

**Association for the Accreditation of
Human Research Protection Programs, Inc.SM (AAHRPP)SM**

Accreditation Procedures

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 Organizations that use humans in research. Standards exceed federal regulatory requirements for protection and are reasonable, attainable, and representative of current best practices.

The initial step in the accreditation process is for an Organization to engage in a thorough self-assessment. This will enable the Organization to identify and remedy program weaknesses. Prior to seeking accreditation, the Organization should develop a clear concept of the programmatic entity that will be seeking accreditation.

The results of the internal review are submitted to AAHRPP in the form of an application and program description. Next, AAHRPP site visitors review the application and conduct their own comprehensive assessment, which includes an on-site evaluation. AAHRPP must have sufficient information to evaluate adequately an applicant's program. In general, this will require that site visitors be permitted to enter any and all facilities in which participants are observed, treated or interviewed, as well as administrative work areas. Further, the site visitors must have access to all relevant records, policies, procedures, minutes, budgets, sample protocols, consent forms and other materials. To perform these tasks, the site visitors must sign confidentiality agreements with AAHRPP prior to the visit and may also sign confidentiality agreements with the applicant organization. AAHRPP will not accredit Organizations that cannot be thoroughly evaluated.

The applicant's program description and results of the on-site evaluation form the basis of a program evaluation and report, which are submitted to AAHRPP's Council on Accreditation. The site visit team leader presents the program evaluation and report to the Council. The Council reviews the report and makes a determination regarding accreditation. The decision of the Council is approved by the Board of Directors and communicated to the applicant organization.

Accreditable Entity

It is AAHRPP's intention to accredit any entity that seeks and is eligible for accreditation. Any public or private (non-profit or for-profit) entity engaged in human research may be accredited. The entity seeking accreditation, referred to as the Organization, must have a Human Research Protection Program. Most entities 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, companies are involved in marketing and distribution activities. AAHRPP will accredit only an Organization's Human Research Protection Program.

The Organization seeking accreditation must be a functionally separate entity, which has a single chief executive officer or 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 entities to fulfill critical roles in their research protection programs such as a contractual arrangement for ethics review (IRB review) by another independent organization. It is AAHRPP policy to accredit whole programs and not individual components of Human Research Protection Programs (e.g., IRBs or Investigators). It is also AAHRPP policy not to accredit subunits within a functionally separate entity.

This definition of an accreditable entity is interpreted as follows:

- (1) 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 entity. 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 entity if the university can demonstrate that each smaller unit has its own organizationally separate Human Research Protection Program, e.g., a separate Federal-Wide Assurance. However, AAHRPP policy is to accredit academic institutions at the "campus" level. It is AAHRPP policy 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 entity 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 will consider such requests on a case-by-case basis.

- (2) Hospitals: A hospital under a single chief executive officer or director is an accreditable entity. 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 as individual hospitals.
- (3) Government agencies: An agency within a Department under a director, commissioner, or administrator is an accreditable entity. 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 unit if the agency can demonstrate that each smaller unit has its own organizationally separate Human Research Protection Program.
- (4) Private corporations: A corporation, either non-profit or for-profit, under a single chief executive officer is an accreditable entity. 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 as individual entities.
- (5) Independent Review Boards: An independent review board under a single chief executive officer is an accreditable entity. 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 five domains, when applicable.
- (6) Other entities: Other entities that have Human Research Protection Programs may apply for accreditation. Such entities should contact the AAHRPP office to discuss eligibility.
- (7) International entities: Entities that fall into one of the categories described above and are located outside of the United States are accreditable entities. Such entities should contact the AAHRPP office to discuss eligibility.

Site Visitors

Following the submission of an application and program description to the AAHRPP office, an on-site evaluation conducted by peer site visitors will be conducted. Site visitors will evaluate the program's performance with respect to each Standard. The Elements for each Standard identify the more concrete practices that are evidence of the Standard in the program's daily operation. Each Organization will be evaluated initially by a team of not fewer than two site visitors chosen by AAHRPP. The site team leader will be a member of AAHRPP's Council on Accreditation or an experienced site visitor. At its option, AAHRPP may use one site visitor for periodic or special site visits after the initial site visit has been concluded. No Organization will be accredited by AAHRPP without a site visit. Accredited Organizations will be routinely revisited at 3-year

intervals. Additional interim or follow-up visits may be required to confirm correction of deficiencies or if there are major changes in programs. Costs of mandatory revisits will be the responsibility of the Organization.

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

An AAHRPP site visitor or Representative will not participate in a site visit, 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 recently has been connected as a student, employee, staff member, or agent.
- b. An Organization which has or recently has had substantial 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 AAHRPP Representative will not act as an external consultant on accreditation matters to any Organization subject to AAHRPP accreditation unless such consultation is requested by and conducted on behalf of AAHRPP. When an AAHRPP Representative is uncertain whether an activity might constitute a consultation, the Representative should disclose the activity to the Executive Director.

Council on Accreditation

The Council on Accreditation will be comprised of members elected by the Board of Directors. Council members ordinarily will be experienced site visitors of AAHRPP. In selecting Council members, AAHRPP's goal will be to seek equal representation from the public/participant, human research protection, research, and institutional perspectives. The Council may conduct business and make decisions using panels or subcommittees.

Public members or participants are individuals who can represent a broad range of human research protection issues. In general, these individuals have demonstrated advocacy experience and leadership ability.

Members representing the human research protection perspective are individuals who are or have been responsible for an organization's protection program. They are likely to be program managers (IRB administrators) or institutional review board chairs.

Members representing the research perspective are individuals who have recognized experience in conducting human research. They hold terminal degrees in their scientific disciplines. An effort will be 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.

Institutional officials are individuals who have experience in the administration of their organizations. Such individuals are likely to be 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 will have the ultimate authority to review all applications and site visit reports and determine the accreditation status of individual Organizations, subject to the rights 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 processes. The Council on Accreditation, comprised of experienced site visitors, reviews all site visit reports and makes a determination regarding accreditation status. The Council on Accreditation will meet no less than three times annually. The Board of Directors approves the Council's determinations.

Categories of Accreditation Status

For new applicants, the categories of accreditation are Full Accreditation, Qualified Accreditation, Provisional Status, and Accreditation Withheld. Only Full Accreditation and Qualified Accreditation carry accreditation status.

Full Accreditation: Organizations placed in this category meet all the standards. Organizations are awarded Full Accreditation for 3 years. At the end of 3 years, they must reapply and be revisited.

Qualified Accreditation: Organizations placed in this category meet most of the standards. Deficiencies are minor, few in number, and administrative; they would not cause direct harm to participants.

Organizations are awarded Qualified Accreditation for 3 years. However, if the noted deficiencies are corrected prior to the next triennial site visit the Council may award Full Accreditation upon acceptance of the Organization's corrective actions.

Provisional Status: Organizations placed in this category have met many of the standards but there are deficiencies of such magnitude that failure to address the deficiency could result in direct harm to participants. It is the opinion of AAHRPP that Organizations placed in this category can correct the deficiencies. Organizations that wish to continue in the accreditation program will be required to submit an Improvement Plan for implementing corrective actions within 3 months of receiving the report from AAHRPP. Based on the overall response, the plan itself, and a required timeline presented in the plan, the Council on Accreditation will determine the length of provisional status. The period could be extended, if appropriate, by vote of the Council up to 24 months as long as there are progress reports along the way that indicate evidence of progress. At its option and based upon the circumstances of each case, the Council will decide whether an additional site visit is required before taking action on any Organization that is in the Provisional Status category. The Council, for example, may vote to place the applicant in either the Full Accreditation, Qualified Accreditation, or Accreditation Withheld category without a revisit.

Accreditation Withheld: Organizations placed in this category have a substantial number of major deficiencies and, in the opinion of the Council on Accreditation, can not take sufficient corrective action within 24 months to meet the criteria for Qualified Accreditation or Full Accreditation. When accreditation is withheld, an Organization may reapply at its own discretion; the application will be reviewed by AAHRPP staff and accepted only if it is determined that the Organization has made the corrective actions and the Organization appears to be accreditable.

For renewing applicants, the categories of accreditation are Full Accreditation, Qualified Accreditation, Probation and Revocation of Accreditation. Only Full Accreditation and Qualified Accreditation carry accreditation status.

Full Accreditation: Organizations placed in this category continue to meet all the standards. Organizations are awarded Full Accreditation for 3 years. At the end of 3 years, they must reapply and be revisited.

Qualified Accreditation: Organizations placed in this category meet most of the standards. Deficiencies are minor, few in number, and administrative; they would not cause direct harm to participants.

Renewing applicants could be placed in this category either because deficiencies of the nature described above were identified or they continue from their first accreditation to only qualify at this level. Organizations are awarded Qualified Accreditation for 3 years. However, if noted deficiencies are corrected prior to the next triennial site visit the Council may award Full Accreditation upon acceptance of the Organization's corrective actions.

Probation: Organizations placed in this category meet many of the standards but have developed deficiencies of such magnitude that failure to address the deficiency could result in direct harm to participants. It is the opinion of AAHRPP that Organizations placed in this category can correct the deficiencies. Organizations that wish to continue in the accreditation program will be required to submit an Improvement Plan for implementing corrective actions within 3 months of receiving the report from AAHRPP. Based on the overall response, the plan itself, and a required timeline presented in the plan, the Council on Accreditation will determine the length of Probation. The period could be extended, if appropriate, by vote of the Council up to 12 months as long as there are progress reports along the way that indicate evidence of progress. At its option and based upon the circumstances of each case, the Council will decide whether an additional site visit is needed before taking action on any Organization that is on Probation. The Council, for example, may vote to place the applicant in either the Qualified Accreditation or Full Accreditation category without a revisit.

Revocation of Accreditation: Organizations placed in this category have a substantial number of major deficiencies and, in the opinion of the Council on Accreditation, can or will not take sufficient corrective action to meet the criteria for Qualified Accreditation or Full Accreditation. In general, an Organization placed in this category will have been placed initially on Probation and either did not take the actions and meet the timeline described in its Improvement Plan or showed ongoing non-compliance that could cause direct harm to research participants. Following either no corrective action on behalf of the Organization or corrective action that did not result in remedying the deficiencies, the Council will notify the Organization that it intends to revoke accreditation. If the Organization does not take the necessary corrective actions or request an appeal hearing within 30 days of receipt of the Council's notice of intent to revoke accreditation, the Council will then notify the Organization that its accreditation is revoked.

Accreditation may also be withdrawn by AAHRPP if an Organization does not pay its fees within 6 months of date of invoice.

Standards will be assessed using a qualitative approach (e.g., satisfactory, marginal, unsatisfactory). The Council on Accreditation will use specific criteria for placing Organizations into each accreditation category.

Accredited Organizations will be rescheduled for their triennial visits at the time they are awarded Full or Qualified Accreditation. AAHRPP will notify Organizations of their next scheduled site visit as part of the decision letter.

Publication of Accreditation Status

AAHRPP will publish the name of the Organization, its category of accreditation and the date it was placed in that category for Organizations that receive Full or Qualified Accreditation. In addition, AAHRPP will encourage accredited Organizations to publicize their accreditation with AAHRPP. When an Organization publicizes its accreditation status, it must specify its accreditation category.

AAHRPP will not release information about new applicants that are in the process of seeking accreditation or those that have been placed in the Provisional Status or Accreditation Withheld categories.

For Organizations that have been placed on Probation or have had Accreditation Revoked, AAHRPP will only release information that the Organization is not in one of the two accreditation categories and refer inquirers to the Organization in question.

Annual and Other Reporting

During the intervening years between triennial site visits, AAHRPP will require accredited Organizations to submit annual reports. The purpose of the annual report will be to keep AAHRPP informed regarding any major changes or problems related to the Organization's human research protection program. Organizations will be requested to submit a standard form that will include the following types of information: suspension of approved research protocols, major problems or deficiencies identified by oversight agencies, serious deviations from the requirements of the Organization's human research protection program identified by the Organization, number of protocols reviewed and approved, description of any significant programmatic changes, key personnel changes, description of services received from AAHRPP, and identification of any special concerns or issues for the next site visit.

In addition to the annual report, Organizations must notify AAHRPP as soon as possible, preferably within 72 hours, of any inquiries from a government oversight office such as the Office of Human Research Protections or the Food and Drug Administration when the inquiry could result in a for-cause investigation or when the inquiry involves

non-compliance with federal regulations. In addition, Organizations must notify AAHRPP as soon as possible, preferably within 72 hours, of any decisions by its IRB that are reported to a government oversight office, or any change in the Organization's human research protection program that might affect its ability to continue to meet AAHRPP standards. Organizations must notify AAHRPP within 24 hours of any sanctions taken by a government oversight office. If an Organization is in doubt about whether to make a report to AAHRPP, it should contact the AAHRPP office for further advice.

The purpose of these prompt report requirements is to ensure that AAHRPP is fully informed of compliance-related activities at accredited Organizations between regular triennial site visits. Through the acquisition of such information AAHRPP may be able to work with accredited Organizations in dealing with these situations.

AAHRPP will not comment publicly on ongoing investigations. It is AAHRPP policy to maintain accreditation of the Organization until the ongoing investigation is complete and the results of the investigation have been evaluated. Organizations that fail to report government sanctions or who fail to provide requested information may be placed on Probation.

Mandatory Revisits

Generally, AAHRPP will not conduct mandatory revisits. For Organizations on Provisional Status or on Probation, AAHRPP will attempt 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 will schedule a revisit. The Organization will be aware of the need for the revisit at the time it receives its report and is placed on Provisional Status or Probation. The Organization will reimburse AAHRPP for the costs associated with the revisit.

A mandatory revisit may be part of AAHRPP's response to an Organization that reports certain types of governmental regulatory sanctions or reports certain types of problems with its Human Research Protection Program. The need for a revisit will be determined on a case-by-case basis and occur only when absolutely necessary. In any case where an Organization purposively deceives AAHRPP, a revisit will be required. The Organization will reimburse AAHRPP for the costs associated with the revisit.

Appeals and Hearings

At the end of each site visit, the site visit team leader will conduct an exit briefing with the leadership of the Organization to identify major commendations, major and minor deficiencies, and suggestions for improvement. Following the site visit, the Organization will receive a draft report of the findings from the site visit. The

Organization is permitted to resolve any misunderstandings between the site visitors and the Organization, correct errors of fact, and to correct any deficiencies or make any improvements that can be accomplished within one month of the receipt of the report.

Before rendering any decision to withhold or revoke accreditation, AAHRPP will notify the Organization in writing of the proposed decision and the factual findings and reasons supporting the proposed decision. Such notice will be sent to the Organization using a return receipt mechanism that confirms delivery and indicates the date of delivery (e.g., registered mail, certified mail, etc.). 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 proposed 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 does not request a hearing within the 30-day period, the proposed decision of the Council on Accreditation will be forwarded to the Board of Directors for approval, and the Board's decision will be final.

If the Organization requests a hearing within the 30-day period, the Council on Accreditation will hold the hearing at its next scheduled meeting after receipt of such request, and the Organization will be given an opportunity at the hearing to present evidence or argument tending to refute or overcome the factual findings and proposed decision of the Council. Counsel may represent the Organization at the hearing. Within 30 days after its meeting, AAHRPP will render its decision after considering the information before it, and will send 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 decision of the Council will be forwarded to the Board for approval, and the Board's decision will be final.

If the Organization requests a hearing before the Board within the 30-day period, the hearing, decision and notice provisions will be the same as noted above for an appeal to the Council on Accreditation. On appeal to the Board of Directors, the records will be 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, will ordinarily not be considered by the Board, unless there is strong reason to do so and two-thirds of the Board of Directors votes to accept such new information.

The decision of the Council on Accreditation will be overturned by the Board 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 Council's decision is overturned by the Board, the matter will ordinarily be returned to the Council, unless there are compelling reasons for the Board of Directors to take other action.

Certificates

AAHRPP will issue 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 have Provisional Status 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 potential participants, sponsors, or other persons, will be 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

All proprietary information made available by Organizations to AAHRPP or its site visitors will be kept confidential to the extent permitted by law. No site visitor will remove or retain copies of any Organization's confidential documents without the permission of the Organization. No site visitor will disclose any of his or her findings to any person or agency except AAHRPP. Site visitors or other AAHRPP employees or contractors who fail to adhere to this policy will be discharged. In addition, AAHRPP may pursue legal action against them.

Applicant organizations must comply with all legal and ethical requirements for disclosing any research records with personal identifiable information. Appropriate procedures will be followed by the Organization and AAHRPP representatives to protect the confidentiality of records; when necessary to protect personal identifiable information, Organizations should "de-identify" records. AAHRPP will not maintain or disclose records with individually identifiable information.

All files and records of AAHRPP will be held in confidence by AAHRPP and its members, and no such confidential data will be released by AAHRPP except pursuant to direction by the Board of Directors or under the order of a court of law or the execution of a valid search warrant.

In some states, statutes pertaining to the "peer review" privilege may be applied and protect institutional peer review materials from subpoena. Applicant organizations should determine whether the AAHRPP accreditation process would be 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 applicant organizations appoint AAHRPP and its site visitors as part of the applicant’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.”

AAHRPP understands that applicant organizations may be a “covered entity” and AAHRPP may be a “business associate” as such terms are defined in the privacy rules adopted pursuant to the Health Insurance Portability and Accountability Act of 1996 and published in 65 Federal Register 82462. AAHRPP is in the process of determining the extent to which the privacy rules might apply to the services it provides to covered entities and analyzing the compliance issues to be addressed in advance of the compliance date. AAHRPP is also aware that a variety of changes to the privacy rules are still under consideration. At least six months prior to the compliance date, AAHRPP will enter into good faith negotiations with applicant organizations to include the contract provisions that a covered entity is required to include in its agreements with business associates (assuming that the privacy rules have not then been revised to be inapplicable).

Records Retention

Applications, program descriptions, reports and other documents from site visits resulting in accreditation will be kept for 10 years from the date of accreditation. Applications, program descriptions, reports and other documents from site visits not resulting in accreditation will be kept for 3 years from the date of the decision to withhold accreditation unless the Organization has within the 3-year period, reapplied for accreditation and the application results in Full or Qualified Accreditation or Provisional Status, in which case the records will be kept for 10 years from the date of Accreditation.