厚生労働科学研究費補助金

医療技術実用化総合研究事業（臨床研究・治験推進研究事業）

倫理審査委員会の認定制度と要件に関する検討

平成２５年度　総括研究報告書

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研究代表者：楠岡英雄（(独) 国立病院機構大阪医療センター　院長）

研究要旨

本研究は、「臨床研究・治験活性化５か年計画 2012」、ならびに、そのアクションプランにおいて求められている倫理審査委員会の認定制度の導入のために、制度設計と認定要件を具体的に策定することを目的としたものである。法律の専門家、研究倫理の専門家、生物統計学者、臨床研究に豊富な経験のある臨床医、医薬開発学の専門家、臨床研究コーディネーター、患者・被験者の対場を代表する者などで研究班を構成し、検討を行った。認定は、特に際立った研究や特殊な研究の審査を行う倫理審査委員会ではなく、持続的に活動を行っている一般的な倫理審査委員会を対象とすることが確認された。その上で、認定の要件として、審査の効率性、倫理審査委員会に関わる人材や資源の状況、教育研修等の視点から、基本要件、追加すべき要件、審査時の提出物、認定後の義務、認定の更新等について項目を策定した。また、認定を行う機関に関する要件も検討した。今年度は、倫理審査委員会の認定要件と認定を行う機関の要件について、最終的な決定には至らず、次年度において引き続き検討することとなった。

研究協力者

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A．研究目的

平成 24 年３月 30 日に厚生労働省・文部科学省より発出された「臨床研究・治験活性化５か年計画 2012」は、今後の我が国の臨床研究・治験の目指すべき方向性を、過去９カ年間の活性化施策に基づいて策定されたものであり、平成 25 年６月 14 日に閣議決定された「日本再興戦略－JAPAN is BACK」、平成 25 年６月 14 日に関係大臣による申し合わせにより決定された「健康・医療戦略」においても、その根幹とされている。この「健康・医療戦略」では、「倫理審査委員会の認定制度を導入すること等により、倫理審査委員会の質の向上を図る。」とされている。

また、「臨床研究・治験活性化５か年

計画 2012」では、「臨床研究等における倫理性及び質の向上」のためには「質の高い臨床研究の実施促進と被験者保護の在り方」の検討が必要であり、＜中・長期的に目指すこと＞として、「倫理審査委員会の認定制度」の導入が上げられている。すなわち、国等による倫理審査委員会の認定制度（倫理審査委員会の質を保証するシステム）を導入することにより、「国等が一定の基準を満たしているものを適切な倫理審査を行える委員会と認め、審査の質を保証するとともに継続的な質の向上を図る」ことをめざし、それにより「医療機関等が認定を受けた倫理審査委員会を積極的に利用するように努める」ことにより研究の質の向上を図ろうとするものである。

さらに、平成 24 年 10 月に策定されたアクションプランにおいても、「国は、海外での倫理審査委員会の認定制度について、広く情報収集・調査を行い、日本での認定制度の在り方について検討を進める。」としている。

本研究は、この倫理審査委員会の認定制度の導入のために必要な制度設計と認定要件に関して検討し、具体的な認定要件を策定することを目的としたものである。

B．研究方法

10 名の研究協力者により研究班を構成し、倫理審査委員会の認定に関する制度設計、認定要件についての検討を行った。研究協力者は、法律の専門家、研究倫理の専門家、生物統計学者、臨床研究に豊富な経験のある臨床医、医薬開発学の専門家、臨床研究コーディネーター、患者・被験者の対場を代表する者などである。本研究の初年度である今年度においては、２回の班会議を開催した。

C．研究結果

１．倫理審査委員会の認定要件

認定は、特に際立った研究や特殊な研究の審査を行う倫理審査委員会の認定ではなく、持続的に活動を行っている一般的な倫理審査委員会を対象とすることが確認された。

その上で、認定の要件として、審査の効率性、倫理審査委員会に関わる人材や資源の状況、教育研修等の視点から、以下の項目を考慮すべきとした。

①基本要件

- 「臨床研究に関する倫理指針」、現在検討中の「疫学研究に関する倫理指針」・「臨床研究に関する倫理指針」の統合指針に定める要件
- 委員名簿や議事録の公開など

②追加すべき要件

- 開催回数、間隔：最低、月に１回の開催
- 取扱件数：年間の新規案件数－活動性の指標、国際共同治験／First in Human試験（医療機器を除く）／多施設共同試験等の審査実績
- 倫理審査委員会の設置者に関する要件
- 共同ＩＲＢへの対応
- 委員の利益相反管理の手順策定
- 教育・研修

③審査時の提出物

- 構成員（資格・専門性、外部委員の割合及び参加状況、経験年数等）、任期等の一覧
- 標準手順書
- 事務局の体制を表すもの

④認定後の義務
・報告：年１回の定期報告、その他
・査察の受け入れ

⑤認定の更新

⑥その他
・審査対象の違い（医薬品／医療機器／その他医療技術等）、分野（がん領域、小児その他）により配慮すべき事項

各項目の詳細については次年度において検討することとした。

２．認定を行う機関に関する要件

倫理審査委員会の認定を行う機関については、その設立母体、設置者の要件等についての検討を行ったが、具体的な結論には至らなかった。ただし、組織内に臨床研究に関する倫理審査委員会を持つ機関は、利益相反等から考えて、妥当ではないとする点ではほぼ一致を見た。

D．考察

海外における倫理審査委員会の認定制度として、アメリカの民間団体である The Association for the Accreditation of Human Research Protection Programs（AAHRPP）による認定、U.S. Department of Health and Human Services（HHS、米国保健福祉省）の Office for Human Research Protections（OHRP、被験者保護局）への登録制度、アジア・西太平洋地域における Forum for Ethical Review Committees in Asia and the Western Pacific Region（FERCAP）による認証等を検討した。この中で、AAHRPP による認定は倫理審査委員会のみを対象としたものではなく、研究組織としての被験者保護プログラム全体の評価・認証であるので、今回の検討の対象とはなりにくいことが明らかとなった。（AAHRPP の Accreditation Procedures を別添資料として掲載。）また、OHRP は登録のみで認証とは言いがたいことも明らかとなった。

倫理審査委員会の認定の具体的要件として、WHO の出しているガイドライン Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants を参考とすることの妥当性について、今後、検討を加えることとなった。

E．結論

今年度は、倫理審査委員会の認定要件と認定を行う機関の要件について検討した。最終的な要件決定には至らず、次年度において引き続き検討することとなった。

F．健康危険情報

なし

G．研究発表

１．論文発表

なし

２．学会発表

なし

H．知的財産権の出願・登録状況

なし

資料

AAHRPP Accreditation Procedures

Approved September 12, 2012

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The AAHRPP Accreditation Program

The AAHRPP Accreditation Program is a voluntary, peer driven, educationally based model of accreditation. It seeks to recognize high-quality Human Research Protection Programs of research organizations. Standards meet or exceed U.S. federal regulatory requirements for protection, and are reasonable, attainable, and representative of current best practices.

Any public or private (non-profit or for-profit) organization that is located in or outside the United States and engaged in human research may be accredited. The organization seeking accreditation, referred to as the "Organization," must have a "Human Research Protection Program", as defined by the Accreditation Standards.

The initial step in the accreditation process is for an Organization to engage in a thorough self-assessment. This enables the Organization to identify and remedy program weaknesses. Prior to seeking accreditation, the Organization should develop a clear concept of the programmatic unit that will seek accreditation. The results of the internal review are submitted to AAHRPP in the form of a Step 1 application. Next, AAHRPP staff review the application and determine whether the written documents meet the Accreditation Standards. Staff will communicate required changes to the Organization. The Step 1 application process, i.e. the Organization's satisfactory response to the Step 1 Review of Materials, must be completed within one year of the date that the Step 1 Review is sent to the Organization. Once the staff determine that the written documents are satisfactory, the Organization submits a Step 2 application and a site visit is scheduled. AAHRPP site visitors review the Step 2 application and conduct an on-site evaluation. AAHRPP must have sufficient information to evaluate adequately an Organization's program. In general, this requires that site visitors be permitted to enter all facilities and have access to all relevant records, policies, procedures, minutes, audits, protocols, consent documents, and other materials. To perform these tasks, the site visitors must sign confidentiality agreements with AAHRPP prior to the visit. AAHRPP will not accredit an Organization that cannot be thoroughly evaluated.

The Organization's application and results of the on-site evaluation form the basis of a site visit report. AAHRPP provides a draft report (known as the "Draft Site Visit Report") to the Organization shortly after the site visit and no later than 30 days after the completion of the site visit. Within 30 days of the date of the Draft Site Visit Report, an Organization has the opportunity to respond in writing to AAHRPP to identify any errors of fact, to describe any corrective actions it has taken in response to areas of concerns identified by the site visitors, and to report any other changes it has made to its Human Research Protection Program since the site visit. The site visit team leader then reviews the Organization's response and writes an evaluation of the response. The Council on Accreditation reviews the Draft Site Visit Report, the Organization's response, and the evaluation of the response. The Council then makes a determination regarding accreditation. The decision of the Council is communicated to the Organization in writing.

Reaccreditation Procedures

The initial accreditation period is three years. Thereafter, the accreditation period is five years.

An Organization that is renewing its accreditation conducts a self-assessment. The results of the internal review are submitted to AAHRPP in the form of a Step 1 application. Next, AAHRPP

staff review the application and determine whether the written documents meet the Accreditation Standards. Staff will communicate required changes to the Organization. The Step 1 application process, i.e. the Organization's satisfactory response to the Step 1 Review of Materials, must be completed within one year of the date that the Step 1 Review is sent to the Organization. Once the staff determine that the written documents are satisfactory, the Organization submits a Step 2 application and a site visit is scheduled. AAHRPP site visitors review the application and conduct an on-site evaluation. AAHRPP must have sufficient information to evaluate adequately an Organization's program. In general, this requires that site visitors be permitted to enter all facilities and have access to all relevant records, policies, procedures, minutes, audits, sample protocols, consent documents, and other materials. To perform these tasks, the site visitors must sign confidentiality agreements with AAHRPP prior to the visit. AAHRPP will not accredit an Organization that cannot be thoroughly evaluated.

The Organization's application and results of the on-site evaluation form the basis of a site visit report. AAHRPP provides a Draft Site Visit Report to the Organization shortly after the site visit and no later than 30 days after the completion of the site visit unless the site visitors make no observations that warrant a response from the Organization. Within 30 days of the Draft Site Visit Report, an Organization has the opportunity to respond in writing to AAHRPP to identify any errors of fact, to describe any corrective actions it has taken in response to areas of concerns identified by the site visitors, and to report any other changes it has made to its Human Research Protection Program since the site visit. The site visit team leader then reviews the Organization's response and writes an evaluation of the response. The Council on Accreditation reviews the Draft Site Visit Report, the Organization's response, and the evaluation of the response. The Council then makes a determination regarding accreditation. The decision of the Council is communicated to the Organization in writing.

When an accredited Organization has a substantive change to its Human Research Protection Program (e.g., a merger of another entity) it must notify the AAHRPP office when the change occurs. AAHRPP will assess along with the Organization whether an individual consultation, submission of materials, or a Limited Site Visit might be needed prior to submitting a renewal application.

Each Organization is assigned to one of the Council on Accreditation quarterly meeting dates. The assignment is based on the Organization's most recent accreditation date. Organizations must submit their applications 12 months in advance of the Council meeting.

Failure to submit renewal applications by the deadline could result in a loss of accreditation status. An Organization that cannot submit by the deadline must notify the AAHRPP office at least 30 days in advance. Extensions will be granted only under unusual or exceptional circumstances.

Organizations that submit renewal applications after the deadline date or fail to complete the Step 1 application in time to complete the accreditation process before the Council meeting at which it is to be review will be placed in Reaccreditation-Pending, on Probation, or lose accreditation status. Organizations must provide justification to the Council on Accreditation to avoid being placed on Probation or losing accreditation status. For Organizations that are placed in Reaccreditation-Pending or on Probation and eventually earn reaccreditation will have a reaccreditation period equal to five-years minus the time spent in Reaccreditation-Pending or on Probation.

Accreditable Organizations

AAHRPP intends to accredit any eligible Organization that seeks accreditation. Most organizations that conduct human research are also involved in other activities that are not directly related to their research activities: universities are involved in teaching and service, hospitals are involved in patient care and community outreach, and companies are involved in marketing and distribution activities. AAHRPP accredits only an Organization's Human Research Protection Program.

The Organization seeking accreditation must be functionally separate and have a single director. Its Human Research Protection Program may be comprised of either units within the Organization, external arrangements that make up the program, or both. For example, some Organizations arrange for functionally separate units to fulfill critical roles in their research protection programs, such as a contractual arrangement for ethics review (IRB review) by another independent organization. Organizations may also share resources to form a single comprehensive Human Research Protection Program. AAHRPP's policy is to accredit whole programs and not individual components of Human Research Protection Programs (e.g., IRBs or investigators). AAHRPP's policy is not to accredit subunits within a functionally separate unit.

As examples, this definition of an accreditable Organization is interpreted as follows:

a. Academic institutions: A single, free-standing university, college, medical school, or other professional school under a single chief executive officer and typically in a single geographical location is an accreditable Organization. The academic institution applies for accreditation as a whole unit regardless of the number of IRBs or separate schools within the university. In rare exceptions, smaller units within a university may be accepted as an accreditable Organization if the university can demonstrate that each smaller unit has its own organizationally separate Human Research Protection Program, e.g., a separate federalwide assurance. However, AAHRPP's policy is to accredit academic institutions at the "campus" level. AAHRPP's policy is not to accredit individual institutional review boards (IRBs) of the academic institution.

   In large university systems, individual universities that are functionally separate with a chief executive officer (e.g., Chancellor) may apply for accreditation as individual universities. Each university applies for accreditation as a whole unit regardless of the number of IRBs or separate schools within the university. In rare exceptions, smaller units within a university may be accepted as an accreditable Organization if the university can demonstrate that each smaller unit has its own organizationally separate Human Research Protection Program. On the other hand, if the university system as a whole wishes to apply for accreditation, AAHRPP considers such requests on a case-by-case basis.

b. Clinical research organizations: A clinical research organization under a single chief executive officer is an accreditable Organization. The clinical research organization applies for accreditation as a whole unit regardless of the number of separate departments within the company. In large clinical research organizations, individual units that are functionally separate and have an executive officer may apply individually. Clinical research organizations that apply for accreditation must be able to meet the Standards in all three domains, as applicable.

c. Contract research organizations: A contract research organization under a single chief executive officer is an accreditable Organization. The contract research organization applies for accreditation as a whole unit regardless of the number of IRBs or separate departments within the company. In large contract research organizations, individual units that are functionally separate and have an executive officer may apply individually.

d. Government agencies: An agency within a department under a director, commissioner, or administrator is an accreditable Organization. The agency applies for accreditation as a whole unit regardless of the number of IRBs or separate units within the agency. In rare exceptions, smaller units within an agency may be accepted as an accreditable Organization if the agency can demonstrate that each smaller unit has its own organizationally separate Human Research Protection Program.

e. Hospitals: A hospital under a single chief executive officer or director is an accreditable Organization. The hospital applies for accreditation as a whole unit regardless of the number of IRBs or separate departments or centers within the hospital. In large hospital systems, individual hospitals that are functionally separate and have chief executive officers or directors may apply individually.

f. Independent Review Boards or independent IRBs: An independent review board under a single chief executive officer is an accreditable Organization. The independent review board applies for accreditation as a whole unit. Independent review boards that apply for accreditation must be able to meet the Standards in all three domains, as applicable.

g. Private corporations: A corporation, either non-profit or for-profit, under a single chief executive officer is an accreditable Organization. The company applies for accreditation as a whole unit regardless of the number of IRBs or separate departments within the company. In large corporations, individual companies, plants, or facilities that are functionally separate and have an executive officer may apply individually.

h. Research sites: A research site under a single chief executive officer is an accreditable Organization. The research site applies for accreditation as a whole unit regardless of the number of the facilities that it has engaged to conduct research. Research sites that apply for accreditation must be able to meet the Standards in all three domains, as applicable.

Other types of Organizations that have a Human Research Protection Program may apply for accreditation. Such Organizations should contact the AAHRPP office to discuss eligibility.

Site Visitors

After submission of the Step 2 application to the AAHRPP office, peer site visitors conduct an on-site evaluation. Site visitors evaluate the Human Research Protection Program's performance with respect to each Accreditation Standard and Element. The Elements for each Accreditation Standard identify the more concrete practices that are evidence of the Standard in the Human Research Protection Program's daily operation. A team of one or more site visitors chosen by AAHRPP evaluates each Organization. Site team leaders are members of AAHRPP's Council on Accreditation or experienced site visitors. At its option, AAHRPP may use one or more site visitors for periodic or special site visits after the initial site visit has been concluded. AAHRPP will not accredit an Organization without a site visit. Subsequent to the initial accreditation

period of three years, an accredited Organization is routinely revisited at five-year intervals. A Limited Site Visit might be required to confirm correction of deficiencies or major changes in the Human Research Protection Program. AAHRPP covers the cost of additional Limited Site Visits.

Site visitors are selected based on their experience and generally represent four perspectives: public or participant, human research protection, research, and organizational. In some cases, individual site visitors might represent more than one perspective. Efforts are undertaken to tailor the site visit team to the needs of the Organization. For example, for each site visit, site visitors should have the appropriate expertise in the type of research conducted (e.g., clinical or social science) and knowledge about the research setting (e.g., community hospital, research site, or university). The number of site visitors assigned to a team depends upon the size and complexity of the Organization's Human Research Protection Program.

An AAHRPP Representative will not participate in the review of an applicant, including, but not limited to, review of an application, site visit, and other matters related to an Organizations accreditation status, in discussions during AAHRPP meetings, or in a vote regarding any of the following Organizations:

a. An Organization with which the AAHRPP Representative or an Immediate Family Member is, or within the last two years, has been connected as a student, employee, staff member, or agent.

b. An Organization which has or within the past two years has had cooperative or contractual arrangements with the organization of the AAHRPP Representative or an Immediate Family Member.

c. An Organization which has engaged the AAHRPP Representative or an Immediate Family Member to act as a consultant on behalf of the Organization within the past two years.

d. An Organization in which the AAHRPP Representative or an Immediate Family Member has any financial, political, professional or other interest that may conflict with the interests of the AAHRPP.

An Immediate Family Member is a spouse or life partner of an AAHRPP Representative or a child, parent, or sibling of an AAHRPP Representative when the AAHRPP Representative has information about the family member's interest.

An AAHRPP Representative shall not act as an external consultant on human research protection or accreditation matters to an Organization for two years following the involvement of the AAHRPP Representative as a site visitor, as a Council member, or as a participant in discussions during AAHRPP meetings or votes regarding the Organization. A consultation is the provision of advice in any form related to human research protection accreditation of Human Research Protection Programs or AAHRPP. Consultative activities include but are not limited to, lectures and training, program evaluations, and federal inspections.

When an AAHRPP Representative is uncertain whether an activity might constitute a consultation, the Representative should disclose the activity to the President and CEO. The President and CEO shall determine whether the AAHRPP Representative has a conflict of

interest. If a conflict of interest exists, the AAHRPP representative shall not participate in the review of an organization unless the President and CEO waives the prohibition to participate. The President and CEO shall consult with the AAHRPP Executive Committee, when needed.

Council on Accreditation

The Council on Accreditation is comprised of individuals elected by the Board of Directors. Council members are experienced site visitors of AAHRPP. In selecting Council members, AAHRPP's goal is to seek representation from the human research protection, research, and organizational perspectives. The Council may conduct business and make decisions using panels or subcommittees. The Council may draw upon former Council members to serve on panels or subcommittees.

Members representing the human research protection perspective are individuals who are or have been responsible for an Organization's Human Research Protection Program. They are likely to be program managers (IRB administrators) or IRB chairs.

Members representing the research perspective are individuals who have recognized experience in conducting human research. They hold terminal degrees in their scientific or scholarly disciplines. An effort is made to identify researchers from a diversity of disciplines (e.g., social science, history, public health, medicine, and the biological sciences). They are also familiar with federal regulations pertaining to human research protection.

Organizational officials are individuals with experience in the administration of their Organizations, such as Vice Presidents for Research, Provosts, Deans, or Directors of Science. They are also familiar with federal regulations pertaining to human research protection.

Granting or Denying Accreditation

The AAHRPP Board of Directors has the ultimate authority to review all Step 1 and 2 applications, Draft Site Visit Reports, responses to Draft Site Visit Reports, and evaluations and determine the accreditation status of an Organization, subject to the right to appeal otherwise provided for in these Procedures.

The Board of Directors delegates to the Council on Accreditation the role, responsibilities, and authorities to facilitate the efficient operation of the accreditation program. The Council on Accreditation, comprised of experienced site visitors, reviews all application materials (all applications, Draft Site Visit Reports, responses to Draft Site Visit Reports, and evaluations) and makes a determination regarding accreditation status. The Council on Accreditation meets no fewer than two times annually.

Categories of Accreditation for New Applicants

Following the site visit, the Council on Accreditation makes a decision about accreditation based on the Step 2 application, Draft Site Visit Report, the Organization's response, and the evaluation of the response. The Council on Accreditation may place the Organization in one of four categories.

For new applicants, the categories of accreditation status are Full Accreditation and Qualified Accreditation.

Full Accreditation: An Organization placed in this category meets all the Accreditation Standards. AAHRPP awards Full Accreditation for three years, which commences on the date AAHRPP makes the award.

Qualified Accreditation: An Organization placed in this category meets almost all the Accreditation Standards. Issues requiring corrective action are minor and administrative in nature. AAHRPP awards Qualified Accreditation for three years, which commences on the date AAHRPP makes the award. However, if the issues requiring corrective action are resolved before the next triennial site visit, the Council on Accreditation, upon acceptance of the corrective actions, may award Full Accreditation for the remainder of the period of accreditation.

Accreditation Withheld: An Organization placed in this category does not meet a substantial number of Accreditation Standards and the Council on Accreditation believes that the Organization will not commit to undertake corrective action or otherwise be unable to meet the criteria for Qualified or Full Accreditation in a reasonable time. When accreditation is withheld, an Organization may reapply at its own discretion; the application will be accepted only if the Organization has made corrective actions and appears to be accreditable.

Accreditation-Pending: The Council on Accreditation places an Organization in the Accreditation-Pending category until it decides to award Full or Qualified Accreditation or to Withhold Accreditation. The Council on Accreditation may place an Organization in the Accreditation-Pending category when the Organization does not meet the criteria for Full or Qualified Accreditation, and the Council believes the Organization is able and willing to commit to take corrective actions to meet the criteria for accreditation within a reasonable time period. An Organization that the Council places in the Accreditation-Pending category must submit an Improvement Plan within the time specified by the Council. Based on the Improvement Plan, the Council may extend the length of time until the accreditation determination will be made, usually seven months (two Council meeting cycles). Based on progress reports and the continued commitment of the Organization, the Council may further postpone a final accreditation determination. At its option, the Council decides whether a Limited Site Visit or other actions are required before making a final accreditation determination.

Categories of Accreditation for Renewing Applicants

Before the end of the accreditation period, an Organization must reapply and be revisited. Following the site visit, the Council on Accreditation makes a decision about the renewing applicant based on the Step 2 application, Draft Site Visit Report, the Organization's response, and the evaluation of the response. The Council on Accreditation may place the applicant in one of five categories.

For renewing applicants, the category of accreditation status is Full Accreditation.

Full Accreditation: An Organization placed in this category continues to meet all the Accreditation Standards. AAHRPP awards Full Accreditation for five years, which commences on the date AAHRPP makes the award.

Probation: The Council on Accreditation places an Organization on probation when the Organization does not meet the criteria for Full Accreditation and can not make changes within a reasonable time period, usually three months; or does not satisfy the Council that the Organization is taking corrective actions as proposed in the Improvement Plan or Status Report. An Organization placed in the Probation category must submit an Improvement Plan within three months. Based on the Improvement Plan, the Council determines the length of time until another accreditation determination will be made, usually seven months (two Council meeting cycles). Based on progress reports and the continued commitment of the Organization, the Council may award Full Accreditation, keep an Organization on Probation, or Revoke Accreditation. At its option, the Council decides whether a Limited Site Visit or other actions are required before making a final accreditation determination.

Accreditation Revoked: The Council on Accreditation revokes accreditation when the Organization does not meet the criteria for Full Accreditation, and the Council believes the Organization has demonstrated an inability or unwillingness to take effective corrective action. It may revoke accreditation at any time, without a revisit. In general, an Organization in this category was placed initially on Probation and did not take the actions to meet the timeline described in its Improvement Plan. Accreditation may also be revoked by AAHRPP when an Organization does not pay its fees within six months of date of invoice.

Reaccreditation-Pending: The Council on Accreditation places an Organization in the Reaccreditation-Pending category until it decides to award Full Accreditation, place the Organization on Probation, or to Revoke Accreditation. The Council on Accreditation may place an Organization in the Reaccreditation-Pending category when the Organization does not meet the criteria for Full Accreditation, and the Council believes the Organization is able and willing to commit to take corrective actions to meet the criteria for accreditation within a reasonable time period. Based on the corrective actions, the Council decides whether to grant Full Accreditation, or place the Organization on Probation.

Limited Site Visits

For an Organization that is in the Accreditation-Pending or Reaccreditation-Pending categories or on Probation, the Council on Accreditation attempts to resolve corrective actions through written communication. However, if the corrective actions are of such a magnitude that an on-site visit is required to complete the evaluation then AAHRPP schedules a Limited Site Visit. Limited site visits are also conducted when the Council on Accreditation deems it necessary to verify compliance with the standards or resolution of areas in transition. Generally, AAHRPP notifies the Organization of the need for a Limited Site Visit at the time it is placed in the Accreditation-Pending or Reaccreditation-Pending categories or placed on Probation; however, AAHRPP may notify the Organization that a Limited Site Visit is required following the Council's review of a Status Report. The costs of the limited site visit are the responsibility of AAHRPP.

Status Reports

The Council on Accreditation may request that the Organization provide a Status Report. Failure to submit an Annual Report within 30 days of the deadline may result in revocation of accreditation.

The purpose of the Status Report is to document for the Council on Accreditation activities performed to achieve compliance with a standard in which the Council has a specific concern or to report on progress of any areas or activities in transition. Examples include activities such as implementation of policies or forms or completion of an education or training program. The Council may request a Status Report from an Organization when awarding Full or Qualified Accreditation, Accreditation-Pending or Reaccreditation-Pending, or Probation. When the actions described in the Status Report do not satisfy the Council, the Council may place the Organization in Accreditation-Pending or on Probation.

Fees

Organizations pay a one-time application fee and annual fees thereafter. Annual fees cover the reaccreditation costs. An Organization that submits an application pays the application fee when it submits the application and begins paying annual fees one year after the submission of the application.

Fees are on a sliding scale and are based on the size of the Human Research Protection Program. They are published on the AAHRPP website.

Publication of Accreditation Status

AAHRPP publishes the name of the Organization, the components, if any, of the Human Research Protection Program, the type of organization, the name and email address of a designated contact person, its category of accreditation, and the date it was initially accredited. In addition, AAHRPP encourages the accredited Organization to publicize its accreditation status with AAHRPP. When an Organization publicizes its accreditation status, it must specify its accreditation category.

AAHRPP does not release information about an Organization that is in the process of seeking accreditation or that has been placed in the Accreditation-Pending or Accreditation Withheld categories.

AAHRPP does not release information about an Organization that is in the process of renewing its accreditation or that has been placed in the Reaccreditation-Pending category. An Organization that is placed in the Reaccreditation-Pending category remains on the published list of accredited Organizations. Once the Council makes a final accreditation determination, the Organization remains on the published list if re-accredited or is removed if the Organization is placed on Probation or has Accreditation Revoked.

From the published list of accredited organizations, AAHRPP removes the name of an Organization placed on Probation or that has Accreditation Revoked. AAHRPP only releases information that the Organization is not in one of the two categories that hold accreditation status and refers inquirers to the Organization in question.

Annual and Other Notification Reporting

During the intervening years between site visits, AAHRPP requires an accredited Organization to submit Annual Reports. Failure to submit an Annual Report within 30 days of the deadline may result in revocation of accreditation.

The purpose of the Annual Report is to notify AAHRPP of changes related to the Organization's Human Research Protection Program. An Organization must submit a standard form found on the website that includes the following information:

- Organizational Changes:
  - Change in name of the Organization.
  - Change in ownership of the Organization.
  - Change in governance of the Organization (e.g., President or Chief Executive Officer).
  - Change in the organizational official.
  - Change in the leadership of the Human Research Protection Program (i.e. the individual responsible for the day-to-day operation).
  - Change in the application contact.
- Changes in Resources:
  - Significant change (10% or more) in the balance of resources and active research protocols.
  - Significant reduction (10% or more) in resources in the past 12 months and the consequences on the HRPP, such as reduction in FTE and dissolution of an IRB, committee or other function.
- Changes in Program Scope:
  - Any mergers or acquisitions.
  - Addition of new research program (i.e. research not previously conducted or reviewed by the Organization such as planned emergency research. Research involving children or gene transfer research).
  - Addition of functions, committees or IRBs.
- Changes in method of providing services, such as use of external IRBs or use of contracting services of another organization.
- Catastrophic event that results in an interruption or discontinuance in a component of or the entire Human Research Protection Program.

An Organization must report to AAHRPP within 24 hours that the Organization or Investigator (if the Investigator is notified rather than the Organization) becomes aware of the event:

- Any sanctions taken by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, and FDA Restrictions Placed on IRBs or Investigators.
- Any lawsuits related to human research protection.

If an Organization is in doubt about whether to report a particular item to AAHRPP, it should contact the AAHRPP office for further advice.
The Council on Accreditation will review major changes to the Human Research Protection Program and determine whether any action is indicated, such as a request for additional written information or a Limited Site Visit.

Mandatory Revisits

A mandatory revisit can be used as part of AAHRPP's response to an Organization that reports certain types of governmental regulatory sanctions or as part of AAHRPP's response when an Organization deliberately deceives AAHRPP. The need for a revisit is made on a case-by-case basis and occurs only when absolutely necessary. In these cases, the Organization must reimburse AAHRPP for the costs associated with the mandatory revisit.

Appeals and Hearings

When the Council on Accreditation makes a decision to Withhold or Revoke Accreditation, AAHRPP notifies the Organization in writing of the decision and the factual findings and reasons supporting the proposed decision. Such notice is sent to the Organization using a return receipt mechanism that confirms delivery and indicates the date of delivery (e.g., registered mail or certified mail). Within 30 days after receipt of such notice, the Organization may offer written evidence or argument tending to refute or overcome the factual findings and decision of AAHRPP or appeal the proposed decision by submitting a written request for an oral hearing before the Council on Accreditation.

If the Organization requests a hearing within the 30-day period, the Council on Accreditation holds a hearing at its next scheduled meeting after receipt of such request, and the Organization is given an opportunity at the hearing to present evidence or argument tending to refute or overcome the factual findings and decision of the Council. Counsel may represent the Organization at the hearing. Within 30 days after its meeting, AAHRPP renders its decision after considering the information before it, and sends written notification of its decision to the Organization using a return receipt mechanism that confirms delivery and indicates the date of delivery.

If, following the hearing, the decision of the Council on Accreditation is to Withhold or Revoke Accreditation, the Organization may appeal the decision within 30 days after receipt of notice of the decision by submitting a written request for an oral hearing before the Board of Directors. If the Organization does not request a hearing within the 30-day period, the Council forwards its decision to the Board for approval, and the Board's decision is final.

If the Organization requests a hearing before the Board within the 30-day period, the hearing, decision and notice provisions are the same as noted above for an appeal to the Council on Accreditation. On appeal to the Board of Directors, the records are the materials the Council had at the time it made its decision, the Council's decision, the request of the Organization for an appeal, and the Council's response (if any). New information, not available to the Council when it made its decision, is ordinarily not considered by the Board, unless there is strong reason to do so and two-thirds of the Board of Directors vote to accept such new information.

The Board overturns the decision of the Council on Accreditation only if the Organization demonstrates that the findings of the Council were clearly unreasonable in a significant way, that the Council incorrectly applied the Accreditation Standards or Procedures to the material disadvantage of the Organization, or that the additional information referenced in the preceding paragraph is compelling. If the Board overturns the Council's decision, the matter is ordinarily returned to the Council, unless there are compelling reasons for the Board of Directors to take other action.

Certificates of Accreditation

AAHRPP issues a Certificate of Accreditation to each Organization that receives Full Accreditation or Qualified Accreditation. If an Organization has its accreditation revoked, the Certificate of Accreditation must be returned to AAHRPP. Organizations that are placed in Accreditation-Pending are not entitled to receive Certificates of Accreditation.

Display or use of any outdated, revoked, defaced or fraudulent AAHRPP certificate or of facsimiles that might deceive or mislead prospective participants, sponsors, or other persons, is considered a serious offense with the potential for harming the public confidence in research and the research protection system. Appropriate legal action may be taken by AAHRPP based on the facts of any such deception.

Confidentiality

Information about specific AAHRPP clients (and the third parties with whom they do business or from whom they receive information) is confidential ("AAHRPP Client Confidential Information"). This applies to an Organization that participates at any level, including potential clients that have only indicated their intent to apply for accreditation. The only information that may be released by an AAHRPP Representative about the accreditation status of a participating Organization is that the Organization is or is not accredited. AAHRPP Client Confidential Information includes (but is not limited to) all information regarding the client's business, personnel, facilities, management, technical and scientific information, and deliberations or comments originating from the accreditation process, as well as all information regarding third parties with whom the Organization does business or from whom the Organization receives information.

All AAHRPP Client Confidential Information made available by an Organization to AAHRPP or its Representatives is kept confidential to the extent required by law. No Representative may remove or retain copies of any Organization's confidential documents without the permission of the Organization. No Representative may disclose any of his or her findings to any person or agency except AAHRPP, except to the extent required by applicable law. AAHRPP Representatives who fail to adhere to this policy may be discharged. In addition, AAHRPP may pursue legal action against them.

Organizations must comply with all legal and ethical requirements for disclosing any research records with participants' personally identifiable information. The Organization and AAHRPP Representatives must follow appropriate procedures to protect the confidentiality of records. Without limiting the foregoing, an Organization should "de-identify" records provided to or made available to AAHRPP. AAHRPP will not hold, maintain, or disclose records with research participants' personally identifiable information.

AAHRPP and its Representatives will hold all files and records in confidence, and no confidential data will be released by AAHRPP except pursuant to direction by the Board of Directors, under the order of a court of law, pursuant to the execution of a valid search warrant, or as otherwise required by applicable law.

In some states, statutes pertaining to the "peer review" privilege may be applied and protect institutional peer review materials from subpoena. An Organization should determine whether the AAHRPP accreditation process is considered to be a "peer review" process and AAHRPP

and its site visitors part of the institution's "peer review committee." AAHRPP recommends that the governing bodies of an Organization appoint AAHRPP and its site visitors as part of the Organization's peer review committee prior to the submission date of the application in order to maximize the likelihood that the accreditation process will be considered "peer review."

Protected Health Information

An Organization is not asked to submit protected health information as part of its application or other correspondence to AAHRPP. If, however, outside of a site visit protected health information is disclosed to AAHRPP or its Representatives, AAHRPP will abide by its confidentiality policy. AAHRPP, however, cannot commit to comply with HIPAA regulations or an Organization's "Notice of Privacy Practices" for protected health information disclosed to it, or its Representatives, outside of a site visit.

During a site visit, an Organization should de-identify protected health information from records provided to site visitors whenever practical. AAHRPP understands that at times such de-identification may be impractical, and protected health information may be disclosed to AAHRPP Representatives during the conduct of a site visit. In such circumstances AAHRPP Representatives will not record or disclose protected health information.

Because of the potential for disclosure of protected health information to AAHRPP Representatives, AAHRPP may be considered a "business associate" of an Organization who is a "covered entity," as defined in the privacy rules adopted pursuant to the Health Insurance Portability and Accountability Act of 1996. For the Organization's convenience, AAHRPP has developed a "business associate agreement" that is available upon request. Should an Organization wish to enter into a business associate agreement with AAHRPP, the Organization should include a signed copy of a business associate agreement with its application for accreditation. AAHRPP will sign and return the business associate agreement as of, or prior to, its site visit.

Release and Indemnification

By submitting an application, an Organization certifies that the information contained in the application is accurate. The Organization agrees to release AAHRPP, its members, directors, officers, employees and agents (the "AAHRPP Representative") from any and all claims, and to indemnify and hold harmless the AAHRPP Representatives from and against any and all liability and costs incurred by them, including attorneys' fees, resulting from the application or site visit of its Human Research Protection Program.

Records Retention

Applications, reports, and other documents from site visits resulting in accreditation and all documents following and relating to that accreditation are kept for 10 years from the date of that accreditation. Applications, reports, and other documents from site visits not resulting in accreditation are kept for three years from the date of the decision to Withhold Accreditation unless the Organization has within the three-year period, reapplied for accreditation and the application results in Accreditation, in which case the records are kept for 10 years from the date of accreditation.