



AAHRPP Accreditation Procedures

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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. AAHRPP's Accreditation Standards meet or exceed U.S. federal regulatory requirements and the International Committee on Harmonisation — Good Clinical Practice (E6) guideline 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 assigns a Step 1 Reviewer who evaluates the Step 1 application and determines 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 Step 1 Reviewer determines 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. The length of time of a site visit varies depending upon the size and nature of the research portfolio, and generally ranges from two to four days in length. 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 and adequately evaluated.

The Organization's Step 2 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 (but no later than 30 days after) the completion of the site visit. Within 30 days of the date that the Draft Site Visit Report is sent to the Organization, the 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 concern 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 application, Draft Site Visit Report, the Organization's response, and the evaluation of the response. At its quarterly meeting, 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 assigns a Step 1 Reviewer who evaluates the application and determines 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 according to the time schedule provided by AAHRPP to ensure that the Organization's renewing application for accreditation is reviewed at the assigned meeting of the Council on Accreditation. Once the Step 1 Reviewer determines 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. The length of time of a first¹ reaccreditation site visit varies depending upon the size and nature of the research portfolio, in the same manner as an initial accreditation. 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 date that the Draft Site Visit Report is sent to the Organization, the 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 application, Draft Site Visit Report, the Organization's response, and the evaluation of the response. At its quarterly meeting, the Council then makes a determination regarding accreditation. The decision of the Council is communicated to the Organization in writing.

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 Step 1 applications 12 months in advance of the Council meeting to which they are assigned.

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 in writing at least 30 days in advance. Extensions will be granted by the President and CEO 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 the Organization is to be reviewed, will be placed in Reaccreditation-Pending, on Probation, or lose accreditation status. Organizations must provide justification to the Council on Accreditation to avoid

¹ See below for definition of reaccreditation procedures for "AAHRPP Legacy Organizations."

being placed on Probation or losing accreditation status. 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.

Optional Reaccreditation Procedures for Legacy Organizations

Organizations that have obtained reaccreditation at least once (“Legacy Organizations”) may be eligible for a streamlined review procedure when applying for reaccreditation. The streamlined procedure is optional, and involves a revised application and generally involves a shorter site visit with a more narrow focus. The Standards used to evaluate Organizations applying for reaccreditation using the streamlined procedure remain the same, and the timeframe from submission of the reaccreditation application to Council review remain the same. Eligible Organizations have the choice of applying under the same process used for initial reaccreditation, or may opt to apply under a streamlined procedure. The streamlined procedure applies to Organizations that have not had significant events, as determined by AAHRPP, within the previous five years. Examples of significant events generally include, but are not limited to, implementation of new types of research (such as an organization that at the time of last reaccreditation conducted only social science research, but acquired a medical school or hospital and is now engaged in biomedical research) or decisions to expand the program to cover additional regulations (such as an Organization that becomes an IRB for a Veterans Affairs hospital), or mergers and acquisitions, or major changes in policies (such as decisions to discard all policies used at previous accreditation and implement a new set or toolkit of policies), and substantial staff reorganization or reduction in resources, or other events reported in the Annual Report. However, depending on how an Organization has implemented programmatic changes, a streamlined application procedure may still be possible. Organizations that participate in the streamlined procedure submit an application that describes changes since the previous reaccreditation cycle, and provides revised written documents showing the changes since the previous reaccreditation. AAHRPP staff assigns a Step 1 Reviewer who evaluates the application and determines whether the written documents meet the Accreditation Standards, focusing on the changes since the previous accreditation cycle. The presumption of the Step 1 Process for participating organizations is that existing policies already meet all accreditation Standards and do not require revisions, or that any revisions are limited in scope, such as due to a need to implement revised federal regulations or AAHRPP standards. AAHRPP 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 according to the time schedule provided by AAHRPP to ensure that the Organization’s renewing application for accreditation is reviewed at the assigned meeting of the Council on Accreditation. Once the Step 1 Reviewer determines that the written documents are satisfactory, the Organization submits a Step 2 application and a site visit is scheduled. Site visits using the streamlined procedure are generally limited to one and a half to two days. AAHRPP site visitors review the application, focusing on changes since the prior reaccreditation cycle, and conduct a targeted on-site evaluation. Site visitors will conduct a targeted review, in general focusing on changes since the previous reaccreditation cycle, and any Areas of Concern at the time of the most recent reaccreditation. In addition, time will be allocated to allow an Organization to showcase innovations and improvements to the program that have occurred since the last accreditation evaluation.

The timelines are the same for both the standard and streamlined reaccreditation processes. That is, 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 date that the Draft Site Visit

Report is sent to the Organization, the 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 application, Draft Site Visit Report, the Organization's response, and the evaluation of the response. At its quarterly meeting, the Council then makes a determination regarding accreditation. The decision of the Council is communicated to the Organization in writing.

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 Step 1 applications 12 months in advance of the Council meeting to which they are assigned.

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 in writing at least 30 days in advance. Extensions will be granted by the President and CEO only under unusual or exceptional circumstances.

Accreditable Organizations

AAHRPP will 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 distinct and have a single chief executive officer (who may be referred to by a different title). 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 federal wide 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 distinct 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 that has its own 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, centers or similar subunits 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 entities: A corporation or other incorporated entity, either non-profit or for-profit, under a single chief executive officer, is an accreditable Organization. The entity applies for accreditation as a whole unit regardless of the number of IRBs or separate departments within the entity. In large entities, individual divisions, plants, facilities or other parts that are functionally separate and have an executive officer may apply individually.
- h. Dedicated Research sites: A dedicated 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 might be eligible to 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, a team of one or more site visitors chosen by AAHRPP staff conducts an on-site evaluation of the Human Research Protection Program's performance with respect to each Accreditation Standard and Element. Site visit team leaders are members of AAHRPP's Council on Accreditation or experienced site visitors, and are selected by AAHRPP staff. At its option, AAHRPP may use one or more site visitors for Limited Site Visits (described below), Mandatory Site Visits (described below) 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.

Site visitors are selected by AAHRPP staff 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. Not all four perspectives need to be represented by a team. 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 type of 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.

Recusals

An AAHRPP Representative (as defined below) 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 AAHRPP site visitors. 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 retains the ultimate authority to review all Step 1 and 2 applications, Draft Site Visit Reports, responses to Draft Site Visit Reports, and evaluations, and to determine the accreditation status of an Organization, subject to the Organization's 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 (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.

Full Accreditation: An Organization placed in this category meets all the Accreditation Standards. AAHRPP awards Full Accreditation to new applicants 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. Qualified Accreditation is only available to new applicants; upon reaccreditation the only category of accreditation available to applicants is Full Accreditation, meaning the Organization meets all the Accreditation Standards.

Accreditation-Pending: The Council on Accreditation places an Organization in the Accreditation-Pending category until it decides whether 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.

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 is otherwise 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 creditable.

Categories of Accreditation for Renewing Applicants

Before the end of its then-current 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 four categories.

Full Accreditation: An Organization placed in this category continues to meet all the Accreditation Standards, or in the case of an organization awarded Qualified Accreditation, meets all Standards at time of reaccreditation. Regardless of whether an organization is awarded Full Accreditation or Qualified Accreditation at time of initial review, at the time of reaccreditation, AAHRPP awards Full Accreditation for five years, which commences on the date AAHRPP makes the award.

Reaccreditation-Pending: The Council on Accreditation places an Organization in the Reaccreditation-Pending category until it decides whether 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, usually three months. Based on a review of the Organization's response to the corrective actions, the Council decides whether to grant Full Accreditation, or place the Organization on Probation.

Probation: The Council on Accreditation places an Organization on probation when the Organization does not meet the criteria for Full Accreditation and cannot 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 (as described below). An Organization placed in the Probation category must submit an Improvement Plan within three months of the Council meeting when it was placed on Probation. 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 may revoke accreditation when an 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, historically, 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 for failure to comply with AAHRPP requirements, including those related to the payment of fees, as described here:

- a. If an Organization fails to submit payment of its annual fee within 90 days of the date on its invoice, it will be placed on Financial Hold by the Chief Financial Officer. Financial Hold means that until an Organization pays its fees, AAHRPP will not process any submissions related to its Accreditation (including but not limited to, Annual Reports, Step 1 Applications,

Step 2 Applications). If an Organization does not pay its fees within 6 months of receiving its annual fee invoice, its accreditation will be revoked.

- b. If an Organization fails to submit Accreditation materials by their respective due dates, the Organization will be notified of its failure to submit by the Director of Operations. The Organization will be provided with one extension to its submission deadline, if appropriate. If the Organization fails to meet its extension deadline, the Organization will be presented to the Council for its consideration and determination of the Organization's Accreditation status.

Voluntary Withdrawal from AAHRPP Accreditation

If an Organization wishes to withdraw from AAHRPP Accreditation, the following actions will take place. If an Organization alerts AAHRPP, in writing, of its desire to no longer be accredited, AAHRPP will withdraw the Organization from its list of accredited Organizations. The Organization will receive an official letter from the President and CEO alerting it that AAHRPP has received the Organization's correspondence and has withdrawn the Organization from the program, effective as of the date on the letter.

Limited Site Visits

On occasion, the Council on Accreditation will request a Limited Site Visit.

Inability to Conduct Initial Site Visit

For an Organization seeking Accreditation or Reaccreditation, AAHRPP may require a Limited Site Visit in situations when the initial Site Visit was compromised and not able to be completed. In situations where the inability to conduct the initial Site Visit was beyond the Organization's control, for example, a Site Visitor was unable to travel or became ill during the visit and could not complete the Site Visit activities, AAHRPP will bear the cost of the Limited Site Visit. Conversely, in situations where the Site Visit could not be completed due to the Organization's failure to meet AAHRPP's stipulated requirements related to Site Visit preparation, such as, the Organization's failure to produce the required documents, the Organization will bear the cost of the Limited Site Visit.

Other Reasons for Limited Site Visit

There are other situations in which AAHRPP may require a Limited Site Visit. For an Organization that is awarded Full or Qualified Accreditation, the Council on Accreditation may require a Limited Site Visit to occur during the accreditation period to assess major changes in a Human Research Protection Program or otherwise to ensure that compliance with the Accreditation Standards is maintained. In this situation, AAHRPP will bear the cost of the Limited Site Visit.

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 and/or confirm the correction of deficiencies, then the Council may require 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 other requirements or in response to information reported in an Annual Report or Status Report. Generally, AAHRPP notifies the Organization of the need for a Limited Site Visit at the time it is awarded accreditation, placed in the Accreditation-Pending or Reaccreditation-Pending categories or placed on Probation, or following the

Council's review of a Status Report. In these situations, the costs of the Limited Site visit are the responsibility of the Organization unless AAHRPP determines otherwise.

Status Reports

The Council on Accreditation may request that an Organization provide a Status Report at any time. Failure to submit a Status Report within 30 days of its due date 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 generally requests a Status Report from an Organization when awarding Full or Qualified Accreditation, Accreditation-Pending or Reaccreditation-Pending, or Probation. The Council may request a Status Report in response to reviewing an Annual Report or upon receiving information from the Organization about a change to its Human Research Protection Program. When the Status Report does not satisfy the Council, the Council may request additional information or place the Organization in Accreditation-Pending or Reaccreditation-Pending or on Probation.

Fees

Organizations pay a one-time application fee and annual fees thereafter. Application and annual fees may be pre-paid. 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 and may be changed by AAHRPP from time to time.

Publication of Accreditation Status

Subject to the limits specified below, AAHRPP publishes the name of the Organization and its components, 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 AAHRPP accreditation status. When an Organization its components publicize its accreditation status, it must do so accurately and not in a manner that could be misleading and it must specify its accreditation category.

AAHRPP does not publish the name of or 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 it is re-accredited, or is removed from the list if it is placed on Probation or has its Accreditation Revoked.

When AAHRPP receives an inquiry about an Organization, AAHRPP only releases information that the Organization is not in one of the two categories that hold accreditation status (Full or Qualified Accreditation) and refers inquirers to the Organization in question.

Annual and Other Notification Reporting

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

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

- Organizational Changes, including but not limited to:
 - Change in entity type or corporate structure.
 - Change in name of the Organization.
 - Change in ownership or control of the Organization.
 - Any mergers or acquisitions.
 - Change in leadership or 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, including but not limited to:
 - 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 or dissolution of an IRB, committee or other function.
- Changes in Program Scope, including:
 - Addition of new research program, including but not limited to a type of research not previously conducted or reviewed by the Organization such as planned emergency research, research involving children or gene transfer research).
 - Addition, removal or modification of functions, committees or IRBs.
- Changes in method of providing services, such as use of external IRBs or contracting for services from another organization.
- Catastrophic event that results in an interruption or discontinuance in a part of or the entire Human Research Protection Program.

An Organization must report to AAHRPP as soon as possible but within 48 hours after the Organization or any Researcher (if the Researcher is notified rather than the Organization) becomes aware of:

- i. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and

corresponding compliance actions taken under non-US authorities related to human research protections

- ii. Any litigation, arbitration, or settlements initiated related to human research protections
- iii. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP

Using the foregoing as a guide to AAHRPP's reasonable expectations related to Organizational reporting, if it is unclear whether a particular item is reportable to AAHRPP, the Organization must contact the AAHRPP office for further advice.

When an accredited Organization or its Human Research Protection Program has a substantive change, including but not limited to a change in corporate structure, a change of ownership or leadership, or a change of name, it must notify the AAHRPP office when the change occurs within 30 days. If the Organization is unsure whether a change constitutes a substantive change that must be reported to AAHRPP, the Organization must request clarification from AAHRPP.

The Council on Accreditation will review information regarding the Human Research Protection Program that is provided through the reporting mechanisms described above and will determine whether any action is indicated, such as a request for additional written information or a Limited Site Visit.

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Mandatory Revisits

A mandatory revisit can be used as part of AAHRPP's response to an Organization that receives certain types of governmental regulatory sanctions or as part of AAHRPP's response when an Organization deliberately deceives AAHRPP, or otherwise in the discretion of the Council on Accreditation. 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 delivery mechanism that permits package tracking and confirmation of delivery. 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 may appeal the decision by submitting a written request to President and CEO 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, which shall be conducted by the Council in its reasonable discretion, and shall not be required to follow any rules of evidence or civil procedure. 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 delivery mechanism that permits package tracking and confirmation 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 to the President and CEO 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 removed from display by the Organization or returned to AAHRPP, all references to AAHRPP accreditation and any use of the AAHRPP accreditation seal must be removed from all Organization materials, and the Organization may no longer represent itself (or permit others to identify it) as accredited by AAHRPP. Organizations that are placed in Accreditation-Pending are not entitled to receive Certificates of Accreditation.

Display or use of any revoked or fraudulent AAHRPP certificate or of any AAHRPP seal or other identifiers 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 use.

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, and 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, and may not provide AAHRPP with records or information that are not de-identified. 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, a court order, a valid search warrant, or as otherwise required by applicable law.

In some states, statutes pertaining to the "peer review" privilege may be applicable to protect institutional peer review materials from subpoena. An Organization should determine for itself whether (1) the AAHRPP accreditation process is considered to be a "peer review" process, (2) AAHRPP and its site visitors are or should be considered part of the Organization's "peer review committee," and the governing bodies of an Organization should 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." AAHRPP bears no responsibility for making these determinations, or for withholding its information from disclosure due to peer review privilege.

Protected Health Information

AAHRPP is not a covered entity subject to the Health Insurance Portability and Accountability Act or its implementing regulations ("HIPAA"). In addition, because Organizations are required to de-identify all information provided to AAHRPP, and are not permitted to provide AAHRPP with any information that is not de-identified, AAHRPP is also not a business associate of any Organization that is a covered entity. To the extent that Site Visitors or other AAHRPP Representatives might inadvertently come into contact with an Organization's protected health information ("PHI"), AAHRPP will use good faith efforts to cause them to (1) comply with HIPAA and the Organization's internal policies and (2) not record or disclose such PHI.

Release and Indemnification

By submitting an application, an Organization certifies that the information contained in the application and thereafter provided to AAHRPP is accurate, complete and not misleading in any way. The Organization agrees to release AAHRPP and each of its members, directors, officers, employees and agents (the "AAHRPP Representatives") from any and all claims, and to indemnify and hold harmless AAHRPP and the AAHRPP Representatives from and against any and all liability and costs incurred by them, including attorneys' fees, resulting directly or indirectly from any

applications, site visits, evaluations, and decisions regarding the accreditation 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.