As sub-committee of the Trust Board, the Operational Board has responsibility for final approval or rejection of any outline business case submitted to the Committee with regard to the introduction of any new intervention or technique.

CSC Management Team: The CSC Management Team has responsibility to approve or reject a proposal for the introduction of any new intervention or technique, prior to any submission to the SMT.

Medical Devices Management Committee (MDMC): The MDMC has responsibility for the consideration of any potential equipment issues associated with the proposal, when new equipment is being proposed.

CSC Governance Committees: The CSC Governance Committee has responsibility to approve or reject a proposal for the introduction of any new intervention or technique, prior to submission to the CSC Management Team and for ensuring that this policy has been adhered to. The CSC Governance Committee is responsible for assuring themselves that the new technique/procedure is being monitored effectively. Where there is no Specialty Governance Group, the Committee will need to assure themselves that the outcomes of audits related to the effectiveness of the new intervention/technique are being monitored by an appropriate group. The outcome of the introduction of any new technique/procedure must be reported to the Governance and Quality Committee within the CSC Governance report.

Speciality Governance Groups: The Specialty Governance Groups have responsibility for the initial consideration and approval or rejection of a proposal for the introduction of any new intervention or technique, prior to submission to the CSC Governance Committee. The specialty governance group is responsible for ensuring that the outcomes of audits related to the effectiveness of the new intervention/technique are monitored. The group is responsible for escalating any issues arising from any audits to the CSC Governance Committee.

Speciality Clinical Directors: Speciality clinical directors are responsible for supporting individual clinicians in the introduction of a new interventional technique or procedure and will act as sponsor for the new intervention/procedure proposal.

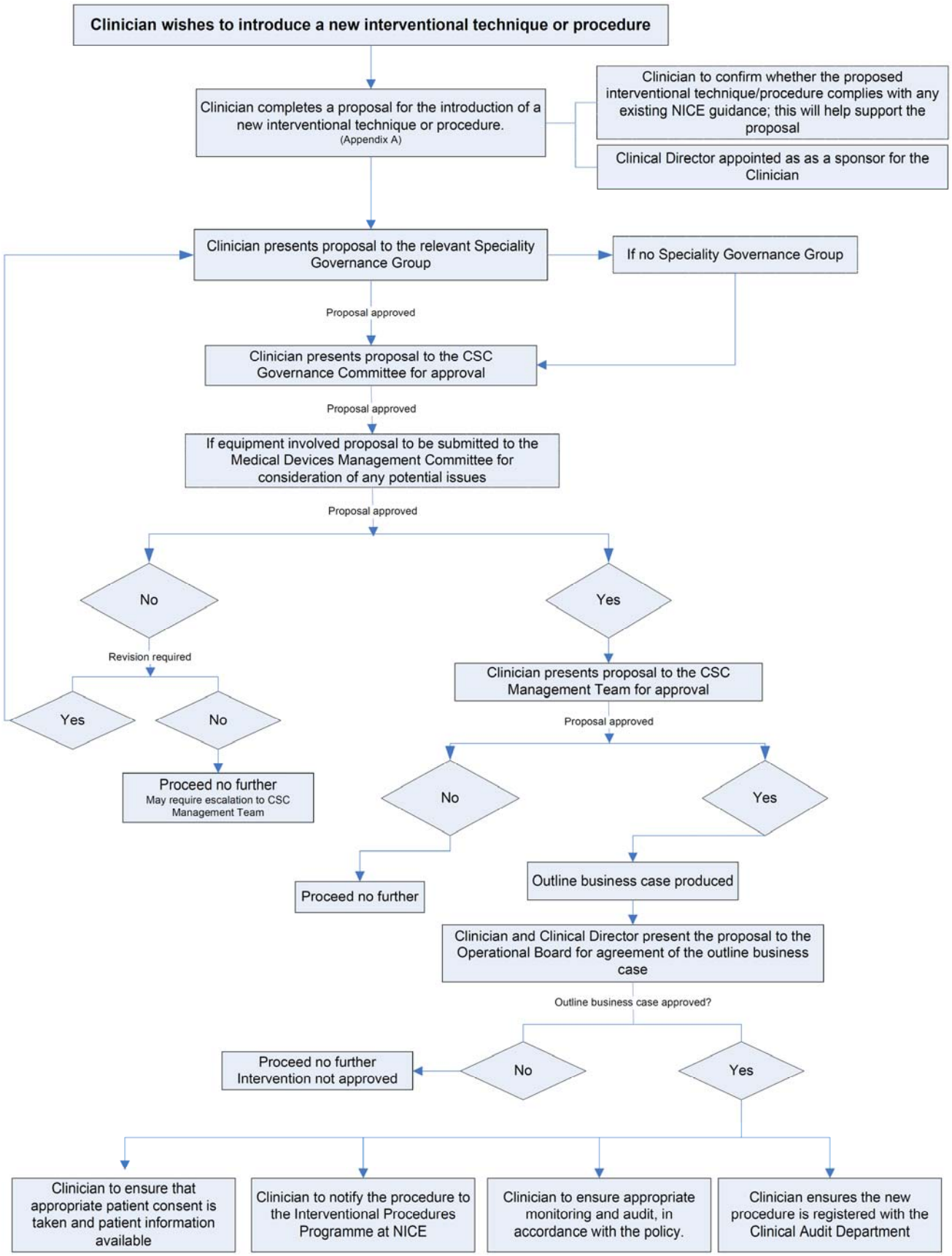
Individual Clinicians: Individual clinicians have responsibility for:

- The introduction of any new interventional technique or procedure to their patients, including providing appropriate information and gaining appropriate consent;
- Ensuring that before any new interventional technique or procedure is introduced Trust agreement is obtained in accordance with this policy;
- Ensuring an audit of the effectiveness and outcomes of any new interventional technique or procedure is undertaken and registering that audit with the Clinical Audit Department;
- Reporting the results of the audit to the relevant Specialty Governance Group, the CSC Governance Committee and the Clinical Audit Department; and
- To notify the procedure to the Interventional Procedures Programme at NICE.

Clinical Audit Department: The Clinical Audit Department are responsible for providing advice and support to individual clinicians on audits undertaken in relation to the introduction of any new intervention or technique, and for maintaining a register of these audits.

PROCESS

Introduction of New Interventional Technique or procedure



Consent

The information given prior to consent by a patient must include specific reference to the fact that the technique or procedure is new. Patients need to understand that the procedure's safety and efficacy may be uncertain, and must be informed of the anticipated benefits and possible adverse effects of the treatment and of the alternatives, including no treatment. If written consent is not usually required for the normal procedure, consideration should be given to seeking written consent as a means of documenting the information given to the patient, and their agreement to it.

Audit

Any new technique or procedure introduced to the Trust must have guidance developed to accompany it and must be subject to ongoing monitoring and audit: the proposal for introduction must include arrangements for that audit. Results of the audit must be reported to the specialty governance group, the CSC Governance Committee and the Clinical Audit Department. The frequency of the audit will depend on the intervention. The Specialty Governance Group will ask for a report from the clinician, on the first 20 patients treated. For less frequently performed interventions, the group will require a report from the clinician after the first 6 months of introducing the intervention; if 20 patients have not been treated by that time.

Adverse Incident Reporting

Any adverse incident or near miss which occurs when undertaking a new interventional technique or procedure must be reported immediately, in accordance with the Trust's Policy for the Safety Learning Events and Near Misses Policy or the Trust's Policy for the Serious Incident Requiring Investigation Management Policy depending on the severity of the adverse incident. The completed adverse incident reporting form must clearly indicate that the incident occurred during the course of a new interventional technique or procedure.

Emergency Situations

In very exceptional circumstances, it may be necessary to expedite approval for the use of a new interventional technique or procedure. This should only occur in an emergency situation where there is a clear clinical need for the management of the patient and where delay in using the intervention would be life threatening. It is expected that appropriate horizon scanning will offer an ongoing process of prioritisation; ensuring decisions about intervention are made before an emergency is present. Under these circumstances, the clinician involved should seek the advice of the Medical Director or in his absence his deputy, who will approve the intervention if deemed appropriate.

TRAINING REQUIREMENTS

Any clinician who wishes to introduce a new interventional technique or procedure will:

- Provide evidence of training and competency to under take the new procedure
- Identify the training needs of all other staff who will be involved in the new procedure and how those needs have been, or will be, met.

No proposal will be accepted without details of required training and competence.

MONITORING COMPLIANCE WITH THIS POLICY

This document will be monitored to ensure it is effective and to assure compliance.

Key Performance Indicator	Lead Responsible for Audit	Evidence	Reviewed by / Frequency	Lead Responsible for any Required Actions
All new interventional techniques or procedures will be approved by the CSC Management Team	Author of policy	Minutes of meetings	Annual	Medical Director
All new interventional techniques or procedures will be approved by CSC Governance Committees	Author of policy	Minutes of meetings	CSC Governance Committees Six monthly	Medical Director
All new interventional techniques or procedures will be ratified by SMT	Author of policy	Minutes of meetings	SMT Six monthly	Medical Director

Proposal for the Introduction of a new procedure / technique

PROPOSAL FOR THE INTRODUCTION OF A NEW PROCEDURE/TECHNIQUE	
Lead Clinician	Name Title Contact number
Title of procedure with brief description of what is involved in the intervention	
Target patient group and benefits for patient	
Evidence of effectiveness, quality and safety (including confirmation of review of NICE guidance) *Contact R&D office for advice / support*	
Evidence of Lead Clinician training and competence to undertake procedure.	
Name and title of any other persons undertaking procedure	
Evidence of training and competence of other persons to undertake procedure	
Arrangements for audit / review of effectiveness *Contact Clinical Audit Department for advice/support*	
If this intervention impacts on other teams / services have they been contacted	
Describe the impact on the other teams / services	
What patient information is to be provided? *Contact Health Information Resource and Advice Centre officer for advice/support*	
Capital costs (equipment, training etc.) *Contact CSC Finance Manager for advice / support*	
Recurring costs (disposables, theatre time, length of stay etc)	
Efficiency gains or cost savings	
Funding Source	
Options appraisal *Briefly assess the benefits, costs and risks of each option*	
Do nothing	
Partial implementation *(i.e. for particular cohort of patient)*	
Full implementation	
Recommended option	
Reviewed by Specialty Governance Group Date Approved by *(on behalf of Speciality),* Contact number	
Reviewed by CSC Governance Committee Date Approved by *(on behalf of CSC Governance Committee),* Contact number	
Reviewed by MDMC *(if new equipment involved)* Date Approved by *(on behalf of MDMC)* Contact number	
Reviewed by CSC Management Team Date Approved by Chief of Service *(on behalf of CSC)* Contact number	
Reviewed by Operational Board *Proposing Clinician must attend with CSC Sponsor* Date Approved by *(on behalf of Speciality)* Contact number	
Ratified by Operational Board Date Approved by *(on behalf of Operational Board)* Contact number	
Added to New Interventions register Date Name Contact number	
Notified to NICE Date	

Portsmouth Hospitals NHS
NHS Trust

Equality Impact Screening Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval for service and policy changes/amendments.

Stage 1 - Screening			
Title of Procedural Document: New Clinical Procedures, Interventions and Techniques Introduction Policy			
Date of assessment	27 October 2016	**Responsible Department**	Corporate
Name of person completing assessment	Jan Newman	**Title**	Governance Coordinator

Does the policy/function affect one group less or more favourably than another on the basis of :	**Yes/No**	**Comments**
• Age	No	
• Disability: Learning disability; physical disability; sensory impairment and/or mental health problems	No	
• Ethnic Origin (including gypsies and travellers)	No	
• Gender reassignment	No	
• Pregnancy or Maternity	No	
• Race	No	
• Sex	No	
• Religion and Belief	No	
• Sexual Orientation	No	
If the answer to all of the above questions is NO, the EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 2		
More Information www.legislation.gov.uk/ukpga/2010/15/contents		

Stage 2 – Full Impact Assessment			
What is the impact	**Level of Impact**	**Mitigating Actions** (what needs to be done to minimise / remove the impact)	**Responsible Officer**

Monitoring of Actions	
The monitoring of actions to mitigate any impact will be undertaken at the appropriate level	
Specialty Procedural Document:	Specialty Governance Committee
Clinical Service Centre Procedural Document:	Clinical Service Centre Governance Committee
Corporate Procedural Document:	Relevant Corporate Committee
All actions will be further monitored as part of reporting schedule to the Equality and Diversity Committee	

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Introduction and Development of New Clinical Interventional Procedures

Version No.:	2.1
Effective From:	27 November 2017
Expiry Date:	7 January 2019
Date Ratified:	26 October 2017
Ratified By:	New Interventional Procedures Committee

1 Introduction

1.1 As of 13th November 2003, medical practitioners planning to undertake new interventional procedures need to seek approval from the Trust's "New Interventions Procedure Committee" before doing so (see HC2003/11).

1.2 This policy lays down the procedures to be followed to comply with the requirements of HC2003/11.

2 Scope

This policy applies to all members of staff and covers the introduction of new clinical procedures into the Trust.

3 Aims

Advances in clinical care can often only be made by allowing the introduction of new techniques. However, patient safety must not be compromised. It is important, therefore, that the Trust has a policy to enable new interventional procedures to be introduced safely and with full communication with patients and staff.

4 Roles and Responsibilities

4.1 New Interventional Procedures Committee (NIPC)

The NIPC will develop and monitor strategies for the introduction of new clinical procedures within the Trust. The NIPC will provide assurance to the Clinical Governance and Quality Committee that new interventional procedures have undergone a thorough appraisal by an appropriately constituted Committee prior to making recommendations to the Clinical Governance and Quality Committee regarding approval of new interventional procedures for use within the Trust.

4.2 Clinical Governance and Quality Committee

Final approval for the use of new interventional procedures within the Trust will be granted by the Chair of the Clinical Governance and Quality Committee. The Medical Director's Group is also authorised by exception to grant final approval

4.3 Clinical Governance and Risk Department

The Clinical Governance and Risk Department will maintain the Trust's Procedures Register, recording the date of the introduction of the new procedure in the Trust, the arrangements for ongoing audit with the Directorate/Department and the review date for reporting on progress back to the New Interventional Procedures Committee (NIPC).

4.4 Research and Development

Research and Development (R&D) will liaise with the NIPC regarding the development and introduction of new clinical procedures. In particular, R&D should notify the New Interventional Procedure Committee of any new high risk interventional procedure which is submitted to the R&D Committee as part of a trial. The procedure will require approval by the New Interventional Procedure Committee prior to use within the context of a research trial and before being used as standard practice.

4.5 Medical Directors' Group

The Medical Directors Group will have responsibility for ensuring that appropriate documentation is completed by project leads and proctors prior to commencement of the actual procedure.

5 Definitions

5.1 An interventional procedure is a procedure used for diagnosis or treatment which involves one of the following.

- Making a cut or a hole to gain access to the inside of patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel;
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body, for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth.
- Using electromagnetic radiation (which includes X-rays, lasers, gamma- rays and ultraviolet light) – for example, using a laser to treat eye problems.

5.2 An interventional procedure is considered new if it has not been carried out before in this Trust.

5.3 A proctor provides training to and objectively evaluates the clinical competence of another physician. A proctor, for these purposes, is defined as an external practitioner who attends to supervise and train a Newcastle Hospitals clinician when they undertake an approved new interventional procedure on Newcastle Hospitals premises.

6 The New Interventional Procedures Committee (NIPC)

6.1 The Secretary of the Trust's New Interventional Procedures Committee will check to see if the new procedure has been notified to the Interventional Procedure Programme at the National Institute for Health and Care Excellence (NICE).

6.2 If it is registered, the NIPC will consider whether the proposed use of the procedure complies with the guidance before approving it.

6.3 If the interventional procedure is not already listed under the NICE Interventional Procedure Programme, following approval from the New Interventional Procedures Committee, the applicant will ensure that the procedure is notified to the Interventional Procedures Programme at NICE. The NIPC will prepare an overview of the evidence about the procedure and decide whether to issue guidance or seek better information. NICE will prepare a brief overview of the evidence on the procedure's safety and efficacy and consult its Specialist Advisors. As part of this process, NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with it. NICE consults publicly on all its guidance and its advisory committee will consider response to consultation before guidance on any procedure is issued.

6.4 Where the interventional procedure has been used in an emergency so as not to put a patient at serious risk, i.e. where no other treatment option exists, the medical practitioner must inform the Chair or Deputy Chair of the NIPC within 72 hours of the procedure taking place and notify NICE accordingly.

7 Registering a New Procedure within the Trust

7.1 Senior clinicians planning to undertake a new interventional procedure are asked to complete the Registration form at Appendix 1 and send the completed form to the secretary of NIPC by electronic mail.

7.2 The practitioner proposing to undertake the new procedure will also need to provide evidence of training and competency which meets externally set standards. The practitioner will be required to attend the NIPC meeting to present the application to members present.

7.3 Where NICE guidance is available (see NICE process Appendix 2) the applicant should ensure that they have clearly demonstrated that their proposed use of the procedure complies within this guidance.

7.4 If the NICE has not issued guidance on the procedure the Committee should only approve its use if:

- The clinician has met externally set standards of training.
- All patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded. Patients need to understand that the procedure's safety and efficacy is uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
- The NIPC is satisfied that the proposed arrangements for clinical audit are robust and will capture data on clinical outcomes that will be used to review continued use of the procedure.

7.5 All new interventional procedures must have a specific patient information leaflet and the NIPC will

agree on clinical content but the leaflet itself must be approved by the Patient Information Panel before the procedure can be undertaken. If the NIPC is happy that all issues have been satisfactorily addressed, it will recommend the procedure for approval to the Clinical Governance and Quality Committee. Once approval is received from the Clinical Governance and Quality Committee, the practitioner will notify NICE of unregistered procedures using the electronic facilities on the NICE website (with the support of CGARD).

7.6 Where the Committee considers that more information/evidence is required before a decision can be made; this will be communicated to the practitioner, including details of the next meeting of NIPC. In cases where the committee has identified several key issues, the practitioner will also be required to attend the meeting and represent the application.

7.7 All new interventional procedures ratified by the NIPC will be signed off by the Chair or Deputy Chair, recorded within the committee minutes and on the Trust's New Procedures Register.

7.8 It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use procedure in a clinical emergency so as not to place a patient at serious risk. If a doctor has performed a new interventional procedure in such circumstances he/she must inform the Chair or Deputy Chair of the NIPC within 72 hours. The Committee will consider approval of the procedure for future use as above.

7.9 When NICE is collecting data under this Programme, clinicians should supply the information requested on every patient undergoing the procedure. The Trust is encouraged to support this to enable the National Health Service to have access more speedily to guidance on the procedure's safety and efficacy. The collection of data from patients will be governed by the Data Protection Act.

7.10 The only exception to the above process is when the procedure is being used only within protocol approved by a Joint Research Ethics Committee (JREC). In this case, notification to NICE is not needed, as patients are protected by the JREC's scrutiny. However, JREC should notify the NIPC when they approve a protocol involving an interventional procedure. Use outside the protocol should only occur after approval from NIPC as set out above.

7.11 If an adverse incident occurs in association with a new interventional procedure, the NIPC Chairman should be notified immediately, reported to the National Patient Safety Agency through the Trust Incident Reporting system in the normal way.

8 Proctors

Where new procedures are complex and require technical skills which the lead clinician / staff who are going to be undertaken the procedure do not already possess, the identification of an appropriate proctor may be required.

8.1 The procedures to be followed by proctors are detailed in Appendix 3a.

8.2 Proctors must have appropriate experience to undertake the procedures themselves and to supervise an inexperienced practitioner.

8.3 They must discuss the specific case with the clinician undertaking the procedure prior to commencement of the procedure.

8.4 Proctors must be present throughout the procedure being undertaken Proctors must ensure that the Newcastle Hospitals clinician has adequate prior training to undertake the new interventional procedure. On completion of the training, which will include both supervising and observing the intended operators, the proctor will evaluate the performance of the clinician in undertaking the new interventional procedure, and the wider operating team.

8.5 A written evaluation from the proctor is required (see Appendix 3b) which will either provide assurance that the proctor is assured of the competency of the operator in undertaking the procedure, or that further action / training is required before the operator can deliver the procedure independent of the proctor.

8.6 The evidence and documentation should be submitted to the Medical Director's Group for approval.

9 Training

There is no specific training associated with this policy.

10 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals

or groups on any grounds. This document has been appropriately assessed.

11 Monitoring and Review of Policy

Standard / process / issue	*Monitoring and audit*			
	Method	*By*	*Committee*	*Frequency*
The registration process and maintenance of the Procedures Register is compliant with the system outlined in this policy	Audit	CGARD	NIPC	Annual

12 Consultation and review

This policy has been discussed with the NIPC, Clinical Governance and Quality Committee and the R&D Department.

13 Implementation (including raising awareness)

This policy will be publicised on the Trust intranet and via the Trust Policy Newsletter.

14 References

- Health Service Circular HSC 2003/11
- National Institute of Health and Care Excellence web site

15 Associated Policies

- Consent to Examination and Treatment
- NICE Guidelines Implementation Policy
- Engagement of Proctors Policy

Appendix 1

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

New Interventional Procedure Registration Form

Notes

What is an Interventional Procedure?

The NICE definition of an interventional procedure is one that is used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy, i.e.

- Making a cut or a hole to gain access to the inside of patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel The clinician has met externally set standards of training;
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body, for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth;
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.

If you are not sure whether your procedure is "interventional" please discuss your submission with the Chair / Deputy Chair of the Trust's New Interventional Procedures Committee (NIPC) before sending in your registration form.

What is a *New* Interventional Procedure?

An interventional procedure should be considered new if it has not been carried out before in this Trust**. This also applies to any new high risk interventional procedure which is performed as part of a trial, including those which have been approved by the Research and Development Committee.**

Any person considering use in the Trust of an interventional procedure which has not been performed in the Trust before, should seek the prior approval of the Trust's New Interventional Procedures Committee. They should state whether the procedure is the subject of National Institute for Health and Care Excellence (NICE) guidance as listed on their website, http://www.nice.org.uk/guidance/published?type=IPG . If it is, the Committee will consider whether the proposed use of the procedure complies with the guidance before approving it.

Where no NICE guidance on the procedure is available the committee will only approve its use if:

- The clinician has met externally set standards of training
- All patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded. Patients need to understand that the procedure's safety and efficacy is uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment
- The Committee is satisfied that the proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure.

It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new procedure in a **clinical emergency** so as not to place a patient at serious risk. If a clinician has performed a new interventional procedure in such circumstances he/she must inform the Chair or Deputy Chair of the New Interventional Procedures Committee **within 72 hours**. The Committee will consider approval of the procedure for future use as above.

Senior clinicians planning to undertake a new interventional procedure are asked to complete this form and send the completed form to the secretary of the New Interventional Procedures Committee by

electronic mail at least 14 days prior to the next NIPC meeting.

Arrangements will then be made for the request to be discussed at the next meeting of the New Interventional Procedures Committee. It is important that you provide the committee members with adequate information. Where NICE guidance is available you should ensure that you have clearly demonstrated that your proposed use of the procedure complies within this guidance. Where no NICE guidance on the procedure is available, you must demonstrate that you have met standards of training, describe the procedure for obtaining informed consent, and define how you will subject the procedure to clinical audit of outcomes. You should provide a summary of the supporting evidence and provide enough abstracts or papers to support the case.

Applicants will be advised of the committee's decision / recommendation after the meeting and, where appropriate, when clearance for use has been given under the Newcastle upon Tyne Hospitals NHS Trust's corporate governance arrangements.

What if no NICE guidance is available?

If no NICE guidance on the procedure is available, following approval from the New Interventional Procedures Committee, the applicant will ensure that the procedure is notified to the Interventional Procedures Programme at NICE.

A new notification to NICE will initiate the following:

- NICE will prepare a brief overview of the evidence on the procedure's safety and efficacy and consult its Specialist Advisors
- A NICE advisory committee will decide either to issue guidance on the procedure or to seek more information before doing so. As part of this process, NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with it.
- NICE consults publicly on all its guidance and its advisory committee will consider response to consultation before guidance on any procedure is issued.

The only exception to the process of registering with NICE is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). In this case, notification to NICE is not needed, as patients are protected by the REC's scrutiny. However, RECs will notify the Trust's New Interventional Procedures Committee when they approve a protocol involving an interventional procedure. Use outside the protocol should only occur after approval from the New Interventional Procedures Committee as set out above.

Patients, managers, commissioners and others can also notify procedures directly to NICE through its website.

Adverse Incidents

If an adverse incident occurs in association with a new interventional procedure, this should be reported to the National Patient Safety Agency through the Trust system in the normal way via the national reporting and learning system for adverse events implemented across the NHS.

CLINICIANS SHOULD DISCUSS THEIR REQUESTS AND OBTAIN SUPPORT FROM ANY RELEVANT COLLEAGUES AND THEIR CLINICAL DIRECTOR AND / OR OTHER CLINICIANS WORKING IN THEIR SPECIALITY PRIOR TO SUBMITTING A REQUEST.

New Interventional Procedure Registration Form

REQUEST MUST BE MADE BY A CONSULTANT OR SENIOR CLINICIAN
Please type

<table>
<tr><td colspan="2">Clinician's Name:</td><td>Hospital:</td></tr>
<tr><td colspan="2">Position:</td><td>Phone:
Fax: Email:</td></tr>
<tr><td>Department/Directorate</td><td>Clinical Director</td><td>Directorate Manager</td></tr>
<tr><td colspan="3">Procedure Title:</td></tr>
<tr><td colspan="3">Outline of procedure:</td></tr>
<tr><td colspan="3">Is the procedure listed on NICE's Website? Yes □ No □
If Yes, please quote the number and title of the procedure, e.g. IPG789 …:
…….. (and submit a copy of this guidance electronically with this application).
If No, the lead operator / clinician must <u>register</u> the procedure with NICE once approval has been granted.</td></tr>
<tr><td colspan="3">Has the procedure been approved by R&D? Yes □ No □ N/A □

If Yes, what is its 4-digit R&D Reference Number? ……..</td></tr>
</table>

Please describe the procedure and its benefits for lay people (no more than 50 words):
Which patients will benefit:
Advantages over existing procedures:
Would this procedure replace any established procedure?

Evidence base for procedure:

Does this procedure require the support of a proctor? Yes ☐ No ☐
If yes, how many cases will be undertaken with the proctor in attendance? ……..
Has the appropriate governance arrangements in relation to proctors been sought in line with "Individuals Undertaking Unpaid Work Within The Trust (Honorary Contracts, Letters of Access, Observer Status and Clinical Access) Policy"

?.....Yes ☐ No ☐

Training received in the procedure and supervision proposed for its introduction:

Implications for multidisciplinary teams (including training). Include details of disinfection procedures, if needed:
Assessment by profession peer group: Who: When: Consensus:

Risks:
(Have any additional risks for people with protected characteristics been considered?
age; disability; gender reassignment; maternity and pregnancy; sex; sexual orientation; race; religion.
For descriptions of protected characteristics please refer to the Equality and Diversity pages on the intranet)

Describe consent procedure:

Resources involved including within own directorate and others such as within Laboratory or Diagnostic Services.

Number of patients likely to be treated per year in directorate:	Estimated cost:	
	This financial year £	Next financial year £

Please provide details of how these costs will be met:

If funded via R&D funding a four digit R&D number should be supplied above. If not funded via R&D the Directorate Manager and Directorate Finance Manager are required sign off that arrangements to cover the costs are in place and have been agreed. Details should be provided above. Eg business case agreed, agreement that directorate budget is able to cover the additional cost, tariff increases will cover cost increases or costs are less than existing procedure or other cost reductions.
Directorate Manager :
Directorate Finance Manager:
How will the procedure be subjected to clinical audit and outcomes evaluated? Is this part of any national clinical audit or registry? If so, who is the lead contact / sponsoring organisation?
Declaration of Interest Details of any support (financial or in kind, personal or departmental) or sponsorship (for staff, clinical trials, other research, materials, equipment, etc.) received or likely to be received from manufacturer(s)/supplier(s)/sponsor(s) associated with this procedure within the last/next 12 months. If none state NONE.

Other information you may wish to include (including details of support from Clinical Director and/or Clinical Colleagues):
Proposed start date: Signed: .....Designation: Signed: .....Clinical Director Date:

Developing NICE Interventional Procedures

This is a brief summary of how NICE develops interventional procedures guidance.

1. Procedure notified to NICE.
Although clinicians most frequently notify procedures, anyone can make a notification. NICE assesses whether the notified procedure falls within the scope of the Interventional Procedures programme.

2. Interest registered.
NICE lists all notified interventional procedures on the website. Individuals and organisations can register an interest in any interventional procedure. Consultees will be notified by email when consultation begins, and can submit comments.

3. Overview prepared.
NICE consults at least three specialist advisors and prepares an overview of information about the procedure. An independent advisory committee considers the procedure, (Interventional Procedures Advisory Committee, IPAC).

4. Consultation document produced.
If IPAC decides to produce guidance, NICE issues a consultation document on the safety and efficacy of the procedure. This is posted on the NICE website for a four-week consultation.

5. Final interventional procedures document produced.
IPAC considers the comments from the consultation, then produces final recommendations for the procedure. This is submitted to NICE for approval.

6. Consultees notified.
Once NICE formally approves the final guideline, consultees are notified. They can request a resolution if they think the guidance is inaccurate or the guidance development process has not been followed.

7. Guidance issued.
If there are no resolution requests, NICE issues its guidance to the NHS.

Appendix 3a

Proctors for new surgical interventions

A proctor, for these purposes, is defined as an external medical practitioner who attends to supervise and train a Newcastle Hospitals clinician when they undertake an approved new interventional procedure on Newcastle Hospitals premises.

The requesting practitioner is the Newcastle Hospitals clinician who has gained approval to undertake a new interventional procedure, for themselves or for themselves and colleagues.

Responsibilities of the requesting practitioner

1. To obtain approval via the New Interventional Procedures Committee (NIPC), the Clinical Governance and Quality Committee, and where appropriate, research governance approvals, for the new interventional procedure, detailing the need for proctors and the prior training of Newcastle Hospitals clinical staff.
2. To identify appropriate proctor(s) and obtain appropriate governance approvals including those according to the "Engaging Proctors policy".
3. To discuss the case(s) with the proctor in advance, including the indications and pre- operative evaluation.
4. To inform the patient of the role of the proctor.
5. To ensure that the new interventional procedure is conducted under the full supervision of the proctor.

Requirements and responsibilities of the proctor

1. To be a clinician in good standing with their own regulatory body and must have appropriate experience to undertake and supervise the new interventional procedure
2. To ensure they have appropriate governance approvals as in (2) above
3. To ensure that they have discussed the case with the clinician undertaking the procedure in advance, including pre-operative indications and investigations
4. To confirm that they will be available for and participate in the pre-interventional procedure team briefing (WHO checklist) to include:
    a. the anticipated timeline for the procedure, how this will be monitored and by whom, and how any concerns about the timeline will be communicated to the Consultant and by whom
    b. how any complications perceived by the proctor during the procedure will be communicated to the Consultant
    c. consideration of how such complications would be managed This must all be documented contemporaneously on the day
5. To satisfy themselves that the Newcastle Hospitals clinician has adequate prior training to undertake the new interventional procedure under supervision
6. To evaluate the performance of the clinician in undertaking the new interventional procedure, and the wider operating team
7. To undertake whatever action is reasonably necessary to protect the patient including taking over the procedure at any time should they believe that intervention is warranted to prevent harm to the patient – the proctor must confirm in advance of the procedure that they will remain physically present on sit for the full duration of the procedure
8. To review the results of the proctored new interventional procedure with the clinician and to complete a proctoring evaluation report. Any concerns about the case or future undertaking of the interventional procedure must be communicated to the Chair of the New Interventional Procedures Group as part of the proctoring evaluation report.

Proctor's evaluation form for new interventional procedure

Procedure:
Date:
Patient details:
Clinician undertaking the new interventional procedure:

Proctor's evaluation

To be completed prior to the procedure

The new interventional procedure is appropriate for this patient	Y	N
The patient has given appropriate consent	Y	N
The clinician has adequate prior training	Y	N
Facilities are adequate to undertake the procedure	Y	N

To be completed after the procedure

I confirm that I have supervised and reviewed the clinician's performance and discussed my findings with the clinician	Y	N
The procedure has been completed satisfactorily	Y	N

If no, please give further information

Recommendations for further performance of this procedure by this clinician

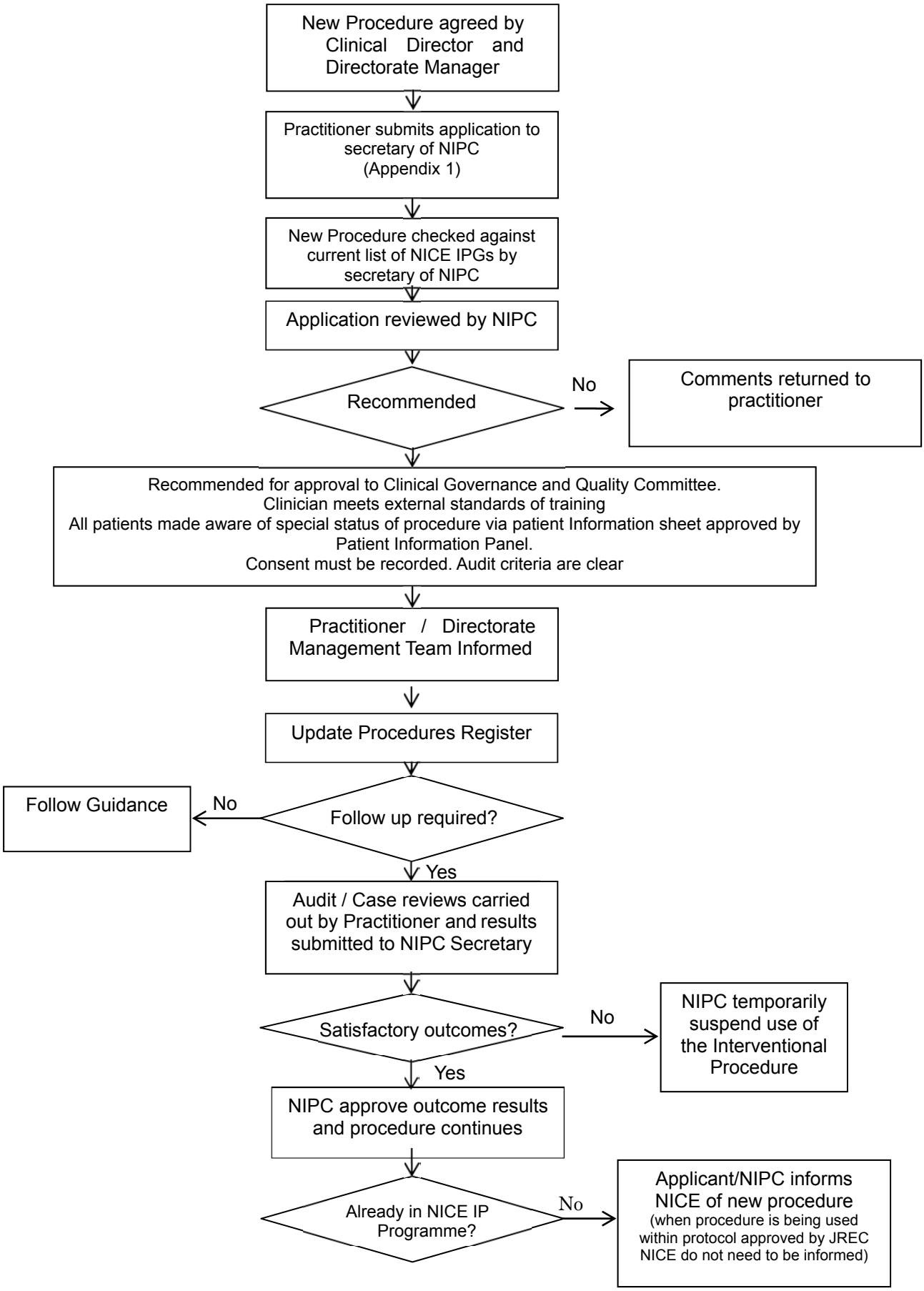
Further training should be undertaken before the procedure is performed again (please specify the nature of the training)	Y	N
This procedure should be undertaken with supervision	Y	N
This procedure may be undertaken without supervision	Y	N

Further comments:

Name:
Signature:
Date:

Appendix 4

New Interventional Procedures Committee (NIPC) Process Flow



Policy for the Implementation of National Guidance

1. INTRODUCTION AND PURPOSE

1.1 The purpose of this policy is to clearly set out the process within Solent NHS Trust for:

Ensuring that agreed best practice, as defined in all National Institute of Clinical Effectiveness (NICE) guidance (where appropriate) National Service Frameworks, National Confidential Enquiries and other High Level Enquiries that make recommendations for patient safety, are taken into account in the context of the clinical services Solent NHS Trust provides Responding to National Confidential Enquiries and Inquiries.

1.2 This policy describes: the processes for identifying and disseminating relevant, guidance and for conducting an organisational gap analysis, the responsibilities of managers and clinical leaders in the implementation and monitoring of guidance and recommendations, and finally the process for documenting any decision not to comply with guidance or recommendations.

1.3 This policy will enable Solent NHS Trust to meet Outcome 4, - regulation 9 and Outcome 16, Regulation 10 of the Care Quality Commission Essential Standards of Quality and Safety.

2. SCOPE AND DEFIINITIONS

2.1 SCOPE

2.1.1 This document applies to all directly and indirectly employed staff within Solent NHS Trust and other persons working with the organisation in line with Solent NHS Trust's Equal Opportunities Policy.

2.2 DEFIINITIONS

2.2.1 The National Institute for Clinical Excellence (NICE)

2.2.1.1 NICE was set up as a Special Health Authority for England and Wales on 1 April 1999. Its principal role is to provide patients, health professionals and the public with authoritative and reliable guidance in relation to the use of health technologies, the clinical management of specific conditions, and the safety and efficacy of interventional procedures. On 1 April 2005 NICE joined with the Health Development Agency to become the new National Institute for Health and Clinical Excellence (also to be known as NICE).

2.2.1.2 Currently, NICE produces the following types of guidance:

Technology appraisals - guidance on the use of new and existing medicines, technologies and treatments within the NHS in England and W ales. Implementation of technology appraisals is mandatory. The Secretary of State has directed that as a general principle, the NHS should make funding available for treatments recommended by a NICE technology appraisal within three months of publication, unless instructed to extend this period by the Secretary of State.

Clinical guidelines - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and W ales. Clinical guidelines are standards that provide guidance on the appropriate treatment and care of people with specific diseases and conditions. While implementation is not mandatory organisations are required to make every effort to comply with guidelines that are relevant to their services.

Interventional procedures - guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in England, W ales and Scotland.

Public Health Programme guidance - public health programme guidance deals with broader action for the promotion of good health and the prevention of ill- health. This guidance may focus on a topic, such as smoking, or on a particular population, such as young people, or on a particular setting, for example, the workplace.
Quality Standards - a set of specific, concise statements that act as markers of high quality, clinical and cost effective patient care, covering the treatment and prevention of different diseases and conditions. Derived from the best available evidence, such as NICE guidance and other relevant sources accredited by NHS Evidence, they are developed independently by NICE.

2.2.1.3 The clinical guidelines and interventional procedures work programmes are not subject to mandatory funding. Nevertheless, once guidance has been published, NHS professionals are expected to take it fully into account when exercising their clinical judgement.

2.2.1.4 NICE recommendations are based on reviews of clinical and economic evidence carried out by independently constituted Guideline Development Groups within the National Collaborating Centres affiliated to NICE. The involvement of the Department of Heath in the development of NICE guidance is limited to topic selection.

2.2.1.5 Healthcare organisations must ensure that they conform to NICE technology appraisals and, where it is available take into account nationally agreed guidance when planning and delivering treatment and care.

2.2.2 National Service Frameworks (NSFs)

2.2.2.1 NSFs set national standards and define service models, put in place strategies to support implementation and delivery, and establish performance measures against which progress within an agreed time-scale is measured and monitored.

2.2.2.2 Each NSF has been developed with the assistance of an External Reference Group which brings together health and social care professionals, service users and carers, health and social care managers, partner agencies, and other advocates. These reference groups have adopted an inclusive process to engage the full range of views.

2.2.3 High Level Enquiries

2.2.3.1 A High level enquiry can be defined as any published enquiry with recommendations for implementation nationally e.g.: Shipman Enquiry (2003), Climbie Enquiry (2004), Mid Staffordshire Review (2009)

2.2.4 National Confidential Enquiries/Inquiries

2.2.4.1 National Confidential Enquiries/Inquiries have been established as national research to:

Investigate the contribution of deficiencies in care to serious adverse patient outcomes

Identify areas where clinical practice needs to be improved and to make appropriate recommendations for changes that will improve outcomes for patients.

2.2.4.2 There are three 'National Confidential Enquiries' at present:

The Confidential Enquiry into Maternal and Child Health (CEMACH)

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness.

2.25 National Guidance Implementation Leads

2.2.5.1 National guidance Implementation leads (to be referred to as leads from this point on in this policy) are members of clinical staff who have been identified by Heads of Care Delivery Units (HCDUs) and service managers as the lead for scoping and implementing national guidance or responding to National Confidential Inquires within a specific service. It may be beneficial for leads to establish working groups to develop common strategies and processes; this will be at the discretion of individual HCDUs (Appendix 1).

3. PROCESS

3.1 Identification of Guidance and Dissemination

3.1.1 National guidance from national and local bodies including but not exclusively the Department of Health, the Strategic Health Authority, and the Care Quality Commission is communicated to the Chief Executive, Medical Director and Director of Nursing and Quality. They will in the first instance determine the relevance for the organisation of received guidance.

3.1.2 All relevant guidance, and any request for information from a National Confidential Enquiry or Inquiry will be forwarded to the Head of Quality Improvement and the Quality and Patient Safety Manager who will act as the central point for dissemination throughout the organisation via the Clinical Audit & Effectiveness Group.

3.1.3 NICE guidance will be identified through 'E-guidance' from NICE via automatic email bulletin to the Quality and Patient Safety Manager on the 4th Wednesday of each month.

3.1.4 NICE guidance will, in the first instance, be reviewed by the Clinical Audit & Effectiveness Group who will determine relevance for services provided by the organisation, seeking advice from the Medical Director, Chief Pharmacist and lead clinicians where necessary.

3.1.5 The Quality and Patient Safety Manager will send a monthly bulletin to HCDUs and leads which will include a brief description of the NICE guidance released that month, a hyperlink to the guidance and any implementation support tools.

3.1.6 HCDUs, service managers and leads will be responsible for onward dissemination of national guidance and ensuring that all clinical and relevant staff are notified of all national and NICE guidance pertinent to their practice.

3.1.7 The Quality and Patient Safety Manager will "horizon scan" guidance in development and alert HCDUs and leads of relevant guidance to enable services to proactively plan for potential implications of future guidance. Leads should also undertake this for their clinical specialities.

3.1.8 National Guidance (including NICE, National Confidential Enquiries / Inquiries) will be a standing item on the monthly meetings of the Clinical Audit & Effectiveness Group The group is a sub group of the Quality and Patient Safety Sub Committee and Integrated Governance and Performance Committee (IGAP), are comprised of senior clinicians and managers and are the primary forum for seniors to engage in and lead quality improvement across services.

3.2 Assessment and Implementation

3.2.1 New outputs from the National Confidential Enquiries, High Level Enquiries, requests for data for National Confidential Inquires and National guidance other than NICE will be tabled and implications discussed at the next Quality and Patient Safety Sub committee (QPS) and Integrated Governance and Performance Committee (IGAP). The committee will determine what action is required by Solent NHS Trust. Minutes will show the discussion and audit trail. Service level actions will be implemented by Service Managers and progress monitored by the Associate Director of Nursing and Quality, HCDUs, QIPS and IGAP.

3.2.2 Leads will ensure that all new NICE or other relevant national guidance is discussed at the next Care Delivery Unit/Service governance meeting.

3.2.3 Leads must conduct an initial base line assessment (Appendix 2) and gap analysis i.e. an evaluation of current practice against the recommendations within the national guidance and identify areas of current practice requiring change.

3.2.4 In conjunction with the Service Manager leads will be responsible for the development of an action plan (Appendix 3) (a copy to be sent to the HCDU) to ensure that the recommendations set out within the guidance are implemented; this should include as a minimum:
Actions required to implement the recommendations Any additional resources required
Names of people responsible for implementing the action plan Date by which the action plan will be implemented
Any barriers to implementation that cannot be resolved by the Service/Care Delivery Unit

Any risks associated with implementing the guidance

3.2.5 Risks associated with the implementation of the guidance, include finance, workforce, education / training, or patient safety related risks. These risks must be recorded on the appropriate service risk register, and escalated according to current risk management strategy and policy

3.2.5 Leads will send the baseline assessment and any subsequent proposed action/implementation plan to the Quality and Patient Safety Manager and HCDU. The initial baseline assessment should be returned to the Head of Quality Improvement within two months of receipt of new guidance.

3.2.6 Guidance or recommendations that have funding implications or a change to current service specification must be brought to the attention of the appropriate Associate Director, incorporated into business unit action plans and agreed via the contracting process and with commissioners. Any funding implications must also be brought to the attention of the Associate Director for Finance.

(abridged)

3.3 Process

3.3.1 Process for identifying documents

3.3.1.1 All NSFs and reports of high level enquiries are received into the organisation through the Chief Executive's office.

3.3.1.2 All Nice guidance and guidelines are received in to the organisation through the Quality and Patient Safety Manager.

3.3.2 Process for disseminating documents

3.3.2.1 The Chief Executive disseminates copies of the NSF,s, Confidential enquiries / high level inquiries / reports of high level enquiries to the Medical Director and Director of Nursing and Quality, who will appoint a responsible lead to consider the relevance of the document for the Trust and take appropriate action.

3.3.2.2 The Audit and Patient Safety Manger disseminates the reports to the Associate Director of the service involved who will appoint a responsible lead to consider the relevance of the document for the Trust and take appropriate action.

3.3.3 Addressing the requirements of documents

3.3.3.1 The responsible lead will consider the relevance and requirements for the Trust and will, if necessary, appoint a working party for implementation.

3,3,3,2 Many of the documents received cross a number of services and departments: in these cases the working party must be multi-disciplinary in nature.

3.3.3.3 The responsible lead and/or working party will undertake a gap analysis, using the template in Appendix 3.

3.3.4 Undertaking a gap analysis

3.3.4.1 The responsible lead/working party will assess the extent of the Trust's compliance with each of the recommendations in the report and determine the actions required.

3.3.4.2 The types of issues that might be considered are:

Service Issues

Will major changes in practice be required?
Will protocols need to be updated?
What patient/public involvement issues apply?

Resource Issues

Will there be capacity or resource issues associated with the required changes?
Will there be additional costs, both in terms of implementation and for future practice?
Do potential costs need to be built into service planning?

Workforce Issues
Will there by any workforce implications? Will there be any training needs for staff?
Will people be receptive to required changes?

Risk
Are there any potential risks to implementation?
Are there any reasons not to implement recommended practice?
Are there any risks identified, which need to be entered onto the relevant risk register

Management Issues
What might some of the barriers be to implementation? Where does implementation fit in relation to other priorities?
Can the recommendations be implemented in appropriate/required timescales?
Should any information be made available to the public?

3.3.4.3 Following the gap analysis, the outcome must be formally recorded on the template (Appendix 3). In some cases, however, the responsible lead/working party may need to produce more detailed action plans.

3.3.4.4 The Responsible Lead must escalate any immediately identifiable issues or problems to the Lead Director.

3.3.4.5 A record of progress against the action plan must be clearly documented and securely retained. The action plan should be submitted to the Quality and Patient safety Manager for inputting onto the database.

3.3.5 Ensuring recommendations are acted upon

3.3.5.1 The Responsible Lead will report bi-annually to the Quality Improvement Group.

3.3.5.2 The report will contain:
Progress against existing action plans
Details of any barriers to achievement of original time scales

Details of the reasons for any departure from recommended practice Details of risks placed on Divisional or Trust risk registers
Details of the Trust's compliance against newly published reports and associated new action plans.

3.3.5.3 Following presentation at the Quality Improvement Group a copy of the progress report will be forwarded to the Risk Management Department for information and evidence of compliance with the NHSLA Risk Management and reported through to the Integrated Governance and Performance Committee.

3.3.5.4 IGAP is responsible for ensuring recommendations based on outputs from the National Confidential Enquiries, High Level Enquiries and other similar guidance are acted upon at corporate level. Implementation progress will be reviewed regularly by the committee. HCDUs are accountable for ensuring that actions agreed by IGAP are implemented at service level.

3.3.5.5 The Quality and Patient Safety Manager will be responsible for maintaining a centralised database for outputs from the National Confidential Enquiries, High Level Enquiries and other similar guidance, and will ensure that:
Action plans to implement any recommendations made in response to guidance are maintained
Action plans are reviewed regularly and evaluated by the Quality Improvement Group and IGAP
The organisational risk register is updated as the post visit action plan is progressed and realised.

3.3.5.6 The Quality and Patient Safety Manager will submit quarterly reports to IGAP on the implementation status of NICE guidelines across the organisation. The reports include areas of non-compliance, details of barriers to implementation and progress against action/implementation plans.

3.3.5.7 The Quality and Patient Safety Manager will, for external reporting and internal monitoring purposes, maintain a database of all published NICE guidelines and implementation status across the organisation. This information will form the basis of the quarterly reports to IGAP.

3.3.5.8 Where HCDUs, service managers and leads have considered that NICE guidance may not represent best practice because further evidence has been published, the new evidence must be submitted to IGAP by the relevant HCDU for consideration. Any decision not to implement will be included on SNHST`s risk register.

3.3.5.9 Audit is a vital tool for thoroughly exploring to what extent national guidance is being implemented. NICE guidance generally contains sections giving advice on audit and implementation. IGAP will highlight high profile areas of national guidance which will form part of the SNHST`s Annual Clinical Audit Programme. Service should regularly undertake audit against NICE and national guidance, aiming for between one and two audits per annum.

3.3.6 Interventional Procedures

3.3.6.1 In the case of Interventional Procedures Guidance, which is different in terms of its aims and recommendations from either Technology Appraisals or Clinical Guidelines the following apply:

W here clinicians wish to introduce a new interventional procedure guidance (IPG), they must first contact the Medical Director and seek approval from IGAP (as indicated in HSC 2003/011, see Appendix 4)

An interventional procedure should be considered *new* if a doctor no longer in a training post is using it for the first time in his or her NHS clinical practice

Where a new procedure has been used in a clinical emergency, the practitioner must inform the Medical Director and IGAP. The committee will then consider approval of the procedure for future use.

(abridged)

Epsom and St Helier NHS
University Hospitals
NHS Trust

Meeting title	Trust Public Board
Report title	Clinical Quality and Assurance Committee Annual Report
Date	9th June 2017
Lead director	Dr Ruth Charlton, Joint Medical Director 01372 735122/ ruth.charlton@esth.nhs.uk
Report author	Jill Down, Associate Director of Quality 01372 735061/ jill.down@esth.nhs.uk Supported by Chris Sharling, PA to Associate Director of Quality
FOI status	Disclosable

Report summary	This report summarises the work of the Clinical Quality and Assurance Committee for the period April 2016 to March 2017. The report provides evidence that the Clinical Quality and Assurance Committee has established reporting mechanisms in place to receive monitor and review concerns raised by Divisions and to provide assurance to the organisation that patient safety is clinically led and services clinically driven.
Purpose	To note
Recommendation	The Board is asked to note the report.

New Procedures

The Committee review all new technologies and procedures prior to being introduced in the organisation. A condition of approval is that every new procedure has to be audited, the results of which are presented to the Committee to provide assurance good practice is in place. During the year the Committee has reviewed the following proposals:

- Personalised Anticipatory CareE Plan (PACE). From April 2016 there was a plan for a pilot to be run on Buckley ward defining a Ceiling of Medical Care for patients with and without capacity. It was proposed that this link with the Treatment Escalation Plan introduced in February 2017.
- Digital capture of clinical information and printing: In April 2016 surgeons piloted writing electronic operation notes.

Note on the NIH Policy (USA)

Dr. Steven Hirschfeld
NIH

In case a surgeon is trying to implement a new surgical procedure to treat his patient NOT as part of research, so long as he uses the devices and drugs, all already approved by the FDA, in designated ways, his treatment (a.k.a., therapy) is not directly regulated by the Federal laws and/or CFRs.

--As I understand the question, the intent is to improve a procedure using licensed products according to the approved package insert or label. The oversight question then would hinge on the specific type of patient. If the patient has an unknown possibility of harm due to age or medical condition or other factors that are different from the population that the products are approved for, then additional oversight may be necessary. That would typically be from the Institutional Review Board and they would be consulted as to whether they determine a need to provide oversight or not.

The question is: are there any cases (at present or in history in the US) where given therapeutic measures are by law/act/code to be designated as research. For example, think of a case where the Congress enforced a moratorium period on the implementation of gene therapy. I wonder in this case or the other if a new therapy/procedure, apart from the approval of drug/device usage, must be (specially designated to be) implemented ALSO as a research (namely, to prevent the arbitrary introduction, necessitate surgeons to follow the schemes of research approval and oversight, in addition to the usual oversight as a therapy, which is not always present as such).

--If I understand the question, are there classes of research that have additional safeguards or oversight. Again it is generally dependent on the population so pregnant women, prisoners, children, people with limited mental capacity, and active duty military members all have additional safeguards. For example, active duty military by law cannot be enrolled in studies without an expectation of benefit.

Some products such as thalidomide or controlled substances require special permission to perform research using those products. Restrictions also apply on the use of particular cell types.

Do you have a specific set of therapeutic interventions, again apart from the approval of drugs/devices, which are required to be introduced/implemented as research (namely prohibited to be implemented not following the research protocols and procedures).

--A noted above, the target population will always and the product type will sometimes trigger additional review and oversight. Most of the time surgical procedures and many device types require no more than Institutional Review Board approval.

資料
201903　佐藤元

研究と診療の区分

UK

1　Health Research Authority(HRA)
UK Policy Framework for Health and Care Research: definition of research

2　NHS National Patient Safety Agency/ National Research Ethics Service
Defining Research – Guidance from NRES

3　Solent/ NHS Trust
Research, Service Evaluation & Clinical Audit Strategy 2013-16
(clinical audit and service evaluation policy)

4　The University of Oxford Research and Development Department
Clinical audit, research, and Service review

5　University Hospitals Bristol/ NHS Foundation Trust
How to tell if your study is research, audit or service evaluation

6　Northamptonshire Healthcare/ NHS Foundation Trust
Policy and Procedure for Conducting Clinical Audit Projects

US

7　DHHS Office for Human Research Protections
Quality Improvement Activities FAQs
Difference between clinical research and a clinical trial (NIH)
IND application procedures: Exemptions from IND requirements

8　Notes: Response from FDA/NIH

9　Johns Hopkins University School of Medicine, Office for Human Subjects Research
Organization policy on single case reports and case series
Case Report Publication Guidance: IRB review and HIPPA compliance

10　Columbia University Medical Center
IRB/ Privacy requirements for case reports

11　Weill Cornell Medicine, Cornell University
WCM Institutional Review Board, Human Subject Regulations Decision Charts

12　Notes on US oversight frameworks
National Institute of Health/ Dr. Steven Hirschfeld (NIH)
Legal framework on practice and case report publication/ Dr. Jonathan Darrow (Harvard)
Legal framework on practice/ Dr. Holly Lynch (U Pennsylvania)
Duke and Stanford University/ Dr. Bruce Burnett (Duke University and Stanford)
Registration of clinical trials/ Dr. Kevin Fain (National Library of Medicine, ClinicalTrials.gov)

日本
人を対象とする医学系研究に関する倫理指針（抜粋）

UK Policy Framework for Health and Social Care Research definition of research:

For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable[1] new[2] knowledge to answer or refine relevant questions with scientifically sound methods[3]. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part[4] of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non- interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at www.hra- decisiontools.org.uk/research.

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1 NB This definition involves an attempt at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The actual generalisability or transferability of some research findings may only become apparent once the project has been completed.

2 Including new knowledge about existing treatments or care.

3 Projects that are not designed well enough to meet this definition are not exempt from this policy framework – see paragraph 9.10.a.

4 This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey.

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health)
The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate an outbreak or incident to help in disease control and prevention
Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What are the health issues in this population and how do we address them?" Designed to answer: "What is the cause of this outbreak or incident and how do we manage it?"
Quantitative research - addresses clearly defined questions, aims and objectives. Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, quantitative or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.
Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	No allocation to intervention.
May involve randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment/ care/ intervention.
Normally requires REC review but not always. http://hra-decisiontools.org.uk/ethics/	Does not require REC review.	Does not require REC review.	Does not require REC review.

National Research Ethics Service

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society.

Defining research – guidance from NRES

The purpose of this leaflet is to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.

The table in this leaflet helps to confirm if your activity is research, audit, service evaluation or public health surveillance.

When is an NHS REC review required?

Review by an NHS REC is required for research within the scope of the UK Health Departments' Governance Arrangements for Research Ethics Committees available at **www.dh.gov.uk/en/Publicationsandstatistics/ Publications/DH_4005727**

In addition, some legislation, such as the Clinical Trials Regulations, Human Tissue Act and Mental Capacity Act, requires ethical approval from an appropriately recognised REC whether or not the research takes place within the NHS.

Guidance on whether research requires ethical review under either the law or the policy of the UK Health Departments' can be found on the NRES website at **www.nres.npsa.nhs.uk/applications/apply**

If your project will be taking place within the NHS, your local research and development (R&D) office will be able to advise on whether the project is research and requires management within the Research Governance Framework for Health and Social Care. They will also confirm if ethical review by a REC is required, and advise on local governance procedures for other types of project such as audit or service evaluation.

Key discriminants are:

1. **Intent:** The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working. Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project.

2. **Treatment/service:** Neither audit nor service evaluation uses an intervention without a firm basis of support in the clinical or health community.

3. **Allocation:** Neither audit nor service evaluation allocate treatment or service by protocol. It is a joint decision by the clinician and patient.

4. **Randomisation:** If randomisation is used, it is research.

Useful references

Casserat D, Karlawish JH, Sugarman J. Determining when Quality Improvement Initiatives should be considered research. JAMA. 2000; 283: 2275-80.

National Health and Medical Research Council (NHMRC). When Does Quality Assurance in Health Care Require Independent Ethical Review? Canberra: National Health and Medical Research Council. (2003).

Smith R. Audit and Research. BMJ. 1992; 305: 905. Available at: www.bmj.com

Wade D. Ethics audit and all shades of grey. BMJ. 2005; 330: 468. Available at: www.bmj.com

Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	SURVEILLANCE	USUAL PRACTICE (in public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing data or administration of interview or questionnaire to those exposed.	May involve administration of interview or questionnaire to those exposed.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to www.nres.npsa.nhs.uk/applications/apply/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

*** Service development and quality improvement may fall into this category.**

The National Ethics Advisory Committee (NEAC). *Ethical Review of Observational Research, Audit and Related Activities.* (2003). Available at: **www.neac.health.govt.nz**

More detailed guidance on categorising projects is also available on the website of the NHS R&D Forum at: **www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc**

Contact details:
National Research Ethics Service National Patient Safety Agency 4 – 8 Maple Street
London W1T 5HD
NRES main line: 020 7927 9898
NRES fax: 020 7927 9899
W **www.nres.npsa.nhs.uk**
E **queries@nres.npsa.nhs.uk**

Ref: 0987 December 2009

Solent NHS
NHS Trust

Research, Service Evaluation & Clinical Audit Strategy 2013-16

Evidence informed community healthcare improving patient outcomes

Defining Research, Service Evaluation & Clinical Audit

Research	Service Evaluation	Clinical Audit
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care	Designed and conducted to produce information to inform delivery of best care
Quantitative research – designed to test a hypothesis Qualitative research – identifies/ explores themes following established methodology	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"
Addresses clearly defined questions, aims and objectives	Measures current service without reference to a standard	Measures against a standard
Quantitative research – may involve evaluating or comparing interventions, particularly new ones Qualitative research – usually involves studying how interventions and relationships are experienced	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of interview or questionnaire.

Source: National Patient Safety Agency Research Ethics Service: Defining Research leafle

Clinical Audit and Service Evaluation Policy

Summary of Policy

The purpose of this policy is to ensure that Solent NHS Trust meets its statutory and mandatory requirements in relation to clinical audit, and to set out a framework for staff undertaking clinical audit and service evaluation projects in Solent NHS Trust.

Clinical Audit

Clinical audit is “A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Put more simply, clinical audit is all about measuring the quality of care and services against agreed standards and making improvements where necessary.” (National Institute for Health and Clinical Excellence (NICE). *Principles for Best Practice in Clinical Audit.)*

Service Evaluation

Service evaluation does not require systematic comparison against a pre-determined standard but by evaluating current practice can generate useful information to aid local decision making. Service evaluation can stand alone as an individual project, or may be used as a baseline for future audits / research or for benchmarking.

Statutory and Mandatory requirements

Healthcare providers must participate in relevant national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP). Healthcare providers must also implement all relevant recommendations of any national clinical audit.

Healthcare providers must regularly assess and monitor the quality of the services provided. They must use the findings from clinical and other audits, including those undertaken at a national level, and national service reviews to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support. They must also ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies (for example, for revalidation).

Healthcare providers must produce an annual Quality Account, which must include information on participation in national and local audits, and the actions that have been taken to improve services, as a result of the audit.

The Oxford University Hospitals
Research and Development (R&D) Department

Welcome to Research and Development

The Oxford University Hospitals Research and Development (R&D) Department is based in the Joint Research Office at the Churchill Hospital.

https://www.ouh.nhs.uk/researchers/default.aspx

Is my project research?

Early in the study planning process, you need to first assess if the project being developed is **research**, **service evaluation** or **audit**.

Clinical audit: Measures existing practice against evidence-based clinical standards. All clinical audit must comply with the clinical audit governance requirements. If the project is audit it should be registered with the trust clinical audit team.

Research: Generates new knowledge where there is no or limited research evidence available and which has the potential to be generalisable or transferable. All research must comply with research governance requirements of the Oxford University Hospitals.

Service review: Incorporates both service/practice development and service/practice evaluation.

Service / practice development: Introduces a change in service delivery or practice for which there is evidence derived from research or from other health/social care settings that have already introduced and evaluated the change. New developments should always be evaluated.

Service / practice evaluation: Evaluates the effectiveness or efficiency of an existing or new service/practice that is evidence based, with the intention of generating information to inform local decision-making. This type of activity is sometimes referred to as a clinical effectiveness study, baseline audit, activity analysis, organisational audit and benchmarking. All service review activity should comply with clinical governance requirements.

Service/practice development which is concerned with introducing a new treatment or technique must follow the local policy on introduction of new treatments and techniques as summarised below.

Local clinical policy on introduction of new treatments and techniques

This policy could apply to the introduction of:

- a treatment or technique which is understood to be safe and effective but new to your trust
- a treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before
- an existing treatment or technique that is to be adapted for new purposes
- a medicine not on the trust formulary or a new indication for an existing formulary medicine.

The above definitions are from the following document from the Healthcare Quality Improvement Partnership (HQIP):

A Guide for Clinical Audit, Research and Service Review (pdf) - www.hqip.org.uk

Additional information can be found on the HRA website:

HRA decision tool - www.hra-decisiontools.org.uk/research

If your project is Clinical Research, then it is important to consider whether it will be classified as a **Clinical Trial of an Investigational Medicinal Product** (CTIMP) or a **Medical Device Trial**.

This is important because, if so, it will have to be carried out under either the Clinical Trials Regulations or the Medical Devices Regulations, and different processes will need to be followed.

Clinical Trial of an Investigational Medicinal Product (CTIMP)

A CTIMP is defined as any investigation in human subjects intended to:

- discover or verify the clinical, pharmacological and / or pharmacodynamic effects of one or more IMP(s)
- ascertain the safety of one or more IMP(s)
- study absorption, distribution, metabolism and excretion of one or more IMP(s)

The Medicines and Healthcare products Regulatory Agency (MHRA) has developed an algorithm to help you determine whether or not the proposed clinical research is within the scope of the Clinical Trials Regulations.

University Hospitals Bristol
NHS Foundation Trust

How to tell if your study is research, audit or service evaluation

- Research is designed and conducted to create new knowledge. If this research is generalisable (i.e. can be applied beyond UH Bristol), then it falls under the Research Governance Framework, and you need to follow the systems of approval for NHS Research.
- Audit is designed to answer the question "Does this service reach a predetermined standard?" Audits need to go through the UH Bristol Clinical Audit Department
- Service evaluation is designed to answer the question "What standard does this service achieve?" If you are planning a new service, or changing the way you provide an existing service, you may be required by law to involve patients (service users) in this process. Please visit the Patient Experience Team for more information.

It can sometimes be difficult to decide whether your survey project is research, audit or service evaluation. The National Research Ethics Service (NRES) has published the following guidance to help you decide: NRES Guidance PDF.

All three types of study require the approval of each NHS site where the study takes place, but the processes you need to follow will differ depending on whether the study is classed as research, audit or service evaluation. Only research requires REC (Research Ethics Committee) review.

If you've had a look at the NRES leaflet and you're still not sure, you can contact the following people for advice: Research: research@uhbristol.nhs.uk or call the R&I department on 0117 34 20233
Audit: stuart.metcalfe@uhbristol.nhs.uk or call 0117 34 23614
Service Evaluation: paul.lewis@uhbristol.nhs.uk or call 0117 34 23638

Operational definitions of Clinical Audit, Research, Service Evaluation and Service Improvement activity have been agreed between the Trust's Clinical Governance Manager, Research Development Manager and Head of Innovation (September 2007).

Northamptonshire Healthcare NHS
NHS Foundation Trust

Policy and Procedure for Conducting Clinical Audit Projects

Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. The purpose of this policy is to set out the Trust's expectations in relation to conduct and participation in clinical audit activity

Research - is defined as any activity that seeks to generate new knowledge or confirm existing theories within health and health care. It is conducted for the benefit of service users and carers, care professionals and the public in general. Research is differentiated from the clinical audit process in its purpose, as it is not an attempt to measure care against previously agreed standards to assess the quality of a service

Research	Clinical Audit	Service Evaluation
The attempt to drive generic new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Addresses clearly defined questions, aims and objectives in a rigorous manner.	Measures against a standard.	Measures current service without reference to a standard or defined system or approach.
Usually involves collecting data that are additional to those for routine care, but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire.
May involve randomisation	No randomisation	No randomisation

Key duties

- **Chief Executive**

The Chief Executive is responsible for the statutory duty of quality and takes overall responsibility of this policy

- **Trust Board**

NHFT Board has ultimate responsibility for overseeing the direction and development of clinical audit within NHFT and delegates this responsibility to the Medical Director and the Clinical Audit & Effectiveness Committee.

- **Corporate Director**

The Director of Nursing, AHP's and Quality has a corporate responsibility for Quality but the Lead Director for clinical audit activity is the Medical Director. The Medical Director will report and update the Quality Forum and the Trust Board on behalf of the Clinical Audit and Effectiveness Committee.

The Trust will ensure that staff within Quality & Governance are suitability skilled to support its programme of clinical audit activity. The trust will also ensure that these staff have access to further relevant training in order to maintain and develop their knowledge and skills of clinical audit.

- **Clinical Audit and Effectiveness Committee (CAEC)**

The Clinical Audit and Effectiveness Committee is the corporate committee tasked with overseeing the Trust's Clinical Audit Programme. It exists to provide:

- Strategic direction for clinical audit, that ensures integration with other quality processes.
- Assurance that involvement in audit is widespread, appropriate and prioritised.
- Support for staff in ensuring that clinical audit is leading to improvements in the quality of care and clinical effectiveness.
- A focus for NHFT to ensure that audit activity and in particular recommendations and learning from audits, are widely disseminated.
- Assurance that audit activity generated, links with national and local priorities to meet the Care Quality Commission registration requirements, and assists assurance against NHFT Board Assurance Framework. (See Appendix 1)
- Assurance that audit activity is recorded to support systems and processes to learn from them.
- An approval route for clinical audit proposals; where ethical considerations are discussed and resolved.

The CAEC are responsible for ensuring that the requirements set out within this policy are implemented.

- **Pathway Quality Groups (or equivalent)**

Individual clinical teams will report, for clinical audit purposes, to their Pathway Quality Group or equivalent.

Pathway Management Groups/SDM's are responsible for the implementation of audits within their Directorate, that are contained on the NHFT Annual Audit Programme and for complying with the subsequent approval, monitoring, and reporting processes set out in this policy. Pathways are responsible for the agreement, implementation and monitoring of action plans arising from clinical audit undertaken within its sphere of responsibility. Pathways (or relevant Committees or the audit lead) are responsible for reporting progress against action plans back to the CAEC, so that they can provide assurance to the Quality Forum

- **Director of Medical Education**

The Director of Medical Education is responsible for ensuring clinical audit training for the doctors in training takes place in line with this policy.

- **Head of Quality & Governance**

The Head of Quality & Governance is responsible for the coordination and monitoring of the

Trust's Clinical Audit and Effectiveness Committee, which holds the responsibility for approving, monitoring and encouraging staff to conduct Clinical Audit as well as the dissemination of learning from clinical audit undertaken within the Trust. The post-holder will maintain a corporate overview and direct activity in line with external monitoring and requirements.

- **Quality and Governance**

Quality and Governance will maintain accurate and up-to-date information on audit activity within the Trust, through:

- Maintaining an up to date database of Trust audit activity in compliance with external and internal requirements.
- Ensuring links with audit in relation to NICE publications, Policy development and monitoring.
- Projecting an Annual Audit Programme for the forthcoming year which reflects the priorities for clinical audit within NHFT in line with NHFT Board Assurance Framework and CQC registration requirements and other national priorities
- Publishing quarterly and annual reports on audit activity by directorate and celebrating best practice and lessons learnt.
- Collating evidence to support external monitoring

Quality & Governance will screen audit proposals and accompanying data collection tools to ensure sound methodology, unnecessary repetition is avoided and that groups of patients are not over- audited.

Quality & Governance will be available to offer teams and individual team members support and guidance on all stages of a clinical audit project.
This could include: -

- Developing audit proposals
- Questionnaire design
- Report writing
- Leading on corporate audits (as appropriate)
- Involving and facilitating service user engagement (In liaison with Service User Lead)
- Advice on what the audit should cover
- Advice on analysing the results
- Dissemination of best practice and lessons learnt
- Linking audits with national and corporate agendas
- Publication of audit report

- **Managers of Audit Leads**

Managers of individuals proposing to undertake audit must sign off proposals to agree that the audit is a pathway priority, multidisciplinary where possible, and that the necessary resources are available for the project lead to undertake the work. Line managers are also responsible for agreeing, with the audit lead, the recommendations and actions resulting from audit and for ensuring implementation of audit actions. In the absence of the audit lead the Line Manager who signed-off the audit will ensure the audit is completed and take forward any actions arising from the report. Managers are responsible for ensuring that service development and delivery is underpinned by clinical audit and forms part of Continuing Professional Development.

- **NHFT Staff**

There is an expectation that all clinical staff employed within the Trust will undertake or participate in audit on a regular basis. All clinical staff are responsible for engaging with the audit evaluation process, this may take the form of participating in an action plan, attending audit presentations or being aware of the findings from audits. Where the individual responsible for completing a clinical audit project leaves the relevant post, an alternative lead should be identified by the line manager e.g. in the case of Junior Doctors in training this would be the Educational Supervisor unless an alternative individual is identified. Professional staff are individually accountable for ensuring they audit their own practice as defined by their Code of Conduct. NHFT staff are responsible for ensuring that they fulfil their responsibilities under this policy.

Quality Improvement Activities FAQs

How does HHS view quality improvement activities in relation to the regulations for human research subject protections?

Protecting human subjects during research activities is critical and has been at the forefront of HHS activities for decades. In addition, HHS is committed to taking every appropriate opportunity to measure and improve the quality of care for patients. These two important goals typically do not intersect, since most quality improvement efforts are not research subject to the HHS protection of human subjects regulations. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR part 46) may apply.

To determine whether these regulations apply to a particular quality improvement activity, the following questions should be addressed in order:

1. does the activity involve *research* (45 CFR 46.102(d));
2. does the research activity involve human subjects (45 CFR 46.102(f));
3. does the human subjects research qualify for an exemption (45 CFR 46.101(b)); and
4. is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA approved by OHRP.

For those quality improvement activities that are subject to these regulations, the regulations provide great flexibility in how the regulated community can comply. Other laws or regulations may apply to quality improvement activities independent of whether the HHS regulations for the protection of human subjects in research apply.

Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

No, such activities do not satisfy the definition of “research” under 45 CFR 46.102(d), which is “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes include:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

No, such quality improvement activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

Can I analyze data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes without having to apply the HHS protection of human subjects regulations?

Yes, whether or not these activities are research, they do not involve "human subjects." The regulation defines a "human subject" as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.…Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." Thus, if the research project includes the analysis of data for which the investigators cannot readily ascertain the identity of the subjects and the investigators did not obtain the data through an interaction or intervention with living individuals for the purposes of the research, the analyses do not involve human subjects and do not have to comply with the HHS protection of human subjects regulations.

Are there types of quality improvement efforts that are considered to be research that are subject to HHS human subjects regulations?

Yes, in certain cases, a quality improvement project may constitute non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA. For example, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.

If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project fit the regulatory definition of research?

No, the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. The regulatory definition under 45 CFR 46.102(d) is "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

Does a quality improvement project that involves research need to be reviewed by an IRB?

Yes, in some cases. IRB review is needed if the research involves human subjects, is not exempt, and is conducted or supported by HHS or otherwise covered by an applicable FWA.

Does IRB review of a quality improvement project that is also non-exempt human subjects research always need to be carried out at a convened IRB meeting?

No, if the human subjects research activity involves no more than minimal risk and fits one or more of the categories of research eligible for expedited review, the IRB chair or another member designated by the IRB chair may conduct the review.

The categories of research eligible for expedited review are available at: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of- research-expedited-review-procedure-1998/index.html.

If a quality improvement project involves non-exempt research with human subjects, do I always need to obtain informed consent from all subjects (patients and/or providers) involved in the research?

No, the HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when

a. the risk to the subjects is minimal,
b. subjects' rights and welfare will not be adversely affected by the waiver,
c. conducting the research without the waiver is not practicable, and
d. if appropriate, subjects are provided with additional pertinent information after their participation

(45 CFR 46.116(d)).

Other applicable regulations or laws may require the informed consent of individuals in such projects independent of the HHS regulations for the protection of human subjects in research.

If a quality improvement project is human subjects research requiring IRB review, do I need to obtain separate IRB approval from every institution engaged in the project?

No, not if certain conditions are met. The HHS protection of human subjects regulations allow one IRB to review and approve research that will be conducted at multiple institutions. An institution has the option of relying upon IRB review from another institution by designating that IRB on its FWA and submitting the revised FWA to OHRP, and having an IRB Authorization Agreement with the other institution.

Notes:

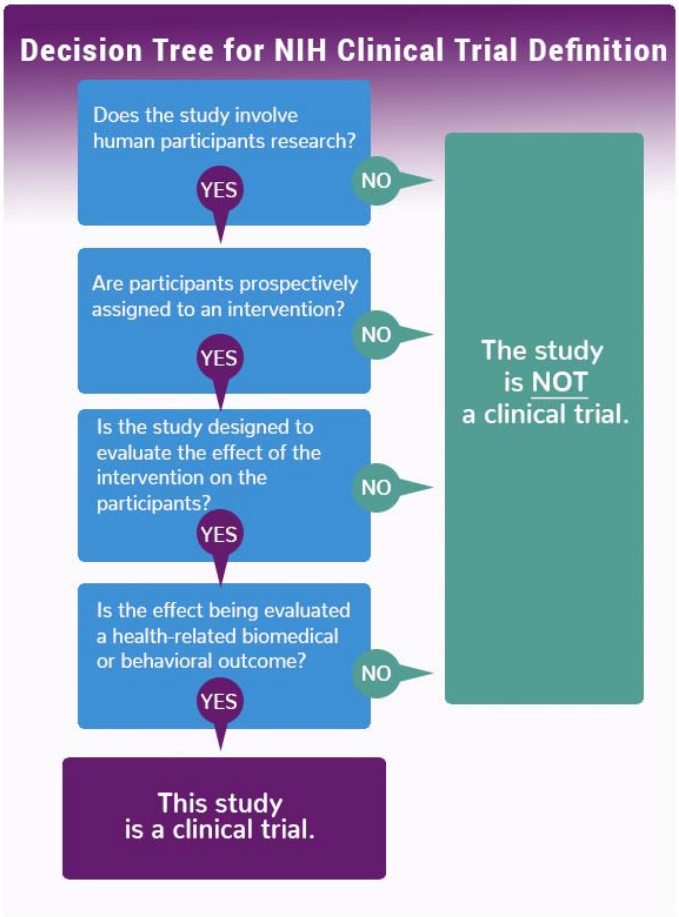
What is the difference between clinical research and a clinical trial?

https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5219

Clinical trials are clinical research studies.

Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available. (https://humansubjects.nih.gov/glossary)

Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.



IND Application Procedures: Exemptions from IND Requirements

Before submitting an IND application, investigators should refer to the Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND (PDF - 210KB (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)) to determine whether their clinical investigations may be conducted without submitting an IND application.

The three most commonly occurring scenarios when clinical investigations may be exempted from the IND application requirements refer to certain limited situations of clinical investigations with approved marketed drugs, bioavailability or bioequivalence studies, or clinical investigations involving radioactive drugs considered safe for certain research uses. For each of these and few other scenarios, the specific criteria for exemption (PDF - 210KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) must be met.

Sponsors who are uncertain if their proposed investigation meets the criteria for IND exemption may seek advice from the FDA Review Division (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTo- bacco/CDER/ucm075128.htm)

responsible for the relevant therapeutic area of the proposed trial. In some cases FDA staff may be able to provide this advice through informal communications (e.g., phone conversation, e-mail). In other cases FDA staff may request that the sponsor submit a summary of their proposed investigation in writing for FDA review before providing advice.

In certain cases, FDA staff may advise the sponsor to submit a full IND application for the proposed investigation for FDA review. If during that review FDA concludes the IND application meets the criteria for exemption, the sponsor will be so notified.

For additional explanation of safety reporting expectations for bioavailability and bioequivalence studies exempted from the IND application requirements refer to Guidance for Industry: Safety Reporting Requirements for INDs and BA/BE Studies (PDF - 227KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf).

(1) Clinical trials and clinical research

FDA regulations do not make the distinction between “clinical trials” and “clinical research” in the manner you describe in your question. Specifically, our regulatory authority applies to all research meeting the definition of a clinical investigation, irrespective of whether it is performed at an academic center or not.

FDA’s regulations at 21 CFR 56.102(c) defines “Clinical investigation” as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. Please note, when reading FDA regulations the terms research, clinical research, clinical study, study, and clinical investigation are often used interchangeably.

(2) Punitive clauses

Do you kindly explain the contents of punitive clauses in your clinical trial/research law? It is also highly appreciated if you kindly clarify whether the punitive clause targets medical doctor oneself and, if yes, about the contents. (reference is also appreciated);

FDA laws and regulations include information related to penalties that may result from a prohibited act by entities (e.g., clinical investigators, sponsors etc.) involved with clinical investigations. Penalties include disqualification, debarment, and civil money penalties. Please see the Federal Food, Drug, and Cosmetic Act, section 301 and 303 for Prohibited Acts and Penalties, respectively ((21 U.S. Code 331 and 333) for the punitive clauses in FDA regulated research.
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIII-sec331.pdf

An example of a penalty that could be applied to a clinical investigator is disqualification. Clinical investigators who are found to have repeatedly or deliberately failed to comply with the regulations governing the conduct of clinical trials, or has repeatedly or deliberatively submitted to the FDA or to the sponsor false information in any required report, may be disqualified (no longer eligible) from conducting studies involving FDA’ regulated products.

See 21 CFR 312.70 at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.70,
and 812.119 at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.119
for additional details on this penalty.

A more detailed discussion about disqualification of a clinical investigator can be learned by reviewing the Federal Registry notification for the rule at http://www.gpo.gov/fdsys/pkg/FR-2012-04-30/pdf/2012-10292.pdf. To assure a transparency and fairness in the disqualification process, FDA posts details about the process of disqualification proceedings at http://www.fda.gov/ICECI/EnforcementActions/ucm321308.htm

In addition to disqualification a clinical investigator may be debarred. Debarment is defined in the Staff Manual Guide (SMG)7712 as "An action taken by FDA, on the basis of a criminal conviction or conduct, as identified in section 306 of the Act, to prohibit an individual, corporation, partnership, or association:

· from submitting, or assisting in the submission of, certain drug applications or providing services in any capacity to the sponsor of an approved or pending drug application;
· from importing an article of food or offering an article of food for import into the United States; or
· from being accredited to perform certain functions related to devices through programs administered by FDA, by other government agencies, or by other qualified non-government organizations and from carrying out activities under agreements with foreign countries to facilitate commerce in devices."

More information on debarment proceedings may be found in SMG 7712 at http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm127622.htm

A listing of persons debarred by the FDA can be found at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm

You may find the following FDA guidance documents helpful for explanations of the requirements for clinical investigators and FDA regulatory actions:

(1) Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors Clinical Investigator Administrative Actions – Disqualification
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214008.pdf

(2) Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigator
http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afdagen/documents/document/ucm126553.pdf

(3) Guidance for Industry Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects
http://www.fda.gov/ucm/groups/fdagovublic/@fdagovdrugsgen/documents/document/ucm187772.pdf

102.3 Organization Policy on Single Case Reports and Case Series

August 2013

It is the policy of the Organization that a "single" case report (three or fewer cases) does not require review by the JHM IRB. If an investigator wishes to have the project assessed by the JHM IRB to see if it meets the Organization's definition of a single case report, the investigator should contact the JHM IRB. If the project qualifies as a single case report, the JHM IRB will send to the investigator a form letter that states:

"The IRB received your request (dated 'x'), concerning a single case report you wish to publish. The JHM IRBs have determined that a case report does not produce generalizable knowledge, nor is it an investigation of an FDA regulated product. IRB review is not required for this activity."

Investigators should inform the IRB if a journal does not accept the IRB's decision. The issue will then be brought to an IRB Chairs Meeting for resolution.

A case series (more than 3 cases) meets the definition of human subjects research and requires the submission of a new protocol application in eIRB.

NOTE: Case reports for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the patient, or, if the patient is deceased, the patient's family. Publication of a case report containing PHI is a disclosure of PHI. The Privacy Officer or designated HIPAA authority at the applicable location within the Organization should be consulted prior to submission of the case report to assure proper authorization was obtained.

For guidance please see:

Case Report Publication Guidance: IRB Review and HIPAA Compliance - (https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/case_report.html)

Guidance for Investigators HIPAA Requirements for Case Reports - (https://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/hipaa_case_reports.html)

Case Report Publication Guidance
IRB Review and HIPAA Compliance

October 2006

Background:

Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case. The JHM IRBs have adopted a policy to address the following question and answers.

Q: What constitutes a "case report"?

A case report for IRB purposes is a retrospective analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity will constitute "research."

Please review the JHM Organization Policy on Single Case Reports and Case Series (Policy No. 102.3) - (https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_3.html) .

Q: Do faculty who prepare a case report as an article for submission to a journal require IRB approval prior to preparation?

No. A case report is a medical/educational activity that does not meet the DHHS definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, the activity does not have to be reviewed by a JHM IRB.

Q: Are there HIPAA implications associated with publication of case reports?

Yes. Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, characteristic, or code…." Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information." (See: Definition of De-Identified Data - (https://www.hopkinsmedicine.org/institutional_review_board/forms/diddef.doc).)

- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.
- Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed HIPAA compliant authorization. This authorization does not need to be submitted to the IRB for review. The appropriate authorization form for use with a single case report may be found on the HIPAA web site HERE. -

(http://intranet.insidehopkinsmedicine.org/privacy_office/_docs/policies_and_forms/provider_forms/A_2_1_v_Providers_Authorization_Use_PHI_Case_Report.pdf)

- If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a "unique characteristic" which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must contact the HIPAA Privacy Officer to discuss the required steps to take prior to publication.

Guidance for Investigators HIPAA Requirements for Case Reports

October 2006

A single, retrospective case report is an activity intended to develop information to be shared for medical and educational purposes. Under JHM policy, a "single case report" - (https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_3.html) is a retrospective analysis of one, two, or three clinical cases but is not research that must be approved by the IRB. (If more than three cases are involved in the analytical activity, the activity will constitute research.)

Although IRB approval is not required, certain HIPAA Privacy Rule requirements apply to the use and disclosure of PHI for a single case report:

- Investigators who remove HIPAA identifiers from the case report data prior to disclosure of the data (e.g., prior to submission of the case report to a journal) do not need to obtain a signed privacy authorization from the subject of the case report.

Please note that in addition to removing the 18 listed HIPAA identifiers, the investigator must determine that no photo or illustration in the case report could lead to identification of the patient, and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts.

- Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (i.e., that contains any direct or indirect identifiers), must first obtain each patient's signed HIPAA-compliant authorization. It is not necessary to submit this authorization form to the IRB for review.

The HIPAA authorization form used to obtain a patient's authorization to use and disclose PHI for a single case report may be found at the JH Privacy Office website at: Use of Protected Health Information in a Case Report (A.2.1.v) - (http://intranet.insidehopkinsmedicine.org/privacy_office/_docs/policies_and_forms/provider_forms/A_2_1_v_Providers_Authorization_Use_PHI_Case_Report.pdf)

COLUMBIA RESEARCH

Columbia University Medical Center

IRB/Privacy requirements for Case Reports

A case report is a description of (a) the course of medical treatment with one or more patients that has a unique outcome or (b) the handling of a unique clinical case; which in either case did not involve the investigator having any research intent at the time of the intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)].

Clinicians may have the opportunity to present unique clinical cases at professional meetings, to medical students or to colleagues within the institution. Many case reports are also published in medical journals. Prior to presentation or publication of a case report, some institutions or journals may require documentation from an IRB that IRB approval was obtained or was not required

Harlem Hospital requires form 2423 to be completed in the primary language of the patient/parent. To obtain this form:

1. Open the Generations+/Northern Manhattan webpage
2. Click on "HHC Intranet Site" in the lower right corner
3. Click on "Forms Index" on the left side
4. Go to page 9 and select form HHC 2423 "Authorization to Disclose Health Information to the Media" in the appropriate language.
5. This form requires the patient/parent's signature

Columbia University requirements (http://www.cumc.columbia.edu/dept/irb/policies/docs/Case_Report_Policy.doc):

1. Case report on a single patient:

A case report describing the treatment of a single patient does not meet the federal definition of human subjects research on the basis that the information in the case report is not generalizable knowledge. Therefore, clinicians at the University are not required to obtain IRB approval for case reports of a single patient.

Investigators who are asked by a journal or other entity to provide documentation from the IRB that such a case report was either approved by the IRB or did not require review by the IRB may present the Columbia University IRB/Privacy Board Policy on Case Reports as evidence that the case report does not require IRB approval. Some journals may require that the institution provide written attestation that the informed consent of the subject has been obtained prior to publication of the case report. Such written documentation can and should be provided by the Department with which the investigator is associated.

In most cases, the Privacy Office requires case reports to be de-identified, i.e., the presentation or article must not contain any of the 18 identifiers of an individual that are described in the Privacy Rule (name; addresses; all elements of date; telephone and facsimile numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers; device identifiers; web URLs; IP addresses; biometric identifiers; full face photographic images and any comparable images; any other unique identifying number, characteristic, or code).

If the case report involves a living person and the information is de-identified, an Investigator's Certification for Research with De-Identified Data Form (Form G) must be submitted to the Privacy Office. If the case report involves a patient who is deceased, the investigator must instead submit an Investigator's Certification for Research with Decedents' Information (Form E). Both forms can be found on RASCAL under "HIPAA". Neither form is required to be approved by the Privacy Board and

formal approval letters are not generated.

In the situation of a case report including a facial photograph or other image showing a unique identifier, or of a report of a case that is so unique that the identity of the subject would be readily known upon publication, the investigator should contact the Privacy Office before proceeding with the presentation or publication. In those cases, patient authorization will be needed prior to the presentation or publication.

2. Case report involving more then one patient:

A case report involving more than one living individual may meet the definition of human subjects research and may require IRB review. A brief summary describing the case, the type of information that will be included, and the safeguards for protecting confidentiality should be submitted to the IRB prior to abstracting patient data. The submission may be sent by e-mail to <irboffice@columbia.edu> with "Case Report" indicated in the subject line. The IRB will make a determination whether the activity is human subjects research requiring further IRB review, and will so notify the investigator.

A case report that describes more than one patient who is de-identified or that involves deceased patients does not require patient authorizations, but would require submission of Form G or Form E. If a patient is living and identifiers are used, the investigator should contact the Privacy Office before proceeding with the presentation or publication. In those cases, patient authorization would typically be needed. Such case reports would rarely, if ever, qualify for a waiver of authorization from the Privacy Board as it would be difficult to show that it would be impractical to obtain actual authorization from a small number of patients.

https://research.columbia.edu/human-research-policy-guide

For questions regarding Columbia IRB review or requirements, please contact the **IRB office at (212) 305- 5883**. For questions regarding HIPAA related matters, please contact the **Privacy Office at (212) 342-0059**.

WCM Institutional Review Board

A designated IRB's primary responsibility is to ensure that the rights and welfare of human subjects in research are protected. In doing so, the IRB must ensure that the human subject research is conducted ethically, and in compliance with Federal regulations, the requirements of applicable New York State and local law, and institutional policies and procedures. The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their research staff, the subjects who enroll in research, and the Institutional Review Board (IRB).

An IRB is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. In accordance with the Common Rule and FDA regulations, the IRB has responsibility for approving, modifying, and/or disapproving human subject research. The IRB also has the authority to suspend or terminate research in order to protect research subjects and for noncompliance with applicable rules and regulations.

Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions on the following:

- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

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(response from the WCM IRB):

Most case reports, because they only involve one patient report, would not be considered to be a systematic investigation, and therefore would not qualify as human subjects research that needs to undergo IRB review.

However, the decision as to whether a case report needs to be reviewed by the IRB should not be made by the author(s), but by the Office of Research Integrity and Assurance.

https://research.weill.cornell.edu/compliance-integrity/wcm-institutional-review-board

Notes on the US research oversight

Steven Hirschfeld, MD PhD
National Institute of Health

1 Legal codes, mandating researchers to obtain approvals for/ make registered the clinical trials (clinical studies) involving (surgical/ operative, and other therapeutic) procedures. I am guessing that in the US the Common Rule and the FWA (Federalwide Assurance for the protection of human subjects) apply well on this point, so long as research are federally funded.

Response: The requirements for obtaining approval for research projects are variable. Multiple levels and layers of approval and oversight exist and can apply to any given project.

The United States supports but does not mandate international principles and policies such as the Declaration of Helsinki, the documents issued by International Conference on Harmonisation of Technical Requirements For Registration of Pharmaceuticals for Human Use, the Council for International Organizations of Medical Sciences and other global organizations.

The United States has at a federal level laws, regulations, policies, instructions, and guidance documents in a hierarchal priority that apply to research activities that enroll human participants. In addition, individual states, the military, other geographical and political jurisdictions, and institutions may have their own laws, regulations, and policies that apply to clinical research.

Studies that utilize FDA regulated products may need to comply with additional laws, summarized in the following table.

Federal Food, Drug, and Cosmetic Act	Federal Advisory Committee Act
1997 Modernization Act	Federal Advisory Committee Amendments
Administrative Procedures Act	Federal Advisory Committee Act
Congressional Reports Elimination Act of 1982	Government in the Sunshine Act
Controlled Substances Act	Public Health Service Act
Controlled Substances Import and Export Act	FDA Amendments Act
Delegations of Authority to the Commissioner of Food and Drugs	FDA Safety and Innovations Act
Department of Education Organization Act	21st Century Cures Act
FDA Reauthorization Act	

A general principle is that when more than one law, regulation, instruction, or policy applies to a given project, the more stringent is the operative one. Complying with the more stringent will generally always assure compliance with any other applicable requirement.

Some other general principles are that studies that are:

- federally funded must comply with the Common Rule in any of its various editions, depending upon the context and funding source of the study. The Common Rule was revised in 2017 and implementation of the new provisions will begin in January 2019. See https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html for additional information
- utilize Food and Drug Administration regulated products must comply with the Food, Drug & Cosmetic Act, the Public Health Service Act, Title 21 of the Code of Federal Regulations, and any other additional applicable laws and regulations. See examples of laws in the table above and regulations in the following table with hyperlinks.

Applicable FDA Regulations
Protection of Human Subjects (21 CFR 50)
Institutional Review Boards (21 CFR 56)
Biologics (21 CFR 600)
Investigational New Drugs (21 CFR 312)
Investigational Device Exemption (21 CFR 812)

- studies that receive funding from the Department of Defense, enroll DoD personnel, or use DoD facilities must comply with DoD requirements, which are generally more stringent than HHS requirements (see https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Protect-Humans-in-Research)

Studies that use FDA regulated products or are funded by NIH must be listed in clinicaltrials.gov (https://clinicaltrials.gov/) as a designated registry. Most studies that use FDA regulated products are not NIH funded.

All studies regulated by FDA must receive FDA approval, which can be active or passive. If a protocol that utilizes a regulated product is sent to the FDA, and the FDA does not respond by 30 days, then approval is automatic and does not require formal notification.

Federal Wide Assurance is registration of an Institutional Review Board with the HHS OHRP and provides an expectation that when an IRB evaluates a study and makes a determination that the process and outcome will be compliant with federal laws and regulations.

Thus for any given study, the approvals may include not only federal, state, and local approval, but may include other approvals and compliance depending upon the geographic location, the funding source, the target population, and the nature of any intervention.

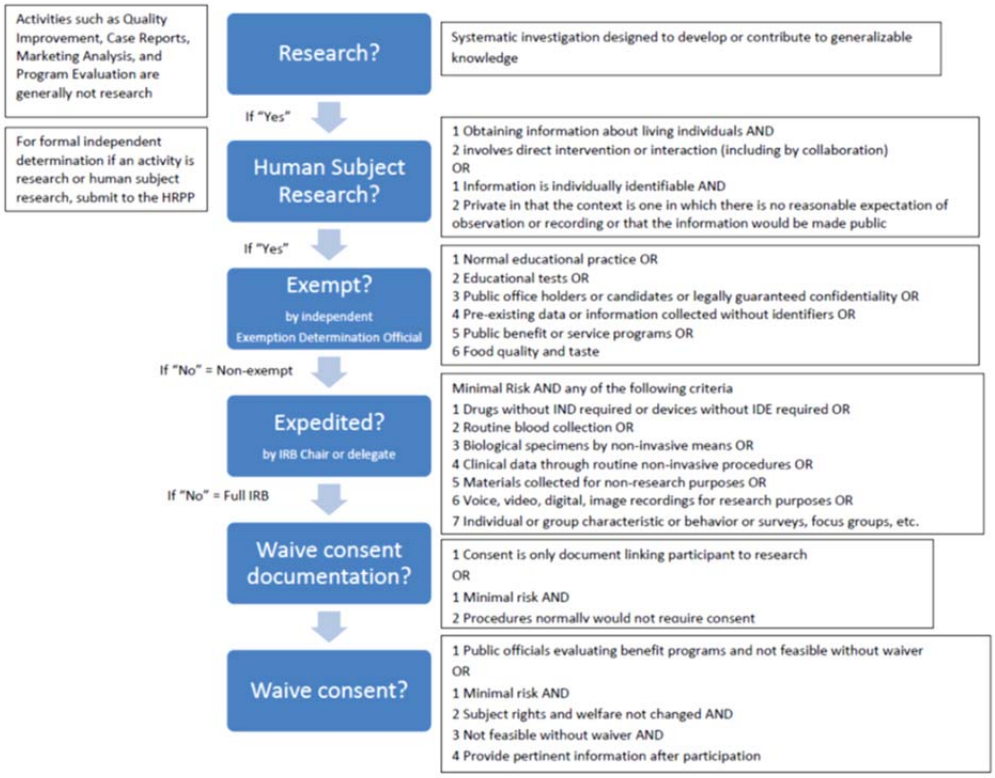
2 Legal codes (and ethical guidelines), which require medical professionals to conduct a specific range of procedures/ therapeutic interventions (e.g., innovative procedures, such as robotic surgeries, gene therapies, and stem-cell regenerative therapies), conventionally implemented as part of therapeutic practices, ALSO AS research. Labeling them investigative (/innovative), we expect, it is made possible that those innovative procedures be scrutinized by the (institutional) review boards, registered to the trial registries, and be made public.

Response: If I understand the question correctly, the context is a procedure or intervention that is already licensed or approved for health care delivery and is now applied in a research setting. The response depends upon the target population and the type of benefit sought.

A general principle is that the higher the anticipated risk, the greater the extent of review and oversight.

One key element regarding oversight and approval is the purpose of the activity. If the activity is research, that is intended to become part of the body of generalizable knowledge, then oversight can be anticipated. If the activity is quality improvement in trying to achieve better outcomes or use less resources or prepare personnel for performing or implementing an intervention, then a lesser degree of oversight may be appropriate. In such circumstances, IRB review, trial registration, and public dissemination are not required or even expected.

A general flowchart for the type of review and extent of oversight calibrated to the potential perceived risk is below. Note that the specific categories and criteria will change in January 2019 as per the reference in the response to the preceding question. See https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html for additional information



If the target population is one that is different than the conventional use and the target population has unknown or greater risk than the target population for conventional use, for example frail elderly or vulnerable children, then if FDA regulated products are involved, FDA oversight is required. The Principal investigator and team must be qualified as for any other regulated study. Even if FDA oversight is not required, a funding agency or even institution may anticipate or perceive risks that must be addressed before approval for the study is granted. The IND Exemption requirements are summarized at this FDA web page https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm362743.htm

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Faculty, Harvard Medical School
Program on Regulation, Therapeutics and Law (PORTAL)
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Division of Pharmacoepidemiology & Pharmacoeconomics, *Department of Medicine*

Original questions:

1. Do physicians/surgeons need any IRB approval before providing an innovative treatment to their patients (not using medicines/devices)?

[[JJD tentative answer: No, so long as the primary purpose is to treat the patient and not to produce generalizable knowledge. See, e.g., the 2013 "Determining" guidance document (attached) p4]]

2. Do physicians/surgeons need any IRB approval for publishing the case report (including case series study) on their innovative treatment (not using medicines/devices)? If so, when should the physicians/surgeons contact the IRB? Before providing the treatment for the first case? When they think about publishing their results after they treated the first case(s)?

[[JJD tentative answer: No (not required by statute/regulation). However, universities or journals may require some degree of IRB review or letter. See, e.g., here or here; also consent issues, e.g., here]]
We understand that it is difficult to define the innovative treatment, but we assume, for example, a new surgical incision approach (size, number, or place) which has not been performed before in the world for the disease.

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Department of Medical Ethics and Health Policy
Perelman School of Medicine, University of Pennsylvania
Founder and Chair, The Consortium to Advance Effective Research Ethics Oversight (AEREO)

I will do my best to be helpful, acknowledging that questions like this are often fact specific and dependent on institutional policy. I agree with Jonathan's answers so far.

If I am a surgeon doing innovative treatment, I need to start with a few questions:
Is my work funded by a Common Rule agency? If not, the Common Rule will not apply, unless my institution has decided to apply it voluntarily to all research conducted there.
Does my work involve any FDA regulated product? If not, FDA regulations will not apply.

If I have federal funding, or my institution applies Common Rule standards even to research funded in other ways, I have to ask if my work satisfies the Common Rule definition of "research" with "human subjects." 45 CFR 46.102 provides that:
(e)(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
(l) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Neither "systematic investigation" nor "generalizable knowledge" are defined in the regulations and they are sources of a lot of debate. If I am not conducting research, the Common Rule will not apply. However, note that most institutions do not allow investigators to make this determination themselves, instead requiring that they seek a determination from the IRB. Something could be research, quality improvement, or both. Whether something will be published is sometimes used as a shortcut to determine whether it is designed to contribute to generalizable knowledge, but that is not a good test. More guidance is available here.

If I am doing work with an FDA regulated product, then I want to know if my project counts as a "clinical investigation" under 21 CFR 50.3:
(c) Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.
(g) Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A healthy subject may be either a healthy human or a patient.

Under the facts you have presented involving a new approach to surgical incision without medicine or device, it seems unlikely FDA regulations would apply.
The other thing, as Jonathan mentioned, is that academic departments often have policies in place requiring some kind of committee approval of innovative surgeries or treatments that are not otherwise regulated. And journal policies will typically either want IRB approval or a letter indicating that the IRB determined that review was not required.

In sum, my advice would be to start with the IRB in any circumstance in which there is ambiguity about whether the activity could count as research with human subjects. They can make the determination, often relatively quickly, and then you will be sure not to run into trouble going forward. By the way, none of this gets at other types of legal obligations, including clinical informed consent even if the innovative treatment is not deemed to be research.

Dr Frank Opelka, MD FACS
Associate Medical Director
American College of Surgeons, Quality and Health Policy

Surgical innovations come in many forms. Some involve devices and the use of new technology. Other forms of innovation are more about the surgical procedure. When considering the oversight of surgical care, it is important to understand the landscape and the evolution of the governing bodies for regulatory activities. The US has federal agencies with oversight as well as State-based entities which seek to regulate care. In addition, each facility has local oversight committees which are required to perform these functions if the local facility is to be certified for receiving payment from government and insurers.

There are several US federal agencies which have jurisdiction over varying parts of the healthcare system. They are all captured under one government entity, the Department of Health and Human Services but they are separately funded by Congress and act quite independently of one another. In other words, these subordinate agencies lack guidance from a master plan. They have each evolved over time and have gotten so large and unwiedy that it would be difficult to rein them back into a cohesive strategy.

Everything tends to fall to the local governance. As surgical care is delivered, and outcomes of care become more transparent, the accountability of the local environment to maintain minimum standards for quality and safety on behalf of the patients and the staff are a function of the facility and its governing board. Because these surgical sciences are so complex, it is difficult for a community member board to understand the care models, the equipment used and the personnel. So, the organized medical staff is used to self-police through a series of governing committees such as infection control, pharmacy, OR operations, etc. I would say that the success of these self-policed programs is limited.

To add to the local governance, external reviews and certifications are the next level of applied standards. The American College of Surgeons is the founder of standards in surgical care. We began certifying surgical care over half a century ago. We now run standards verification programs in many disciplines - such as Trauma, Cancer, and Bariatrics. We have many newly minted programs in early implementation. These are rigorous, difficult standards and the most effective means for assuring care models and implementations of new technologies and innovations. However, without linking these to business models, they are voluntary and not always as widespread as they should be. Government agencies shy away from being overly prescriptive of these standards due to political winds that government interventions are costly and stifling.

An example of success would be in Bariatric surgical care. When first rolled out, the operative techniques varied and the care models differed. Patient mortality rates exceeded 5% and in some instances approached 8%+. When a verification program for the structural aspects of care, the crucial care processes and outcomes data tracking were enacted in order to receive payment, the impact on implementation was a drop to less than 2% mortality nationwide.

My point is that it is more than the technology and the technique. Care has become very complex and should be thought of as more than a moment in time, with an implementable device or use of equipment. It is the totality of care and the implantables and the supporting techonologies. It is important to structure accountability in a more comprehensive manner to best protect all those involved.

To your questions in specific:

Regulatory activity on surgical innovation for implantables and devices used in and around the OR are mostly in the hands of the FDA and the local facility. Guidance for use comes from published randomized controlled trials and from other contributions in the literature, including clinical guidelines. These are all subject to local interpretations.

Implementation of a new technique versus research. This space is very poorly regulated or governed. There is widespread use of newly published research when a local surgeon wishes to explore a new concept. Laparoscopy is one such "experiment." This began outside normal academic science and testing and it spread organically at local levels with nothing more than attendance at

weekend courses. Subsequently many local facility sought guidance from specialty societies for how best to assure quality, safety and appropriate use. Without widespread verification standards, these implementations continue to be problematic. Oftentimes a governing agency such as FDA might step in and regulate restrictive use but this approach is often late in coming. It is reactive rather than proactive. Clearly, as you know, this is a challenge in the balance of being overly restrictive and highly innovative.

I've not yet reviewed the link you have sent. I will do so and add further comments if needed.

I look forward to learning more as you take this journey,

Thanks
Frank

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1 Local oversight and the CMS

I have attached two documents. One of them refers to the need to be a certified facility as a condition of participation in order to be recognized for payment by CMS. The second document comes from the Joint Commission, one of the CMS deemed certifiers, and reflect how they address new procedures. The Joint Commission, as a certifying body, would assess the medical staff executive committee and its privileging committees for effective processes in granting privileges to a surgeon with regards to new technology and procedures. These are not perfect systems and possess lots of work-arounds or loopholes.

2 Research and practice distinction

Everything becomes murky, less clear. The distinction between surgical innovation and research is a blurred line. Most of these are surgeon decisions and with accountability to the surgical chief of staff or department chair. If a concern is raised to the medical staff, it would most likely fall to the surgeon and chief of surgical staff to explain the status of the ethical conduct. In instances where malpractice is alleged, this matter could move to the Courts for a determination of a legal standard. However, there is no formal standard. Each specialty or clinical discipline tends to recommend guidelines but these have not been incorporated into a public standard. (See attached).

Hope these help. Please do not hesitate to explore further.

Best
Frank

Dr Bruce Kendall Burnett, PhD
Duke University School of Medicine, Duke Clinical Research Institute
Interim Executive Director at Laboratory of Cell and Gene Medicine, Stanford University

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Dear Dr. Sato,

You have a very interesting question regarding the legal/ethical oversight of the development of new surgical techniques. In the US, any clinical trial, which could consist of only a single subject, requires a protocol to be approved by the IRB. However, many innovations in the surgical world are not considered 'research' as such. It seems to me that often published research is a retrospective study of reports of surgical outcomes in the literature. And as such, the involvement of IRB or ethics committees is not required.

For new devices, such as robotic surgical devices, there is a clear set of regulations in the US, specifically in 21 CFR 812. And the same goes for new therapeutics such as gene and cell therapies, all of which must be the subject of IRB review as well as IND regulations 21 CFR 312. And clinical trial registration and results information submission requirements are described in Section 801 of the Food and Drug Administration Amendments Act of 2007 (PDF), known as FDAAA 801. There are now both civil and criminal consequences to not complying with registering 'applicable' clinical trials.
I have passed on your question to the new director of the NIH Office of Human Subject Research Protection, Dr. Jonathan Green.

Bruce

I don't think that the US has anything similar to the 'new interventional procedures committee' that UK NHS hospitals have. I will also follow up with our executive director of the IRB here at Duke as well as with Dr. Green at NIH. A very interesting issue, and probably something that should be addressed formally here via regulation.

Fain, Kevin (NIH/NLM/NCBI)
Senior Advisor, National Library of Mediine
NLM ClinicalTrials.gov Program

Thanks for your note. I really enjoyed speaking with you both and learned a lot also. We have many shared interests to discuss.

I also wanted to provide you with weblinks to the documents that I mentioned yesterday:

Daniel Carpenter research article about FDA drug approvals and safety issues
https://www.nejm.org/doi/pdf/10.1056/NEJMsa0706341
Peter Provonost work on quality improvement research -
https://www.hopkinsmedicine.org/news/media/releases/three_years_out_safety_checklist_continues_to_keep_hospital_infections_in_check
https://www.thelancet.com/journals/lancet/ar□cle/PIIS0140-6736(09)61439-2/fulltext

ClinicalTrials.gov checklist to determine if a study is an “applicable clinical trial” and subject to the regulation - https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf
The checklist discusses whether a studied device or drug product is considered “FDA-regulated” for the purposes of the regulation (pages 5-8)

I would enjoy continuing these discussions and would be glad to talk by phone if I can help with any additional questions. I hope we can meet again soon.

（日本）

倫理指針における研究の定義（倫理指針のガイダンス）

人を対象とする医学系研究

人（試料・情報を含む）を対象として、傷病の成因（健康に関する様々な事象の頻度及び分布並びにそれらに影響を与える要因を含む）及び病態の理解並びに傷病の予防方法並びに医療における診断方法及び治療方法の改善又は有効性の検証を通じて、国民の健康の保持増進又は患者の傷病からの回復若しくは生活の質の向上に資する知識を得ることを目的として実施される活動をいう。

人を対象とする医学系研究に関する倫理指針 ガイダンス

平成２７年２月９日
（平成２７年３月３１日一部改訂）
（平成２９年３月８日一部改訂）
（平成２９年５月29 日一部改訂）

第２ 用語の定義
この指針における用語の定義は、次のとおりとする。

⑴ 人を対象とする医学系研究
人（試料・情報を含む。）を対象として、傷病の成因（健康に関する様々な事象の頻度及び分布並びにそれらに影響を与える要因を含む。）及び病態の理解並びに傷病の予防方法並びに医療における診断方法及び治療方法の改善又は有効性の検証を通じて、国民の健康の保持増進又は患者の傷病からの回復若しくは生活の質の向上に資する知識を得ることを目的として実施される活動をいう。この指針において単に「研究」という場合、人を対象とする医学系研究のことをいう。

１ 第２の規定は、この指針の各規定において対象となる客体、主体、行為等に関する基本的な用語の定義を示し、この指針の適用される範囲について定めたものである。

２ 「人を対象とする医学系研究」の定義は、次のような構成となっている。

人（試料・情報を含む。）を対象として、
［■ 傷病の成因
（・健康に関する様々な事象の 頻度 及び 分布 並びに
・それらに影響を与える要因）を含む。］の理解
及び
［■ 病態］

並びに

［□ 傷病の予防方法 並びに □ 医療における 診断方法 及び 治療方法］の ・改善 又は ・有効性の検証

を通じて、

［◆ 国民の 健康の保持増進 又は ◆ 患者の 疾病からの回復 若しくは生活の質の向上］

に資する知識を得ることを目的として実施される活動

3 医学系研究には、例えば、医科学、臨床医学、公衆衛生学、予防医学、歯学、薬学、看護学、リハビリテーション学、検査学、医工学のほか、介護・福祉分野、食品衛生・栄養分野、環境衛生分野、労働安全衛生分野等で、個人の健康に関する情報を用いた疫学的手法による研究及び質的研究が含まれる。医療、介護･福祉等に関するものであっても、医事法や社会福祉学など人文・社会科学分野の研究の中には「医学系研究」に含まれないものもある。

4 侵襲を伴わず、かつ介入を行わずに研究対象者から新たに取得した試料・情報を用いる研究や、既存試料・情報を用いる研究も「人を対象とする」研究に該当する。

5 人体から分離した細菌、カビ、ウイルス等の微生物の分析等を行うのみで、人の健康に関する事象を研究の対象としない場合は、「人を対象とする」研究に該当しないものと判断してよい。

ただし、患者から分離した病原微生物等の分析・調査から得られた情報を用いて、他の診療情報を組み合わせて、感染症の成因や病態の理解等を通じて国民の健康の保持増進又は患者の感染症からの回復等に資する知識を得ることを目的として実施される場合には、「研究」に該当する。

6 ⑴の「健康に関する様々な事象の頻度及び分布」とは、疫学的手法を通じて得られる種々の保健指標、例えば、ある種の疾患の発生頻度、地域分布、性・年齢分布や改善率、生存率、有病率、健康寿命、平均余命等を指す。また、「それらに影響を与える要因」としては、個人における喫煙、食事、運動、睡眠等の生活習慣、個々の医療における診療内容のほか、地域における環境的な要因、社会的な要因などが挙げられる。

人を対象として、特定の食品・栄養成分の摂取がその健康に与える影響を調べる場合は、「研究」に該当する。

7 傷病の予防、診断又は治療を専ら目的とする医療は、この指針でいう「研究」に該当しない。医療従事者が、そうした医療で自ら行ったものにおける患者の転帰や予後等について、例えば

○ 以後の医療における参考とするため、診療録を見返し、又は退院患者をフォローアップする等して検討する
○ 他の医療従事者への情報共有を図るため、所属する機関内の症例検討会、機関外の医療従事者同士の勉強会や関係学会、医療従事者向け専門誌等で個別の症例を報告する（いわゆる症例報告）
○ 既存の医学的知見等について患者その他一般の理解の普及を図るため、出版物・広報物等に掲載する
○ 医療機関として、自らの施設における医療評価のため、一定期間内の診療実績（受診者数、処置数、治療成績等）を集計し、所属する医療従事者等に供覧し、又は事業報告等に掲載する
○ 自らの施設において提供される医療の質の確保（標準的な診療が提供されていることの確認、院内感染や医療事故の防止、検査の精度管理等）のため、施設内のデータを集積・検討する

等、研究目的でない医療の一環とみなすことができる場合には、この指針でいう「研究」に該当しないものと判断してよい。

8 労働安全衛生法（昭和47 年法律第57 号）に基づく労働安全衛生規則第14 条第１項第７号の規定による「労働者の健康障害の原因の調査」や、学校保健安全法（昭和33 年第56 号）の施行規則第11 条の規定による「保健調査」なども同様に、研究目的でない業務の一環とみなすことができ、研究に該当しないものと判断してよい。

他方、それら法令の定める業務の範囲を超えて、当該業務を通じて得られたサンプル・データ等を利用する場合には、「研究」に該当する可能性がある。

9 地方公共団体が地域において行う保健事業（検診、好ましい生活習慣の普及等）に関して、例えば、検診の精度管理のために、当該検診で得られたサンプル・データ等の一部又は全部を関係者・関係機関間で共有して検討することは、保健事業の一環とみなすことができ、「研究」に該当しないものと判断してよい。

他方、保健事業により得られた人の健康に関する情報や検体を用いて、生活習慣病の病態の理解や予防方法の有効性の検証などを通じて、国民の健康の保持増進等に資する知識を得ることを目的として実施される活動は、「研究」に該当する。

10 専ら教育目的で実施される保健衛生実習等、学術的に既知の事象に関する実験・実習で、得られたサンプルやデータが教育目的以外に利用されない場合には、「研究」に該当しないものと判断してよい。

11 特定の活動が「研究」に該当するか否かについては、一義的には当該活動を実施する法人、行政機関、個人事業主の責任で判断するものであるが、判断が困難な場合には、この指針の規定する倫理審査委員会の意見を聴くことが推奨される。

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/index.html