

NCI Best Practices for Biospecimen Resources (2011)		Quality management of biobanks/ biological resource centres (BRCs) and quality of biological resources (2013)	
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		10.5.4 Data authenticity / linking to stocks of biological material	If the nature of the biological resource allows it, the information contained in the database shall be periodically cross-checked against the biological material in stock. This should be documented. If it is not possible, a control should be implemented when samples are removed from the stock (or when they are supplied to a stakeholder) The BRC should, if possible: a) record and archive the data source (for example, the name of the depositor, or scientist responsible for validating the data associated with the sample). b) establish data validation, modification and elimination workflows, as well as approval and traceability workflows for any such changes, thereby creating a log history of all modifications to the data. A history of revisions and changes shall be available, indicating the name of the person involved and the dates.
B.6.3 双方向の運用性	B.6.3.1. ヒト生物資源保管施設を臨床情報と研究情報に対応させてネットワークに配置するため、研究と臨床の双方向からの運用が可能なシステムでなければならない。 B.6.3.2. 他の臨床情報システム(解剖病理検査情報システム、臨床病理検査情報システム、がん登録など)と統合できなければならない。 B.6.3.3. B.6.3.4. 他システムとの双方向の運用を目標として、caBIGとの互換性がなければならない。 B.6.3.5. 情報処理システムは、Cancer Data Standards Repositoryのような標準メタデータセンターの情報要素を使用すること。 B.6.3.6. 情報処理管理システムは、報告や規制の要求基準を満たしたり、予定している科学研究のために生物試料を探すといったさまざまな目的で、適切かつ個人識別不能化(deidentified)された生物資源情報を遠隔地の使用者と共有できるものとする。 B.6.3.7. 生物試料を用いた研究から得た実験結果の情報は、通常、ヒト生物資源保管施設の管理に用いる情報システムの範疇には含まれない。		
B.6.4 ヒト生物資源保管の情報処理管理システムの開発	システムをゼロから開発する場合は、これらの実務要領を考慮しなければならない。 B.6.4.1. 業務のSOPによって情報処理システムの設計を決定すべきである。 B.6.4.2. 初期開発および後続の修正は、ソフトウェア開発およびシステム開発の方法論に従うこと。 B.6.4.3. ソフトウェアおよびシステムを構築する機関は少なくともCapability Maturity Model Integration (CMMI) レベル3Iに適合することが推奨される。	7.5.2 Software	Software containing personal data shall comply with current regulatory requirements. Software that is used to manage data/annotations relating to the biological samples shall fulfil the needs and specificity requirements of the BRC. Software maintenance shall be performed and documented.
B.6.5 ヒト生物資源保管の情報処理管理システムの選択	B.6.5.1. ヒト生物資源保管施設は、自施設の現在および今後のニーズに対応するため、ソフトウェアのニーズと保管のニーズに関する最小限の要求基準を特定しなければならない。 B.6.5.2. 前項で特定した基準を用いて、他の要素(履行しやすさ、インフラのニーズ、支援のニーズ、購入費および維持費を含む)を勘案しながら、成熟したオープンソースの市販システムの是非を判断。	7.5.2 Software	Software containing personal data shall comply with current regulatory requirements. Software that is used to manage data/annotations relating to the biological samples shall fulfil the needs and specificity requirements of the BRC. Software maintenance shall be performed and documented.
B.6.6 ヒト生物資源保管の情報処理システムの検証および運用	B.6.6.1. 運用を1日24時間、週7日サポートする運用インフラを設置しなければならない。 B.6.6.2. システムの故障時間や災害復旧に対応する措置を規定・配備しなければならない。 B.6.6.3. 定期的な評価して、実務要領で提唱されている基準とヒト生物資源保管施設の最新ニーズを満たさなければならない。 B.6.6.4. 外科病理報告書といった自由記載による情報から体系的な情報を抽出するプログラムなどについては、抽出された情報が正確になるように機能評価を行うこと。 B.6.6.5. 個々の研究機関にある全てのヒト生物資源データベースは安全な場所に設置し、各機関が監視しなければならない。	7.5 IT system	For the purposes of this standard, the term 'IT system' covers computer hardware (7.5.1), software (7.5.2), and access to IT networks where appropriate (7.5.3). The IT system installed at the BRC shall be adapted for: a) creation of computer database b) data management; c) data security; d) data processing. e) data diffusion (for example as catalogue) f) data recovery if the software manufacturer ceases activity - A documented procedure for data security shall be established to manage: a) access control (for example a password); b) updates and maintenance; c) data backup and recovery; d) IT network access according to the applicable procedures.

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B.6.7	<p>情報処理システムに関連する規制上の問題</p> <p>本文 本ガイドラインの倫理、法律および政策の項で記載した問題のほかにも、該当する場合、以下の規制上の問題に対応すること。 B.6.7.1. 州政府および連邦政府の要求基準 B.6.7.2. 情報処理システムの適切なセキュリティレベル National Institute of Standards and Technology Special Publication 800-30の『Risk Management Guide for Information Technology Systems』</p>	7.5	<p>IT system</p> <p>For the purposes of this standard, the term 'IT system' covers computer hardware (7.5.1), software (7.5.2), and access to IT networks where appropriate (7.5.3). The IT system installed at the BRC shall be adapted for: a) creation of computer database b) data management; c) data security; d) data processing. e) data diffusion (for example as catalogue) f) data recovery if the software manufacturer ceases activity – A documented procedure for data security shall be established to manage: a) access control (for example a password); b) updates and maintenance; c) data backup and recovery; d) IT network access according to the applicable procedures.</p>
C	<p>倫理上、法律上および政策上の実務要領</p> <p>研究におけるヒト生物資源の収集、保管、配布および使用に関連する主要な規制および勧告について説明する。本書で考察する規制および基準の提言は、米国内でヒト生物試料を使用する研究を対象としている。多くの国々では、ヒト生物試料の使用に関する、ある場合には特別条項のように、被験者を対象とした研究について独自の倫理的・法的規範を定めている。研究者やヒト生物資源保管施設は、新規に共同研究や収集を開始する前に、適用される可能性のある国際基準に配慮し、かつ、米国の規制基準と国際的な規制基準の違いを明らかにし、それに対応しなければならない。</p>		
C.1	<p>管理者責任 (responsible custodianship) の原則</p> <p>管理者の責任として、慎重な計画立案と透明性を持つ方針によって、長期にわたる生物試料の物理的な質の確保、ヒト研究参加者のプライバシー保護、関連情報の機密性保護、生物試料と情報の適正使用が求められる。透明性を担保するため、ヒト生物資源保管施設の方針は、電子的またはオンライン検索できるように公表されなければならない。</p>	5	<p>Management responsibility</p> <p>Management commitment can be manifest as a) establishing and communicating a quality policy b) communicating to the BRC the importance of complying with the present standard, the legislative and regulatory requirements and the stakeholders' requirements c) ensuring that the conditions for accepting (acquiring or receiving), conserving and providing collections or biological resources are defined in a documented procedure; d) ensuring that measurable quality objectives are established, tracked and analysed as part of a continuous improvement of the stakeholder satisfaction (6.1.2); e) leading management reviews (5.7); f) making sure that appropriate resources are fully available for the implementation of the QMS (7).</p>
		5.1	<p>Management commitment</p> <p>a) identify its stakeholders (3.6); b) determine their needs and expectations; c) identify those needs and expectations that the BRC is able to meet (4.2.1 f).</p>
		5.5.2	<p>BRC quality manager</p> <p>Top management shall appoint one individual tasked with coordinating quality management activities at the BRC. This person shall be trained in quality management. His/her missions must be clearly defined and documented. NOTE The person tasked with this quality management role may be a member of the BRC who also has other responsibilities in the BRC. The quality representative shall be given the responsibility and authority to: a) ensure that the quality management system is established, implemented, kept up to date and improved, through cooperation with the BRC team; b) report to the top management of the BRC for issues relative to the efficiency and adequacy of the quality management system; c) inform and /or train the BRC staff about the QMS and its implementation; d) ensure that efficient measures are taken and implemented for reviewing and updating the BRC's knowledge on current legislation and regulations.</p>
C.1.1	<p>ガバナンス</p> <p>自施設の実務手順の一環として、収集された生物試料および関連情報を保管・管理する公的かつ持続的な責務に取り組まなければならない。 (1)ヒト生物資源保管施設は生物試料の質の完全性をどのように確保するのか、 (2)ヒト生物資源保管施設は、生物試料に添付されるヒト研究参加者情報の無謬性の確保をどのように行うのか、 (3)サンプルを研究者に配布するためにどのような計画および手順を策定するのか、 (4)ヒト生物資源保管施設のディレクターおよび同ディレクターが所属する機関はどのような役割と責任を担うのか。</p>	5.4	<p>Planning of the quality management system</p> <p>Operational management shall ensure that: a) quality management system planning is consistent with the aim of meeting the requirements of the present standard as well as the BRC's quality objectives; b) the quality management system remains coherent when changes are scheduled and implemented. c) Any change in the running of the BRC is analysed in terms of the potential consequences for the QMS.</p>

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		5.5 Responsibility and authority	
		5.5.1 General requirements	Top management shall ensure that responsibilities and authorities are clearly defined and communicated across the BRC so as to guarantee that the quality management system operates efficiently and continues to do so.
		5.5.2 BRC quality manager	Top management shall appoint one individual tasked with coordinating quality management activities at the BRC. This person shall be trained in quality management. His/her missions must be clearly defined and documented. NOTE The person tasked with this quality management role may be a member of the BRC who also has other responsibilities in the BRC. The quality representative shall be given the responsibility and authority to: a) ensure that the quality management system is established, implemented, kept up to date and improved, through cooperation with the BRC team; b) report to the top management of the BRC for issues relative to the efficiency and adequacy of the quality management system; c) inform and /or train the BRC staff about the QMS and its implementation; d) ensure that efficient measures are taken and implemented for reviewing and updating the BRC's knowledge on current legislation and regulations.
C.1.2 レガシープラン／危機管理計画	(1)助成金の交付期間の終了、(2)管理者(management)の喪失または資金援助の終了、(3)研究の特定目的の達成、(4)生物試料を使い切ったとき、(5)重要データエンドポイントの達成、(6)ヒト研究参加者の参加撤回。以上のいずれかの時点で、保管されている生物試料にまだ研究的価値があるのか評価する。研究的価値があるのなら、ヒト生物資源保管施設は財政的に自立できるか検討する。あるいは、インフォームド・コンセント文書およびIRBによって許可されるならば、生物試料を適切な研究施設に譲渡できる旨を適切な手段によって研究者社会に広く知らしめる。ヒト生物資源保管施設は、他のヒト生物資源保管施設に生物試料を譲渡する際、研究者個人に生物試料を譲渡するときと同じ意思決定基準を用いる。このような生物試料の譲渡は、被験者に関する規制、生物試料と情報が最初に収集されたときのインフォームド・コンセント、その他の該当する事前同意や機関内方針に準じていなければならない。		
C.1.3 保管に関する方針	生物試料と情報の保管に関して分かりやすい方針を策定し、文書化しなければならない。さらに、試料移転合意文書(MTAsなど)によって、受領者である研究者の保管・使用方針を定める。	5.3 BRC quality policy	The quality policy consists of the various orientations for improvement chosen by the management allowing continuous improvement of the stakeholder satisfaction. The quality objectives should, when possible, be measurable and reflect the quality policy; they are generally based on efficacy indicators relevant to identified processes: management, support, performance, and continuous improvement The quality policy needs to: a) be adapted to the entity's fundamental aims; b) conform to all legislative and regulatory requirements and to the requirements defined in collaboration with the stakeholders; c) include the commitment to improve the efficiency of the quality management system continuously; d) provide a framework for setting and reviewing quality objectives; e) be communicated, implemented and maintained across all levels of the BRC; f) be regularly reviewed to make sure it always remains appropriately focused.
C.1.4 利益相反	管理責任者として、現存する利益相反と利益相反の可能性を管理し、利益相反に関する規則(42 CFR Part 50 Subpart F)とその他の該当する規制や方針を遵守しなければならない。	5.2 Stakeholder needs and expectations	The quality policy needs to: a) be adapted to the entity's fundamental aims; b) conform to all legislative and regulatory requirements and to the requirements defined in collaboration with the stakeholders; c) include the commitment to improve the efficiency of the quality management system continuously; d) provide a framework for setting and reviewing quality objectives; e) be communicated, implemented and maintained across all levels of the BRC; f) be regularly reviewed to make sure it always remains appropriately focused.

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C.1.5 機密保持およびセキュリティ	生物試料および関連臨床情報の機密性とセキュリティの維持に関して分かりやすい方針を採用しなければならない。具体的には、コード化されたサンプルと情報を保管するヒト生物資源保管施設は、ヒト研究参加者を特定するリンクまたは対応表を保管する方法について方針を策定する。	5.6.3 Confidentiality	The BRC staff is governed by the obligation of professional secrecy to safeguard the confidentiality of scientific research and, where necessary, to protect the anonymity of donors.
C.1.6 パブリック・コミュニケーション	<ul style="list-style-type: none"> ・生物試料を他の研究者と共有するか否か。 ・利用に関する意思決定がどのように下されるのか、どのようなプライバシー保護が実施されているのか。 ・生物試料を用いて、一般にどのような種類の研究が実施されているのか。 この情報またはウェブサイトへのリンク先をインフォームド・コンセント文書に記載すること。	5.6 Communication 5.6.1 External communication 10.5.2 Data exchange	The BRC shall respond to all queries or claims from any stakeholder, relevant to: a) the quality and availability of its biological resources or collections; b) the conditions of reception or provision of the biological resources or collections. c) the conditions of services supplied by the BRC to a stakeholder The BRC shall provide the stakeholders with access to a catalogue of available biological resources based on validated information. If exchangeable data is confidential, it shall be encrypted or anonymous. The BRC shall ensure that the data exchange process maintains the integrity of the data.
C.2 インフォームド・コンセント	インフォームド・コンセントは、ヒト研究参加者となり得る者が十分な情報を与えられ、理解した上で研究に参加する意志決定を行えるように設計されている。		
C.2.1 インフォームド・コンセントに関連する連邦規制およびガイドライン	C.2.1.1 ヒト生物資源保管施設は、適切なインフォームド・コンセントが存在するか、それが存在しない場合はインフォームド・コンセントが不要である理由を突き止め、保管されている生物試料に関する同意内容に食い違いがあれば是正に努めなければならない。 C.2.1.2 OHRPは、生物試料収集のためのインフォームド・コンセント文書に以下を盛り込むことを推奨している。 ・ヒト生物資源保管施設の業務の明記。 ・受領者である研究者にサンプルと情報が提供される条件 ・ヒト研究参加者のプライバシーおよび情報の機密性を保護する手順 ・研究の性質および目的の具体的記述。 ・ヒト遺伝子研究が予期される場合、DNAタイピングをもたらす結果に関する情報。		
C.2.2 インフォームド・コンセントに関連するNCIの全般的勧告	C.2.2.1. NCIは、実行可能であれば、必ず該当する規制に準拠してインフォームド・コンセントを取得することを推奨している。最優先事項は、研究目的のために情報や生物試料を提供する個人の尊重である。 C.2.2.2. 生物試料を用いる生物医学研究では、個人的、宗教的、文化的な信条や慣習を尊重しなければならない。 C.2.2.3. 医療行為中に生物試料を収集する場合、生物試料の研究目的の使用に対する同意を得るタイミング(医療行為前または後など)は厳格にすべきではなく、倫理に関するガイドラインや運搬上の制約といったさまざまな重要事項に配慮しなければならない。 C.2.2.4. 生物試料の保管、インフォームド・コンセントに関する記録、ヒト研究参加者のプライバシー、その情報の機密性を規定する方針に関する情報は、インフォームド・コンセント文書または補足資料で参加者に提供される		

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C.2.3	<p>インフォームド・コンセントの重要要素および補足資料に関連するNCIの勧告</p> <p>C.2.3.1. 研究参加者の利益のため、重要事項とリスクを端的に記述。 C.2.3.2. どのような種類の情報が収集・使用・保管されるか記載。 C.2.3.3. 適切な場合、生物試料や情報の今後の研究での使用について再度連絡を取ることに快く協力するか否かについて選択する機会をヒト研究参加者に与えること。 C.2.3.4. 研究への参加が参加者の家族や所属社会に利益をもたらしたり、悪影響を及ぼしたりする可能性がある旨を明記。 C.2.3.5. 遺伝子配列解読や遺伝子解析を含む研究では、ヒト研究参加者にもたらすリスクに関する情報。 C.2.3.6. 必要に応じて、民営または営利企業が生物試料や情報を使用すること、研究によって将来的に市販製品が開発される可能性がある旨を記述。 C.2.3.7. 研究結果の個人への開示について。 C.2.3.8. 利益相反、他の研究者や企業とサンプルを共有する機関方針、共有することの財政的影響、機関や研究者への既知または可能性のある利益に関する一般情報について。 C.2.3.9. 段階的同意について。</p>		
C.2.4	<p>研究への参加の中止に関連する問題</p> <p>研究への参加の中止要請に対応する方針をOHRP6とFDAの指針7に準じて策定しなければならない。 研究への参加の中止要請の対処方法を定めたSOPを策定する。</p>		
C.2.5	<p>小児の生物試料の使用に関連する考慮事項</p> <p>採取当時は小児であったヒト研究参加者が研究への同意を行える法定年齢に達したときにインフォームド・コンセントを取得する必要性について考慮すべきである。</p>		
C.3	<p>プライバシーおよび機密性の保護</p> <p>ヒト研究参加者、医師、研究者、およびヒト生物資源保管施設の業務に携わる者の支援と参加を確保するには、可能な限り高い倫理基準を適用する必要がある(Friede et al. 2003)。</p>		
C.3.1	<p>プライバシーに関連する連邦規制</p>		
C.3.2	<p>プライバシーおよび機密性に関連するNCIの勧告</p> <p>ヒト生物資源保管施設は、個人識別可能な情報の機密性保護に関して明確な方針を策定しなければならない。このような方針には、情報の暗号化、コード化(匿名化)、ヒト生物資源保管施設の職員による情報の制限された利用と、機密性の段階的取り決め、非開示契約を利用することなどが含まれる。</p>		
C.4	<p>生物試料および情報の利用</p> <p>サンプルの配布および臨床情報の共有に関するガイドラインを策定すべきである。このようなガイドラインは以下の特徴を備えていなければならない。 ・理解しやすく、採用されやすいように明瞭であること ・多様かつ進化し続ける科学的ニーズに対応できるように柔軟であること ・時の経過に順応できるように修正可能であること</p>	10.4	<p>Provision of biological resources</p> <p>The principles governing access to and provision of biological resources shall be defined and published so as to ensure that they comply both with current legislation and with the contractual requirements established with the stakeholders, including in the event of competing interests. The BRC shall draft a contractual document that includes the conditions governing the provision and use of biological resources. In particular, the quantity of biological material provided shall be compatible with the intended end-use. Any usage other than that intended is prohibited. When samples are handed over, each shall be accompanied by a document containing predefined information, including information on biosafety and biosecurity as appropriate. Records shall be made of every sample supplied.</p>
C.4.1	<p>利用の決定に関連する一般原則</p> <p>・ヒト試料の利用は迅速、公平かつ適切で、運営上の負担を必要以上にかけない。 ・施設の研究実施能力、予定される方法に対して研究者の実績ある経験、および研究課題の解決に適した研究プランからもたらされる科学的メリット ・共同体の考え方や倫理上/法律上の考慮事項を最優先する。 ・利用の手続きにおいて、公平、透明かつ明瞭な意思疎通が行われる。 ・科学研究の性質(発見、普及(有病数)、初回の検証、仮説検証など)および注釈付けの必要性に基づいて生物試料を適切に割り付ける。生物試料と関連情報の個人識別の程度(連結可能匿名化、連結不可能匿名化など;訳者注)は、申請された研究にとって適切なものでなければならない。</p>		
C.4.2	<p>研究の計画</p> <p>利用要請には、科学的に理にかなった適切な研究計画が含まれていなければならない。</p>		

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C.4.3 利用の方針	研究者による生物試料および付随臨床情報の利用が適切であり、かつプライバシーと被験者に関して該当する全ての連邦および州の規制・法規ならびにヒト研究参加者のインフォームド・コンセントに準拠するよう、適切な方針を策定する。		
C.4.4 持続可能性のモデル	ヒト生物資源保管施設の持続可能性モデルとして適切であるためには、社会的信頼を維持する枠組みの中で、生物試料および情報の利用可能性とヒト生物資源保管施設の持続可能性を強調するものでなければならない。		
C.4.5 生物試料の使用可能性			
C.5 知的財産および資源の共有	生物試料を利用して得られた研究データやツールは、可能な限り広範囲に、該当するNIH sharing policiesに準拠しつつ、適時に共有されるべきである		
C.5.1 試料移転合意文書 (Material Transfer Agreements: MTA)	学術組織、非営利組織、産業組織の間で物質をやり取りする際、該当する場合、NIH Research Tools Policy、NIH Data Sharing Policyおよび他の該当するNIH sharing policiesに準じた条件を規定した同意書 (MTAまたは契約書) を用いなければならない。		
C.5.2 発明者要件 (inventorship)	ヒト生物資源保管施設の職員は、生物試料の管理者として、同施設が配布した試料を用いて行われた発明の先行発明者とはみなされない。		
C.5.3 知的財産権	ヒト生物資源保管施設は、同施設から受け取ったサンプルを用いて研究者が行った発明に対するリーチスルーの権利のような、最終使用者の将来のIPに対する権利を持たない。		
C.5.4 ライセンス付与	生物試料研究から生じたIPの独占的使用権が付与される場合、非営利および政府による研究使用と、研究目的や教育目的による資源および情報の利用を認める研究使用ライセンスを保持しなければならない。		
C.5.5 情報および資源の共有	生物試料の使用によって得られた研究データや研究資源は、研究者社会が利用できるようにしなければならない。		
C.6 利益相反			
C.6.1 研究者の金銭的な利益相反	外部研究に関する規則には、研究者の金銭的な利益相反を管理するため、受給される側の機関が課するかもしれない条件または制限の例が含まれる (重大な金銭的利益の公開を含む)。		
C.6.2 機関の金銭的な利益相反	機関の金銭的な利益相反については、必要に応じて考慮・管理しなければならない。		
C.6.3 金銭的でない利益相反	金銭的でない利益相反については、実行可能な範囲で特定・管理する。		
Term 用語解説		3 Terms and definitions	<p>2.1 Biological Resource Centre (BRC) A BRC consist of service providers and repositories of culturable organisms, replicable parts of these, viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics NOTE The term "Biological Resource Centre" has been adopted by the entire international community under the OECD initiative. Other terms may also be encountered, such as biobank, platform, tumour bank, etc. The designation 'BRC' will be used for purposes of the present standard.</p> <p>2.2 Biological resources Generic term covering biological material and the related data (annotations)</p> <p>2.3 Biological material Cultivable organisms (such as microorganisms, plant animal or human cells), replicating parts of these organisms (for example genomes, plasmids, virus, and nucleic acids), organisms, cells and viable but not yet cultivable tissues. NOTE 1 Biological material of human origin may include organs, tissues, cells, biological fluids and their derivatives such as nucleic acids and proteins. This biological material could be kept frozen, fixed, lyophilised, or coated with specific material. NOTE 2 Agronomic material may be an organism, or parts or derived product of these organisms, populations, genetic resources or any other biotic elements from the ecosystem that could be used or have</p>

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			<p>an effective or potential value to humanity.</p> <p>2.4 Collection Set of biological resources grouped together according to common characteristics</p> <p>2.5 Annotations / related data Information associated with the biological material</p> <p>2.6 User Person (physical or moral) using the biological resources provided by the BRC</p> <p>2.7 Stakeholders The stakeholders in a BRC are any person having an interest in the operations of the BRC</p> <p>2.8 Supplier entity or person who provides a product or a service</p> <p>2.9 Catalogue a documentary tool used to list the biological resources and their availability</p> <p>2.10 Facilities (or locale) closed space with controlled access that contains the biological resource kept by the BRC or where the BRC activities take place</p> <p>2.11 Dedicated space in the agronomic field, non-closed space containing the biological resource kept by the BRC or where the BRC activities take place</p> <p>2.12 Critical All elements (purchases, equipment, methods, and steps) that have an impact on the quality of the biological resource, on stakeholder satisfaction, or on staff safety are considered to be critical.</p>

比較表 (NCI2011 vs OECD2007 vs ISO 9001:2008)

NCI Best Practices for Biospecimen Resources (2011)		OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES (2007)		ISO 9001:2008	
目次	本文	目次	本文	目次	本文
Intro. 序文	<p>1. These domain specific best practice guidelines provide the basis for the best practices in the management of Biological Resource Centres (BRCs) that hold and supply human-derived materials.</p> <p>2. In the post-genomics era, human-derived biological materials for basic research use in general and applied science constitute vital tools for clinical, health-related biotechnologies and the development of new pharmaceuticals, medical devices diagnostics and therapies.</p> <p>3. It is widely recognised that BRCs that hold and supply authorised human-derived biological materials should do so in such a way as to provide a high quality service, consistent traceability (from the providers to the end-users) and appropriate transparency, in accordance with national and international legislation and regulations, as well as ethical commitments where these are required to apply.</p> <p>4. These domain specific best practice guidelines assist BRCs to put into practice procedures that comply with relevant national law, regulations and policies. The best practice guidelines aim to provide a reliable basis for research and development in different laboratories and to contribute towards protection of the donor of human-derived biological materials in accordance with ethical principles, the health of laboratory personnel, the public and the environment.</p> <p>5. Rules of ethics concerning the collection, use and safety of samples should be taken into account in the organisation and operation of any BRC so as to protect individuals as well as population groups.</p>	Intro. Introduction	<p>1. These domain specific best practice guidelines provide the basis for the best practices in the management of Biological Resource Centres (BRCs) that hold and supply human-derived materials.</p> <p>2. In the post-genomics era, human-derived biological materials for basic research use in general and applied science constitute vital tools for clinical, health-related biotechnologies and the development of new pharmaceuticals, medical devices diagnostics and therapies.</p> <p>3. It is widely recognised that BRCs that hold and supply authorised human-derived biological materials should do so in such a way as to provide a high quality service, consistent traceability (from the providers to the end-users) and appropriate transparency, in accordance with national and international legislation and regulations, as well as ethical commitments where these are required to apply.</p> <p>4. These domain specific best practice guidelines assist BRCs to put into practice procedures that comply with relevant national law, regulations and policies. The best practice guidelines aim to provide a reliable basis for research and development in different laboratories and to contribute towards protection of the donor of human-derived biological materials in accordance with ethical principles, the health of laboratory personnel, the public and the environment.</p> <p>5. Rules of ethics concerning the collection, use and safety of samples should be taken into account in the organisation and operation of any BRC so as to protect individuals as well as population groups.</p>	Intro. Introduction	
		0.1 General	<p>The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by</p> <ul style="list-style-type: none"> a) its organizational environment, changes in that environment, and the risks associated with that environment, b) its varying needs, c) its particular objectives, d) the products it provides, e) the processes it employs, f) its size and organizational structure. <p>It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.</p> <p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>	0.1 General	<p>The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by</p> <ul style="list-style-type: none"> a) its organizational environment, changes in that environment, and the risks associated with that environment, b) its varying needs, c) its particular objectives, d) the products it provides, e) the processes it employs, f) its size and organizational structure. <p>It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.</p> <p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>
		0.2 Process approach	<p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) continual improvement of processes based on objective measurement. <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.</p> <p>NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as:</p> <ul style="list-style-type: none"> Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies. Do: implement the processes. Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results. Act: take actions to continually improve process performance. 	0.2 Process approach	<p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) continual improvement of processes based on objective measurement. <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. 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NCI Best Practices for Biospecimen Resources (2011)		OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES (2007)		ISO 9001:2008		
目次	目次	本文	目次	本文		
			0.3 Relationship with ISO 9004	ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently. ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements. At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use. ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently. ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements. At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.		
			0.4 Compatibility with other management systems	During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004. This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard		
A 目的、適応範囲および実務						
A.1 目的	2. Scope	6. These guidelines provide best practices that complement the document General Best Practice Guidelines for BRCs. They address the acquisition, maintenance and provision of human-derived biological material (see definition) by BRCs as well as the management of such BRCs. 7. BRCs dealing with human-derived biological material aim to assure the quality of such material, while ensuring that sensitive data are protected and that transactions between the various parties exchanging such material can be traced. BRCs should be organised in a manner that ensures the quality of the storage of biological material and provides for the correct and ethical use and distribution of the biological material. BRCs should adhere to internationally recognised ethical principles, particularly informed consent. 8. Bio-banks for therapeutic and diagnostic purposes are excluded from the scope of these best practice guidelines. The potential scientific value of collections that cannot meet these best practice guidelines should be recognised.	1 Scope			
			1.1 General	This International Standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.		
			1.2 Application	All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.		
A.2 適応範囲および実務						
A.3 NCI実務要領の形式						
B 技術上および実践可能な実務手順						
B.1 ヒト生物資源保管施設の管理および運用	4. Organisational Requirements		6 Resources management 6.1 Provision of resources	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.		

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<p>B.1.1 ヒト生物資源保管施設の組織の概観</p>	<p>4.1. Compliance with law and ethics regulations</p>	<p>10. BRCs must comply with appropriate national and international laws, international rules and regulations and should follow the Ethical Committee's recommendations concerning use of human-derived biological materials and ethics. 11. In particular, human BRCs should respect laws and regulations in the areas of: i) National certification of Biological Resource Centres, where such systems may be in place under the responsibility of national governments. ii) Professional secrecy. iii) Health and Safety (including Good Management Practice) or good manufacturing practice. iv) Ownership of Intellectual Property Rights (IPR), when applicable. v) Ethical matters, including, as appropriate, informed consent and respect for human dignity. vi) Management of data bases and security of associated data. vii) Employee safety. viii) Environmental safety. ix) Transport legislation, including import and export. x) Classification of biological material on the basis of hazard (to take into account the actual or potential infectious status of human-derived biological material). In particular, BRCs should comply with (Best Practice Guidelines on Biosafety for BRCs). 12. When engaged in activities related to the collection and use of human-derived material, BRCs should ensure: xi) The preservation of the donor's dignity. xii) The respect for the autonomy of the donor, particularly through informed consent, up to and including the possibility to withdraw his/her informed consent when samples and derived data have been stored in an identifiable manner. xiii) The right of each individual to decide whether or not to be informed of the results of research if human-derived biological material is not anonymous. xiv) The protection of the confidentiality of data stored or processed for research purposes. xv) That the only samples included in a BRC are those for which enough material for potential future diagnostics and clinical purposes for the donor and/or his/her family, is available. Biological material collected without informed consent can, however, be distributed by BRCs so long as such actions have the approval of an ethical committee in accordance with national regulations.</p>		
<p>B.1.2 ヒト生物資源保管施設に係る職員</p>	<p>5. Staff – qualifications and training 5.1. Staff 5.2. Training 5.3. Hygiene and biosafety</p>	<p>16. Staff should have relevant qualifications, training and competence in human-derived biological material relevant to the scope of material held in the BRC. 17. All persons having access to a BRC should be bound by a duty of professional secrecy. Persons with access to confidential data should be contractually bound to medical secrecy obligations. Rights of access should be managed, traced and limited to authorised persons. Each member of staff shall possess the competence, qualifications and authorisations necessary to perform the missions attributed to them; a) staff competence, qualifications and authorisations shall be documented and kept; b) the delegation of responsibilities shall be clearly defined, implemented, and documented and kept; c) the level of safety training required shall be determined according to position-related requirements; d) one person shall be nominated as Health and Safety officer. a) each member of staff shall be allowed to follow training (internal or external) to acquire the necessary skills. The efficacy of training programmes shall be assessed. All training courses followed are to be recorded; b) members of staff must receive authorisation for tasks, awarded according to in-house training (general technical training, training for specific tasks, tutoring, and so on.). All training shall be recorded; c) all members of staff shall be made aware of health, safety and quality issues and have access to appropriate documentation.</p>	<p>6.2 Human resources 6.2.1 General 6.2.2 Competences, awareness and training</p>	<p>Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. The organization shall determine the necessary competence for personnel performing work affecting conformity to product requirements, where applicable, provide training or take other actions to achieve the necessary competence, evaluate the effectiveness of the actions taken, ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>
<p>B.1.3 計画および開発に係る考慮事項</p>	<p>10. Services of BRCs</p>	<p>48. BRCs may engage in research and development activities relevant to their missions. 49. BRCs may provide services in accordance with ethical and legal regulations. 50. BRC should take reasonable steps to ensure that services from an outside provider are rendered in accordance with the regulations and good practices in force in the appropriate field, that are applicable in the jurisdiction relevant to the BRC as well as in the jurisdiction relevant to where the service is to be performed. 51. Inflows and outflows of biological material should be recorded, and when it is necessary to transport samples, their transport should be documented and carried out in compliance with the applicable standards and regulations.</p>	<p>7.3 Design and development</p>	

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				7.3.1 Design and development planning	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.
				7.3.2 Design and development inputs	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.
				7.3.3 Design and development outputs	The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.
				7.3.4 Design and development review	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
				7.3.5 Design and development verification	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
				7.3.6 Design and development validation	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
				7.3.7 Control of design and development changes	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary acti
B.1.4 ヒト生物資源保管施設のインフラおよび空間計画	6. Premises	24. It is the responsibility of the BRC to provide an environment that is conducive to: i) Handling aseptically human-derived biological material to prevent contamination during processing and facilitate accurate measurement and recording. ii) Ensuring that dangerous organisms that could be misused are not distributed to unauthorised users, in accordance with national law (see Best Practice Guidelines on Biosecurity for BRCs). iii) Assuming confidentiality of associated data. iv) Providing site security.		6.3 Infrastructures	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems).
	7. Equipment use, calibration, testing and maintenance records	25. Cleaning, disinfection/sterilisation and maintenance of laboratory equipment should be performed by authorised and trained staff following documented procedures. 26. Special attention should be paid to the conditions for incubation and storage of biological material. 27. Appropriate maintenance and verification procedures for equipment in BRCs are summarised in Annex 1. The list does not apply to those BRCs that retain solely formalin-fixed material.		6.4 Work environment	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

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B.1.5 運用に係る全般的な考慮事項	<p>8. Documentation management</p> <p>28. All documents should be readable and stored in a place where they can easily be located by authorised staff. They should be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering.</p> <p>29. BRCs should use a data management system that includes a computerised inventory tracking system with appropriate security/data-access control safeguards.</p> <p>30. All BRC procedures should be subject to documentary management throughout their lifetime.</p> <p>31. All movements into or out of the collection of biological material should be documented.</p> <p>32. Often, human BRCs require that stored biological material be linkable to the personal genealogical and clinical data of the donor. It is imperative that security and confidentiality are respected to address privacy issues. Any documentation on biomedical data should be kept in secure cabinets accessible only to authorised personnel.</p> <p>33. The documentation managed by databases should be saved, secured and duplicated in a different site.</p> <p>34. BRCs should develop a disaster plan which includes appropriate privacy protection for personal information and equipment.</p>	<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p> <p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including, where appropriate,</p> <p>a) requirements for approval of product, procedures, processes and equipment,</p> <p>b) requirements for qualification of personnel, and</p> <p>c) quality management system requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p> <p>7.4.3 Checks on purchased products</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p>
B.1.6 ヒト生物資源保管施設の評価および査定	<p>15. Quality Audit and Quality Review</p> <p>91. Internal and external audits are necessary to monitor quality (focus on developing preventative actions and maintenance), and should be performed regularly and duly documented.</p> <p>92. Quality review should be built into the procurement, processing, testing, storage and delivery of material.</p>	<p>5.6 Management review</p> <p>5.6.1 General</p> <p>Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).</p> <p>5.6.2 Review input</p> <p>The input to management review shall include information on</p> <p>a) results of audits,</p> <p>b) customer feedback,</p> <p>c) process performance and product conformity,</p> <p>d) status of preventive and corrective actions,</p> <p>e) follow-up actions from previous management reviews,</p> <p>f) changes that could affect the quality management system, and</p> <p>g) recommendations for improvement.</p> <p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <p>a) improvement of the effectiveness of the quality management system and its processes,</p> <p>b) improvement of product related to customer requirements, and</p> <p>c) resource needs.</p>

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B.2 生物試料の収集、処理、保管、取り出しおよび配布	12.1. Receipt and handling of biological material	56. BRCs should implement safe, documented procedures for the receipt and storage of humanderived biological material that are appropriate to the hazard posed by such material. All incoming parcels that contain unknown or hazardous biological material should be opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological material. Safety procedures should be laid down and documented. 57. Conditions of deposit should be determined and agreed upon, if pertinent, in a material transfer agreement (MTA). Where deposits are outside the remit of a BRC, suitable BRCs should be recommended. 58. The depositor should provide proof that prior informed consent to collect and deposit the primary human-derived biological material in a BRC has been obtained or reasonable efforts have been taken to obtain such consent (with proof of ethical review). 59. On deposit of human-derived biological material, BRCs should record ownership and terms and conditions for further distribution. 60. A unique identification number should be allocated to the biological material, which should never be reassigned to other material even if the original biological material is later discarded. 61. In any situation in which a BRC has in its possession information that could identify a donor, such information should be dissociated from the biological material concerned and any other associated data. 62. Specific care should be taken to ensure that data in the	7 Product realisation	
B.2.1 分析前変動要因および分析変動要因	12.3. Quality checks on biological material	64. BRCs should institute a system of quality control that monitors the process of preparation and conservation of samples received. Such a system should also ensure the quality of the minimum data set generated for each sample received. The quality control methodologies used should reflect the differing nature of the biological material received (see Appendix 3). In each case, specific quality control procedures should be laid down and followed. 65. When validating the quality of human-derived biological material for specific research applications, BRCs should strive to use as little of the biological material as possible.	7.1 Planning of product realisation	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
B.2.2 収集すべき生物試料の決定	11. Preparation of samples	52. Accurate preparation is one of the fundamental steps in the maintenance of biological material and should be given special attention. 53. Sample preparation techniques should be stipulated in procedures and operating instructions that should be validated and revised periodically. 54. BRCs should have documented standards and procedures for all preparations. There should also be written procedures for updating, approving and adopting all documents. 55. Consumable material used should be of a high standard.	7.1 Planning of product realisation	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
B.2.3 基準範囲の設定	11. Preparation of samples	52. Accurate preparation is one of the fundamental steps in the maintenance of biological material and should be given special attention. 53. Sample preparation techniques should be stipulated in procedures and operating instructions that should be validated and revised periodically. 54. BRCs should have documented standards and procedures for all preparations. There should also be written procedures for updating, approving and adopting all documents. 55. Consumable material used should be of a high standard.	7.1 Planning of product realisation	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
B.2.4 根拠に基づいた標準業務手順に求められる要求事項			7.1 Planning of product realisation	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.

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B.2.5 方法の調査研究		7.1 Planning of product realisation The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
B.2.6 生物試料の保管	13. Preservation 66. For each type of human-derived biological material, appropriate preservation method(s) should be chosen by the BRC based on its own experience or on the recommendations of the depositor (examples of technical preservation of applicable material are given in Appendix 4). 67. BRCs should avoid unnecessary thawing and refreezing of frozen biological material. Checks should be in place to assure and validate storage stability. 68. A written procedure should be available for the preservation of samples by each available means of storage. 69. Storage conditions should ensure that loss of material is prevented. Where applicable: i) Storage temperatures should be monitored continuously, and incidents and alarms should be documented and traceable, in relation to the biological material involved. ii) The freezer container should be equipped with an alarm system that ensures an immediate intervention, 24 hours a day, all year round. iii) Procedures for transfer in the event of a breakdown should be defined, including the obligations of staff. 70. An empty functioning freezer should be available in case of single freezer failure. 71. Validation of the methods and procedures used for preservation should be carried out to ensure their reproducibility and reliability by using one of the following approaches: i) Performing blind tests. ii) Calibration. iii) Comparing the results of the same method performed at different times. iv) Comparing results obtained with different methods. v) Comparing the results obtained for the same method performed by different persons. vi) Participation in relevant ring trials. 72. The results of the validation of methods and procedures should be recorded. 73. Where possible, duplicate samples should be made and stored as a duplicate collection at a separate location.	7.5.5 Preservation of product The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
B.2.7 生物試料の取り出し	13. Preservation 66. For each type of human-derived biological material, appropriate preservation method(s) should be chosen by the BRC based on its own experience or on the recommendations of the depositor (examples of technical preservation of applicable material are given in Appendix 4). 67. BRCs should avoid unnecessary thawing and refreezing of frozen biological material. Checks should be in place to assure and validate storage stability. 68. A written procedure should be available for the preservation of samples by each available means of storage. 69. Storage conditions should ensure that loss of material is prevented. Where applicable: i) Storage temperatures should be monitored continuously, and incidents and alarms should be documented and traceable, in relation to the biological material involved. ii) The freezer container should be equipped with an alarm system that ensures an immediate intervention, 24 hours a day, all year round. iii) Procedures for transfer in the event of a breakdown should be defined, including the obligations of staff. 70. An empty functioning freezer should be available in case of single freezer failure. 71. Validation of the methods and procedures used for preservation should be carried out to ensure their reproducibility and reliability by using one of the following approaches: i) Performing blind tests. ii) Calibration. iii) Comparing the results of the same method performed at different times. iv) Comparing results obtained with different methods. v) Comparing the results obtained for the same method performed by different persons. vi) Participation in relevant ring trials. 72. The results of the validation of methods and procedures should be recorded. 73. Where possible, duplicate samples should be made and stored as a duplicate collection at a separate location.	7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities.
B.2.8 サンプルの出荷	14. Supply of biological material	

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	<p>14.1. Order placement</p> <p>14.2. Availability of the biological material ordered</p> <p>14.3. Information provided with the biological material supplied</p> <p>14.4. Packaging</p>	<p>74. BRCs should supply biological material to other BRCs and public or private institutions for research purposes only.</p> <p>75. BRCs should pay specific attention to the authentication of new clients (first orders from new clients should be received on an order form with the client's official letterhead and signed by an authorised person) and of their individual representative(s). BRCs should provide an appropriate and protected follow-up mechanism to maintain adequate authentication.</p> <p>76. A material transfer agreement, if pertinent, should be drawn up between the BRC and the user so the user can be informed of his/her rights and duties relating to the biological material or the collection requested (for example, relating to intellectual property rights, consent, publication, result reporting requirements, quoting BRC accession numbers in publication).</p> <p>77. BRCs should ensure that an appropriate review board has considered and approved proposed research topics prior to releasing human-derived biological material for such purposes.</p> <p>78. An order should only be accepted when the required accompanying documentation is completed, signed and returned.</p> <p>79. BRCs should conduct their operations in accordance with the Best Practice Guidelines on Biosecurity for BRCs.</p> <p>80. Human-derived biological material should be dispatched, where practicable, as soon as possible once necessary licenses and/or documentation are provided.</p> <p>81. With biological material of Risk Group 2 (WHO Biosafety manual, 2004) and higher the BRC should have written and signed documentation proving the user has the appropriate authorisation to import and handle such biological material.</p> <p>82. BRCs should seek to serve the interests of the wider scientific community, in that material should be made available to a broad scientific community for use in high quality research.</p> <p>83. BRCs should develop a distribution strategy that addresses how they will manage possible conflicts between hold and supply activities in cases of rare and/or precious samples as well as for those samples that cannot be replenished.</p> <p>84. If a biological material cannot be immediately delivered, the BRC should inform the user of an estimated date of supply.</p> <p>85. The BRC should at least provide to the user:</p> <ul style="list-style-type: none"> i) A minimum data set according to the type of resource (See Appendix 2) ii) The repository conditions needed to maintain the biological material (temperature, medium, culture conditions etc.), iii) The transportation conditions. iv) A safety data sheet in the case of a material containing a hazardous organism or its derivative, including the containment level required for handling the biological material, disposal measures and measures to take in case of spillage. <p>Human cells, tissues should always be treated as hazardous unless they are tested for infectious diseases or treated with an appropriate inactivation measure (e.g. fixation with formaldehyde). The safety data sheet should be mandatory for any dangerous material and should be included in the package, together with instructions for handling.</p> <p>86. In circumstances in which information is supplied that pertains to a donor's identity, such information should be encrypted (type of code depending on procedures previously determined).</p> <p>87. The packaging of biological material and its transport by postal and other transport services are covered by international and regional agreements and national laws (see Appendix 6). The BRC should ensure that any changes to applicable legislation and regulations are implemented in their procedures.</p> <p>88. Packages of the human-derived biological material should be labelled according to international rules and have the appropriate customs declaration, biological hazard label and import/export permit where appropriate.</p> <p>89. Human-derived biological material, not known to be infectious and derived from a normal risk population may be sent by (air) mail or other means of transport according to the Universal Postal Union (UPLU) requirements (see Appendix 6).</p> <p>90. A BRC should ensure that staff responsible for the distribution of infectious substances via air have the required shipper training certificate.</p>	

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B.3 品質管理	12.1. Receipt and handling of biological material	<p>56. BRCs should implement safe, documented procedures for the receipt and storage of humanderived biological material that are appropriate to the hazard posed by such material. All incoming parcels that contain unknown or hazardous biological material should be opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological material. Safety procedures should be laid down and documented.</p> <p>57. Conditions of deposit should be determined and agreed upon, if pertinent, in a material transfer agreement (MTA). Where deposits are outside the remit of a BRC, suitable BRCs should be recommended.</p> <p>58. The depositor should provide proof that prior informed consent to collect and deposit the primary human-derived biological material in a BRC has been obtained or reasonable efforts have been taken to obtain such consent (with proof of ethical review).</p> <p>59. On deposit of human-derived biological material, BRCs should record ownership and terms and conditions for further distribution.</p> <p>60. A unique identification number should be allocated to the biological material, which should never be reassigned to other material even if the original biological material is later discarded.</p> <p>61. In any situation in which a BRC has in its possession information that could identify a donor, such information should be dissociated from the biological material concerned and any other associated data.</p> <p>62. Specific care should be taken to ensure that data in the possession of a BRC is not misused in such a way as to cause harm to individuals or groups of individuals.</p>	4	Quality management system
B.3.1 品質管理システム	8. Documentation management	<p>28. All documents should be readable and stored in a place where they can easily be located by authorised staff. They should be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering.</p> <p>29. BRCs should use a data management system that includes a computerised inventory tracking system with appropriate security/data-access control safeguards.</p> <p>30. All BRC procedures should be subject to documentary management throughout their lifetime.</p> <p>31. All movements into or out of the collection of biological material should be documented.</p> <p>32. Often, human BRCs require that stored biological material be linkable to the personal genealogical and clinical data of the donor. It is imperative that security and confidentiality are respected to address privacy issues. Any documentation on biomedical data should be kept in secure cabinets accessible only to authorised personnel.</p> <p>33. The documentation managed by databases should be saved, secured and duplicated in a different site.</p> <p>34. BRCs should develop a disaster plan which includes appropriate privacy protection for personal information and equipment.</p>	4.1	<p>General requirements</p> <p>The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The organization shall</p> <ol style="list-style-type: none"> determine the processes needed for the quality management system and their application throughout the organization (see 1.2). determine the sequence and interaction of these processes. determine criteria and methods needed to ensure that both the operation and control of these processes are effective. ensure the availability of resources and information necessary to support the operation and monitoring of these processes. monitor, measure where applicable, and analyse these processes, and implement actions necessary to achieve planned results and continual improvement of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.</p>
B.3.2 品質保証／品質管理 (QA/GC)	8. Documentation management	<p>28. All documents should be readable and stored in a place where they can easily be located by authorised staff. They should be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering.</p> <p>29. BRCs should use a data management system that includes a computerised inventory tracking system with appropriate security/data-access control safeguards.</p> <p>30. All BRC procedures should be subject to documentary management throughout their lifetime.</p> <p>31. All movements into or out of the collection of biological material should be documented.</p> <p>32. Often, human BRCs require that stored biological material be linkable to the personal genealogical and clinical data of the donor. It is imperative that security and confidentiality are respected to address privacy issues. Any documentation on biomedical data should be kept in secure cabinets accessible only to authorised personnel.</p> <p>33. The documentation managed by databases should be saved, secured and duplicated in a different site.</p> <p>34. BRCs should develop a disaster plan which includes appropriate privacy protection for personal information and equipment.</p>	4.2	Documentation requirements
	12.3. Quality checks on biological material	<p>64. BRCs should institute a system of quality control that monitors the process of preparation and conservation of samples received. Such a system should also ensure the quality of the minimum data set generated for each sample received. The quality control methodologies used should reflect the differing nature of the biological material received (see Appendix 3). In each case, specific quality control procedures should be laid down and followed.</p> <p>65. When validating the quality of human-derived biological material for specific research applications, BRCs should strive to use as little of the biological material as possible.</p>	4.2.1	<p>General</p> <p>The quality management system documentation shall include</p> <ol style="list-style-type: none"> documented statements of a quality policy and quality objectives, a quality manual, documented procedures and records required by this International Standard, and documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

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	<p>13. Preservation</p> <p>66. For each type of human-derived biological material, appropriate preservation method(s) should be chosen by the BRC based on its own experience or on the recommendations of the depositor (examples of technical preservation of applicable material are given in Appendix 4).</p> <p>67. BRCs should avoid unnecessary thawing and refreezing of frozen biological material. Checks should be in place to assure and validate storage stability.</p> <p>68. A written procedure should be available for the preservation of samples by each available means of storage.</p> <p>69. Storage conditions should ensure that loss of material is prevented. Where applicable:</p> <p>i) Storage temperatures should be monitored continuously, and incidents and alarms should be documented and traceable, in relation to the biological material involved.</p> <p>ii) The freezer container should be equipped with an alarm system that ensures an immediate intervention, 24 hours a day, all year round.</p> <p>iii) Procedures for transfer in the event of a breakdown should be defined, including the obligations of staff.</p> <p>70. An empty functioning freezer should be available in case of single freezer failure.</p> <p>71. Validation of the methods and procedures used for preservation should be carried out to ensure their reproducibility and reliability by using one of the following approaches:</p> <p>i) Performing blind tests.</p> <p>ii) Calibration.</p> <p>iii) Comparing the results of the same method performed at different times.</p>	<p>4.2.2 Quality manual</p> <p>The organization shall establish and maintain a quality manual that includes</p> <p>a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),</p> <p>b) the documented procedures established for the quality management system, or reference to them, and</p> <p>c) a description of the interaction between the processes of the quality management system.</p>
	<p>15. Quality Audit and Quality Review</p> <p>91. Internal and external audits are necessary to monitor quality (focus on developing preventative actions and maintenance), and should be performed regularly and duly documented.</p> <p>92. Quality review should be built into the procurement, processing, testing, storage and delivery of material.</p>	<p>4.2.3 Control of documents</p> <p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed</p> <p>a) to approve documents for adequacy prior to issue,</p> <p>b) to review and update as necessary and re-approve documents,</p> <p>c) to ensure that changes and the current revision status of documents are identified,</p> <p>d) to ensure that relevant versions of applicable documents are available at points of use,</p> <p>e) to ensure that documents remain legible and readily identifiable,</p> <p>f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and</p> <p>g) to prevent the unintended use of obsolete documents, and to</p> <p>4.2.4 Control of records</p> <p>Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.</p> <p>The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.</p>
		<p>7.5.2 Validation of processes for production and service function</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable,</p> <p>a) defined criteria for review and approval of the processes,</p> <p>b) approval of equipment and qualification of personnel,</p> <p>c) use of specific methods and procedures,</p> <p>d) requirements for records (see 4.2.4), and</p> <p>e) revalidation.</p>
		<p>8 Measurement, analysis and improvement</p>
		<p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>a) to demonstrate conformity to product requirements,</p> <p>b) to ensure conformity of the quality management system, and</p> <p>c) to continually improve the effectiveness of the quality management system.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>
		<p>8.2 Monitoring and measurement</p>
		<p>8.2.1 Customer satisfaction</p> <p>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.</p>

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		<p>8.2.2 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p> <p>8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.</p> <p>8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p> <p>8.3 Control of nonconforming product The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p> <p>8.4 Data analysis The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and d) suppliers (see 7.4).</p> <p>8.5 Improvement</p> <p>8.5.1 Continuous improvement The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p> <p>8.5.2 Corrective action The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing the effectiveness of the corrective action taken.</p>

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			8.5.3 Preventive action	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing the effectiveness of the preventive action taken.
B.3.3 標準業務手順書(SOPマニュアル)	5.3. Hygiene and biosafety	19. Since human cells may be infected by pathogenic viruses or other micro-organisms, all staff should follow the procedures laid down under the appropriate level of containment for human-cells being handled, as defined by WHO's Laboratory Biosafety Manual and as interpreted by national law, regulations and policies, to avoid contaminating samples as well as to avoid the risk of infection. 20. BRCs should therefore institute procedures that ensure a suitable and sufficient assessment of the risks to health and safety to which any person whether employed by BRCs or not may be exposed through their work. Such procedures should be reviewed regularly, and changes to such procedures should be recorded. 21. All staff should follow the procedures laid down under the appropriate level of containments as defined by the World Health Organisation and as interpreted by national law, regulations and policies for micro-organisms that might be handled knowingly or inadvertently through the handling of human-derived biological material. 22. Important elements of a safe work place include: i) Adequate assessment of risks. ii) Provision of adequate control measures. iii) Provision of health and safety information. iv) Provision of appropriate training. v) Provision of adequate individual protection devices. vi) Establishment of records systems to allow safety audits to be carried out. vii) Implementation of current best practices. 23. Best practice requires assurance that correct procedures are actually being followed and this requires a sound and accountable safety policy.	4.2.2 Quality manual	The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.
			7.5.1 Control of production and service provision	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities.
			7.5.2 Validation of processes for production and service function	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable, a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
B.4 バイオセーフティ	5.3. Hygiene and biosafety	19. Since human cells may be infected by pathogenic viruses or other micro-organisms, all staff should follow the procedures laid down under the appropriate level of containment for human-cells being handled, as defined by WHO's Laboratory Biosafety Manual and as interpreted by national law, regulations and policies, to avoid contaminating samples as well as to avoid the risk of infection. 20. BRCs should therefore institute procedures that ensure a suitable and sufficient assessment of the risks to health and safety to which any person whether employed by BRCs or not may be exposed through their work. Such procedures should be reviewed regularly, and changes to such procedures should be recorded. 21. All staff should follow the procedures laid down under the appropriate level of containments as defined by the World Health Organisation and as interpreted by national law, regulations and policies for micro-organisms that might be handled knowingly or inadvertently through the handling of human-derived biological material. 22. Important elements of a safe work place include: i) Adequate assessment of risks. ii) Provision of adequate control measures. iii) Provision of health and safety information. iv) Provision of appropriate training. v) Provision of adequate individual protection devices. vi) Establishment of records systems to allow safety audits to be carried out. vii) Implementation of current best practices. 23. Best practice requires assurance that correct procedures are actually being followed and this requires a sound and accountable safety policy.		
B.4.1 バイオハザードの予防措置				
B.4.2 バイオセーフティの実務要領				

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B.4.3 実験室の一般的安全性	6. Premises	24. It is the responsibility of the BRC to provide an environment that is conducive to: i) Handling aseptically human-derived biological material to prevent contamination during processing and facilitate accurate measurement and recording. ii) Ensuring that dangerous organisms that could be misused are not distributed to unauthorised users, in accordance with national law (see Best Practice Guidelines on Biosecurity for BRCs). iii) Assuming confidentiality of associated data. iv) Providing site security.	6.3 Infrastructures The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems).
B.5 臨床情報の収集および管理	9.1. Data	35. BRCs should ensure a minimum amount of information is available for each accession in the collection (the Minimum Data Set (MDS)). Additional data may comprise a Recommended Data Set (RDS). Best practice for what should comprise each data set is listed in Appendix 2. The MDS should be recorded and made available. 36. The data should be updated with the most recent information related to donor's sample (i.e.clinical data, results of scientific research). 37. Exceptionally, BRCs may accept collections of scientific value that cannot meet the full MDS and should disclose which items of the MDS are missing. 38. The data vocabulary used for the BRC catalogue should be in accordance with an identified thesaurus (e.g.Online Mendelian Inheritance in Man). 39. A procedure for defining the MDS and RDS for a collection should be established before the collection is constituted. 40. BRCs should be equipped with information systems that can handle physical management of samples. This implies a system that records data on all stages of handling from sampling to transfer of all or part of a collection. There should be traceability of analyses undertaken, as well as of quality controls and transformations. 41. Identifying (associated) data may be recorded and transmitted securely, e.g.by e-mail or over the Web, only in accordance with the applicable regulations. 42. Donor identities should be encrypted in databases. The procedure for coding biological material is paramount to the protection of the donor's privacy as well as for allowing distribution and use for research purposes.	
B.5.1 法規制の遵守	4.1. Compliance with law and ethics regulations	10. BRCs must comply with appropriate national and international laws, international rules and regulations and should follow the Ethical Committees recommendations concerning use of human-derived biological materials and ethics. 11. In particular, human BRCs should respect laws and regulations in the areas of: i) National certification of Biological Resource Centres, where such systems may be in place under the responsibility of national governments. ii) Professional secrecy. iii) Health and Safety (including Good ManagementPractice) or good manufacturing practice. iv) Ownership of Intellectual Property Rights (IPR), when applicable. v) Ethical matters, including, as appropriate, informed consent and respect for human dignity. vi) Management of data bases and security of associated data. vii) Employee safety. viii) Environmental safety. ix) Transport legislation, including import and export. x) Classification of biological material on the basis of hazard (to take into account the actual or potential infectious status of human-derived biological material). In particular, BRCs should comply with (Best Practice Guidelines on Biosecurity for BRCs). 12. When engaged in activities related to the collection and use of human-derived material, BRCs should ensure: xi) The preservation of the donor's dignity. xii) The respect for the autonomy of the donor, particularly through informed consent, up to and including the possibility to withdraw his/her informed consent when samples and derived data have been stored in an identifiable manner. xiii) The right of each individual to decide whether or not to be informed of the results of research if human-derived biological material is not anonymous. xiv) The protection of the confidentiality of data stored or processed for research purposes. xv) That the only samples included in a BRC are those for which enough material for potential future diagnostics and clinical purposes for the donor and/or his/her family, is available. Biological material collected without informed consent can, however, be distributed by BRCs so long as such actions have the approval of an ethical committee in accordance with national regulations.	
B.5.2 臨床情報の収集			
B.5.3 長期追跡臨床情報			
B.5.4 情報の追跡を支援する情報処理			