Cooperative Research
Policy and Procedure

Table of Contents

I. Policy

A. Collaborative research activities at off-site locations are subject to special procedures for coordination of research review and may involve more than one IRB responsible for research oversight. In these cases, the HSC has established additional procedures to define the responsibilities of each institution, coordinate communication among responsible IRB committees, and manage information obtained in off-site or multi-site research to ensure protection of human subjects.

B. The HSC and other local institutions that routinely collaborate on human research have established agreements that allow the other institutions to rely on the HSC IRB for the review and continuing oversight of non-exempt human research either conducted by the institution or covered by the institution's Federalwide Assurance. These "affiliated" institutions sign an IRB Authorization Agreement (IAA) and Memorandum of Understanding (MOU) with the HSC.

C. In addition, HSC may enter into formal agreements with other facilities which are not legal entities of the HSC to provide research review (i.e., to act as the IRB of record), to rely on other institutions for research review, or to cooperate in review. HSC enters into these types of arrangements through a Memorandum of Understanding (MOU), IRB Authorization Agreement, or contract with the institution(s) in question.

D. Other off-site research may involve researchers from other (non-affiliated) institutions that may or may not already have an FWA/IRB or may involve individual investigators who either are not employed by an institution (independent investigator) or is employed by an institution that does not routinely conduct research and does not have an FWA/IRB.

E. In coordinating off-site research reviews, the IRB Office (OIRB) staff, the IRB and the Office of Clinical Research (OCR), in consultation with the HSC Department Chair, Assistant VP for Research Administration, Vice President for Research (VPR), and the HSC Legal Counsel take into consideration the source of funding for the research activity, federal and state regulations, specific sponsor regulations governing human research protections, institutional policy and existing IAAs/MOUs.

F. The HSC IRB requires additional information and documentation for research that meets the definition of off-site research. Institutional policies apply to all off-site research involving human subjects regardless of funding source and all non-externally funded off-site research involving human subjects, including educational and other survey research.

1. The IRB application available from the IRB website includes instructions to investigators describing specific institutional and regulatory requirements for obtaining IRB approval of off-site research. The OIRB staff advises investigators on meeting the requirements, as appropriate.

G. Investigators from off-site locations that do not normally conduct research (non-assured institution) may request the HSC extend its Federalwide Assurance to cover their research activities by signing an Individual Investigator's Agreement with the HSC.

H. Collaborative research activities at off-site international locations that are funded or supported by HHS must be conducted under an active international assurance issued by the Office for Human Research Protections. International collaborative research that is not funded or supported by HHS should be conducted under applicable national or international procedural standards that are at least as stringent as the requirements of 45 CFR part 46.

I. In collaborative research activities where the HSC is the Coordinating Center or the HSC investigator is the Lead PI, the HSC investigator is responsible for the management of information that is relevant to the protection of human subjects, such as the reporting of unexpected problems, protocol modifications, oversight problems, and interim results from all satellite sites.

J. Whenever feasible, investigators are encouraged to involve community members in the design, implementation and dissemination of the results to the community.

II. Procedure

A. Cooperative Research Involving Off-Site study locations that are engaged in research.

1. In this type of cooperative research:

a) The HSC investigators (employees/agents) are engaged in research or the HSC will receive a direct federal (DHHS) award to conduct human subjects research, even where all activities involving human subjects are carried out by a non-HSC entity (e.g., subcontractor or collaborator); and

b) The off-site institution is engaged in research, or

c) The independent investigator is engaged in research

2. Off-Site study locations are categorized as either: 1) an institution that is affiliated with the HSC IRB, 2) an institution that is not affiliated, or 3) an independent investigator.

3. Cooperative Research Involving the HSC and an Affiliated Institution or a Relying Institution:

a) The HSC and other local institutions that routinely collaborate on human research have established agreements that allow the other institutions to rely on the HSC IRB for the review and continuing oversight of human research. These institutions are referred to as “affiliated” or “HSC IRB affiliated” institutions. The HSC and other non-local institutions that have collaborated on human research for large consortium groups, multi-site trials have also established agreements that allow the other institutions to rely on the HSC IRB for review and continuing oversight of human research. These institutions are referred to as “relying” institutions.

b) All affiliated or relying institutions operating under a formal agreement must file their own institutional assurance with the OHRP and list all the HSC IRBs as designated IRBs on the assurance. The Signatory Official for each institution signs all formal agreements. The VPR/IO, serves as the Signatory Official for the HSC.

c) Each "affiliated" or "relying" institution signs an IRB Authorization Agreement (IAA) and Memorandum of Understanding (MOU) with the HSC.

d) There are three general categories of affiliated/relying institutional agreements: *broad or reciprocal*, limited and single study:

(1) A broad or reciprocal agreement specifies that the HSC IRB oversight is applicable to all research conducted by the institution or research covered by the institution's Federalwide Assurance

(2) A limited agreement specifies that the HSC IRB oversight is applicable to a subset of human research that is defined in the agreement

(3) A single study agreement specifies that the HSC IRB oversight is applicable to a single study. Single study agreements may be covered under an IAA without a MOU. In the absence of an MOU the Principal Investigator is responsible for providing the affiliated institution's point of contact with all IRB related information.

e) The MOU outlines the relationship between the institutions and documents the authority granted to the institution to serve as the relied upon IRB for the affiliated/relying institution

f) The OIRB maintains a record of current formal agreements on file

g) Information related to cooperative research with affiliated institutions is included in the HSC IRB application. For example, the affiliated institutions participating in a specific study as study sites are provided in the Institutional Form reviewed during initial review. The affiliated institutions are listed in the Progress Report Form reviewed by the IRB during continuing review

h) The list of investigators from affiliated institutions is included in the Inst M – Personnel Form (or similar).

i) Information related to cooperative research with relying institutions is included in the Form K-2 Site Investigator Intent to Rely form (or similar), Single IRB Protocol Specific Form, Single IRB Institutional Profile form, and a Communication Plan from each relying institution. These forms verify appropriate human subjects education and training for investigators at the relying sites as well as information to educate and train HSC IRB members regarding any state or local laws or regulatory issues when conducting their review. See the section on *IRB Knowledge of Local Regulatory Issues* for

additional details

4. Cooperative Research Involving the HSC and a Non-Affiliated Institution

For cooperative research involving the HSC and other institutions that have not previously established an IRB authorization agreement, the procedure for review depends on whether the non-affiliated institution has a Federalwide Assurance (is an assured institution).

a) Assured institutions – the assured institution is responsible for IRB approval of the research for that site in accordance with its FWA and local policy. The HSC PI must obtain evidence of appropriate IRB approval from the assured institution's designed IRB. This documentation must include the Federalwide Assurance (FWA) number for all federally funded research and a copy of the assured institution's (non-HSC) IRB approval letter.

(1) Investigators at the off-site assured institution are not listed on the HSC research application unless the off-site individual:

(i) Conducts research at a HSC affiliated study site;

(ii) Requires specialized skills or training by the IRB;

(iii) Has a conflict of interest;

(iv) Is listed in the informed consent document;

(v) Is the site principal investigator;

(vi) Is the overall principal investigator; and/or

b) Non-assured institutions - Consider whether the non-assured institution should obtain an FWA

(1) OHRP notes that if HHS-conducted or -supported human research activities routinely occur at a non-assured institution, the institution should obtain an OHRP-approved FWA. Also, if the non-assured institution is the primary awardee for an HHS-supported award providing support for non-exempt human subjects research, the institution must obtain its own OHRP-approved FWA. In most cases, if HHS funding is being provided to the non-assured institution, HHS will require the institution obtain an FWA.

(2) If the non-assured institution has no plans to obtain an FWA consider whether an Individual Investigator Agreement (IIA) is appropriate

5. Cooperative Research Involving the HSC and a non-assured institution's Individual Investigator

   a) If the collaborating investigators from the non-assured institution are under the direction and supervision of the HSC principal investigator the HSC may extend its FWA to cover the research activities if the collaborating investigator is:

      (1) not otherwise an employee or agent of the HSC,

      (2) conducting collaborative research activities outside the facilitates of the HSC, and

      (3) acting as an employee or agent of the non-assured institution with respect to his or her involvement in the research

   b) In this situation, the HSC may extend its assurance if the collaborating investigator signs an Individual Investigator Agreement (IIA) with the HSC. IIAs are approved by the VPR/IO designee following coordination through the appropriate HSC Department Chair

   c) Information about the non-assured institution is provided on the Institutional Form

6. Cooperative Research Involving the HSC and an Independent Investigator

   a) For cooperative research involving the HSC and an independent investigator the HSC may extend its FWA to cover the research activities if the collaborating investigator is:

      (1) under the direction and supervision of the HSC principal investigator,

      (2) not otherwise an employee or agent of the HSC,

      (3) conducting collaborative research activities outside the facilities of the HSC, and

      (4) not acting as an employee of any institution with respect to his or her involvement in the research

   b) In this situation, the HSC may extend its assurance if the collaborating investigator signs an Individual Investigator Agreement (IIA) with the HSC. IIAs are approved by the VPR/IO designee following coordination through the appropriate HSC Department Chair

B. Cooperative Research Involving Off-Site study locations that are not engaged in research

1. The PI arranges for the off-site facility administrator to submit official correspondence addressing the following information, where appropriate:

a) Agreement of the facility's administration for the research to be conducted at that site, and

b) Summary of the extent of the institution's involvement (should agree with the designation that the institution is not engaged in research as defined by OHRP).

C. Cooperative Research Involving Off-Site International locations engaged in research

1. The PI arranges for the international site IRB (or equivalent entity) to review the research and submit official correspondence addressing the following information:

a) For VA Research or HHS funded or supported research, the international site's International FWA number and the appropriate IRB approval from the assured institution's designed IRB (including the OHRP registration number for the IRB/IEC). Other requirements are addressed in the section IRB Knowledge of Local Regulatory Issues.

b) For non-HHS funded or supported research, the appropriate IRB (or equivalent entity) approval. Other requirements are addressed in the section IRB Knowledge of Local Regulatory Issues.

c) Cooperative Research Involving Off-Site International locations not engaged in research. Follow procedures for local institutional approval to conduct research at the site.

2. All policies and procedures applied to domestic research are also applied to research conducted at international research site.

a) Initial Review, Continuing Review and review of modifications (see Initial Review of Research Policy and Procedure, Continuation Review Policy and Procedure, Modification and Amendments Policy and Procedure)

b) Handling Complaints, Noncompliance, and Unanticipated Problems (see respective policies)

c) Informed consent process (including language issues). See Informed Consent Policy and Procedure.

D. General Information about Cooperative Research

1. In cases in which research undergoes joint IRB review at HSC and at the non-HSC institution, an IRB Authorization Agreement is usually not necessary unless required by the sponsor. Each situation is evaluated on a case-by-case basis

   a) The VPR/IO, in consultation with the appropriate HSC Department Chair, IRB Director, AVPRA and, if appropriate, HSC Legal Counsel, makes the final determination whether the HSC IRB will serve as the relied-upon IRB for studies involving more than one IRB authority. Protocol specific determinations under a broad or blanket agreement are made by the IRB Director or designee using the Form K-2 Site Investigator Intent to Rely form (or similar).

2. HSC may also agree to defer responsibility for IRB review to a non-HSC institution's IRB. To defer responsibility, the non-HSC IRB must be part of an institution that has an active FWA. It is preferred that the IRB has been accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) or a similar designation of IRB quality. HSC will confirm non-HSC IRB applies applicable standards and regulations and ensures reporting to regulatory agencies. With the exception of minimal risk studies, which will be evaluated on a case by case basis, the non-HSC, IRBs which have not been accredited by AAHRPP may be asked to complete the AAHRPP IRB Evaluation Checklist or undergo an alternative assessment to evaluate the non-HSC IRB for AAHRPP standards. If AAHRPP standards cannot be determined for greater than minimal risk studies additional oversight may be required before the HSC IRB will agree to defer responsibility. Additional oversight activities may include, but are not limited to:

   a) Reviewing relevant portions of the minutes of the IRB.

   b) Reviewing IRB records of the particular study being reviewed.

   c) Evaluating relevant policies and procedures of the reviewing IRB.

   d) Confirming that IRBs in countries outside the US have completed relevant certifications.

   e) Observing a portion of an IRB meeting where the particular study is reviewed.

   f) Having someone from the HSC serve as a consultant to the non-accredited IRB.

   g) Conducting not-for-cause monitoring of the IRB.

   Circumstances in which HSC may defer IRB review may include (but are not limited to) cases where: a Central Institutional Review Board is required (e.g. National Cancer Institute (NCI CIRB); the funding agency requires it; federal regulations, state laws or local policies require use of a specific IRB; the principal investigator(s), a research consortium or sponsor is mandating use of a single IRB, the HSC employee role is limited to data analysis only; the research began at another

institution prior to employment of the investigator at HSC and remains active only at the other institution (and any funds supporting the research remain under the control of the non-HSC institution); the IRB has particular expertise for reviewing the research; and/or the research is not greater than minimal risk. The two institutions negotiate and sign an IRB Authorization Agreement

a) The VPR/IO, in consultation with the IRB Director, AVPRA and, if appropriate, with HSC Legal Counsel, makes the final determination whether the HSC IRB will defer review and oversight responsibility to another institution's IRB. Protocol specific determinations under a broad or blanket agreement are made by the IRB Director or designee using the Form K-2 Site Investigator Intent to Rely form (or similar).

b) In cases where the HSC IRB relies on another non-HSC IRB, the PI ensures that research activity does not begin prior to receiving an institutional activation letter from HSC OCR and/or an affiliate institution, as applicable. Documentation must include IRB approval from the non-HSC IRB, completed Institutional Form and applicable supporting documents

   i. The HSC OCR will review the Institutional Form and supporting documents (see the OCR Institutional Review Policy).
   ii. The HSC OCR provides a monthly report to the VPR/IO, AVPRA and IRB Director containing the studies receiving institutional activation during the corresponding month in which the HSC IRB has agreed to rely on another non-HCS IRB.

3. The IRB Agreement, Implementation Checklist and Documentation Tool will be used for cooperative research under the SMART IRB Agreement to document flexible provisions

4. The PI coordinates with project personnel at the off-site locations to initiate any required off-site research review

5. The OIRB staff assists the PI in identifying required documentation on a case-by-case basis and maintains appropriate regulatory documentation from each off-site facility in the study file

6. When the HSC IRB conducts research reviews for off-site facilities, as appropriate to the agreement and in accordance with its standard policies and procedures for research review and oversight, the IRB ensures sufficient knowledge of local regulatory issues for the off-site location as detailed in the section on IRB Knowledge of Local Regulatory Issues.

7. Relying off-site facilities may communicate directly with the office of the IRB when necessary to discuss questions, concerns, or obtain interpretation of determinations.

E. Cooperative Research Involving Multiple Sites Where HSC is the Coordinating Center/Lead Investigator

1. If HSC is the Coordinating Center in a multi-site study or the HSC investigator is the lead investigator, the PI must provide additional information to the HSC IRB to ensure ongoing communication among the participating IRBs and sites. The HSC investigator must submit the following information along with the IRB application:

   a) For each non-HSC site, submit a letter from the appropriate administrator granting permission for the research to be conducted at its site; Form K-2 Site Investigator Intent to Rely form (or similar) from each relying institution.

   b) Determine the relied upon IRB for each non-HSC site and submit appropriate documentation as needed (if joint review, submit a copy of the non-HSC site's IRB approval letter; if relied upon review, complete an IRB Authorization Agreement).

2. Additionally, the HSC investigator must submit a communication plan for the management of information that is relevant to the protection of human subjects, such as the reporting of unexpected problems, protocol modifications, and interim results from all participating sites.

F. Cooperative VA Research Involving Multiple Sites

1. For a VA multi-site study, not only the principal researcher, but also all local site researchers, must obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.

2. Research cannot be initiated at any given site until the local researcher has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.

G. Research at Geographically Separate Off-Site Location with No Cooperating Institution/Facility/Organization

1. In the IRB application, the PI provides the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects.

2. If the IRB membership does not have the appropriate expertise for conducting the review, OIRB staff and/or the PI assists the IRB in identifying cultural consultants following procedures outlined in the standard OIRB/IRB operating procedures. (See the Initial Review of Research Policy and Procedure, and IRB Member and Consultant Conflict of Interest Policies.) The PI may supply the name of an appropriate consultant in the IRB application.

3. Cultural consultants may review consent forms, and provide guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted. The PI may supply the name of an appropriate consultant upon request by the IRB.

H. Negotiation of Federal Assurances for Collaborating Institutions

1. When the HSC is the recipient of federal funding for research (e.g., NIH grant), it is responsible for ensuring that all performance sites engaged in human research (i.e., subcontracts) operate under an appropriate OHRP or other federally approved assurance. In general, institutions affiliated solely through professional or collaborative arrangements apply to OHRP for their own assurance. The OIRB/IRB determines these additional requirements on a case-by-case basis with the sponsoring agency.

2. Off-site facilities determine the appropriate mechanism with assistance from the OHRP based on such issues as the nature of the research, ownership of the performance site, and the affiliation of the individuals collecting the data.

3. The PI assists performance sites without an IRB which are “engaged” in research in obtaining the appropriate assurance and IRB approvals. The OIRB advises the PI throughout the process, as appropriate.

4. Off-site facilities submit an application for an assurance to the OHRP and designate an institutional Signatory Official with authority to represent and commit the entire institution and all of its components to a legally binding agreement

5. The institution’s assurance may also cover independent investigators who are not agents of the institution only in accordance with a formal written agreement of commitment to relevant human subject protection policies and IRB oversight. The institutions may formalize such agreements under the sample OHRP Individual Investigator Agreement or by a commitment agreement developed by the institutions or by using the Individual Investigator Agreement (For Researchers not affiliated with UT Health Science Center at San Antonio).

I. Negotiation of an IRB Authorization Agreement with Collaborating Institutions

1. IRB Authorization Agreements are between two institutions where one institution agrees to rely on the IRB from the other institution for the review and continuing oversight of its human research. The agreement can cover all human research conducted by the institution, all human research conducted under the institution’s Federalwide Assurance (FWA), a subset of research studies, or a single study.

2. The HSC has established general categories of affiliated institutional agreements. For details see the description above.

3. Cooperative research studies involving multiple institutions may rely on cooperative review. Federally funded multisite studies must use a Single IRB (sIRB) to oversee the portion of the research that takes place within the United States, except for cooperative research for which more than single IRB review is required by law (e.g. tribal law) or research for which the funding agency/sponsor determines and provides documentation that use of a single IRB in not appropriate. In such cases, participating IRBs enter into a written cooperative review agreement (MOU/MOA) identifying the specific IRB designated to provide review and detailing the respective responsibilities of the IRB and each institution under the review agreement.

4. Under an IRB Authorization Agreement, both institutions agree that one institution is responsible for providing IRB review and the second will rely on the other for IRB review for one, several specified or all projects. IRB Authorization Agreements list the federal assurance number for each institution, designate the specific project(s) (if applicable) to which the agreement pertains.

5. The Authorized Officials for both institutions must approve the agreement in writing. The HSC VPR/IO signs all IRB Authorization Agreements and related MOU/MOAs as the Signatory Official for HSC under its assurance. Both institutions maintain an IRB Authorization Agreement on file and agree to submit the document to OHRP upon request

6. The IRB which agrees to review studies conducted at another institution (Reviewing IRB) has the responsibility for initial and continuing review of the research. The Reviewing IRB takes into account the required criteria for approval, the facilities and capabilities of the other institution, the measures to be taken by the participating institution to ensure compliance with the IRB's determinations, and community attitudes or local regulatory issues, as appropriate. (See the section on IRB Knowledge of Local Regulatory Issues for additional information.)

7. The Reviewing IRB under an IRB Authorization Agreement is responsible for conveying approvals to all participating sites, either directly to the IRB or to the institutional research office.

8. In cases in which HSC relies on another designated IRB under an IRB Authorization Agreement, the HSC OCR, may provide information to the non-HSC IRB assuring sufficient consideration of local regulatory issues and institutional requirements for the HSC component(s) of the study

9. When the HSC IRB relies on a non-HSC IRB for review of research under an IRB Authorization Agreement, it agrees to abide by the decisions and determinations made by the non-HSC IRB

10. Likewise, HSC investigators agree to abide by those same decisions and determinations and may not modify or alter the research protocol without prior written approval of the non-HSC IRB.

11. The PI sends all required reports directly to the non-HSC IRB who will notify the OCR, as stipulated in the executed MOU/IRB Authorization Agreement.

12. Additional information on the negotiation of sub-award agreements for off-site sponsored research may be found in the Office of Sponsored Projects section of the Coordination with Other Committees or Offices Policy and Procedure.

13. The IRB Authorization Agreement template (which has been vetted by HSC Legal Counsel) from the Reviewing IRB is presented during negotiations. Any requested changes to a new or existing agreements outside of the HSC IRB approved template language are reviewed by the IRB Director, AVPRA and, if appropriate, HSC Legal Counsel prior to final review by the VPR/IO. All non-HSC agreements receive HSC Legal Counsel review. Modifications to an existing agreement will be processed in the same manner by modifying the full agreement or through an addendum.

J. IRB Knowledge of Local Regulatory issues

1. In accordance with OHRP guidance, when the HSC IRB serves as the Reviewing IRB for another institution or when the research involves distinct subject populations (non-English speaking populations, veterans, etc.), the HSC IRB ensures that it possesses or obtains sufficient knowledge of the local regulatory issues even when the IRB is geographically removed from the off-site research location.

2. Additionally, in accordance with FDA requirements, an IRB may review studies performed at off-site locations as long as the requirements for 21 CFR parts 50 and 56 are met. In these cases, a written agreement, which the local IRB or the administration of the institution signs, allows review by a non-local IRB (See Negotiation of an IRB Authorization Agreement with Collaborating Institutions for more information)

3. The PI supports the IRB in understanding the local regulatory issues by providing the IRB necessary information, as appropriate, on:

   a) The anticipated scope of the off-site facility's research activities;

   b) The types of subject populations likely to be involved;

   c) The size and complexity of the institution;

   d) Institutional commitments;

   e) Applicable law, including law regarding who may serve as a legally authorized representative for a research participant;

   f) Local social and cultural norms applicable to research.

   g) Standards of professional conduct and practice;

   h) Method for equitable selection of subjects;

   i) Method for protection of privacy of subjects;

   j) Method for maintenance of confidentiality of data;

   k) Languages understood by prospective subjects;

   l) Method for minimizing the possibility of coercion or undue influence in seeking consent;

   m) Safeguards to protect the rights and welfare of vulnerable subjects;

4. In cases where the HSC IRB conducts non-local review, members must have sufficient knowledge of the community from which the subjects are drawn to ensure protection of subject rights and appropriateness of the consent process for the subject population. In addition, the IRB must be sensitive to community laws. The IRB may ensure the necessary expertise and knowledge to make appropriate determinations regarding the local regulatory issues through one or more of the following activities, as appropriate to the level of risk and in accordance with OHRP guidance and FDA regulation:

    a) Personal knowledge of the local regulatory issues on the part of one or more IRB members, such knowledge having been obtained through extended direct experience with the research institution, its subject populations, and its surrounding community;

    b) Review of the proposed research by one or more ad hoc or cultural consultants with knowledge of the local regulatory issues. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review, either physically or through audiovisual or telephone conference, when participation is deemed warranted by the consultant(s) or any one member of the IRB;

    c) Systematic reciprocal documented interchange between the IRB and elements of the local regulatory issues through periodic visits to the research site, occurring several times per year, by one or more IRB members in order to obtain and maintain knowledge of the local regulatory issues; periodic discussion with appropriate consultants knowledgeable about the local regulatory issues; regular interaction with one or more designated institutional liaisons; and/or review of relevant written materials;

    d) Site visit by a representative of the IRB;

    e) Appointment of an IRB member from the community in question.

5. The OIRB staff assists the PI in addressing the requirements for information on the local regulatory issues upon request.

6. The OIRB staff assists the IRB in identifying appropriate consultants and distributing appropriate review materials pertaining to the local regulatory issues to IRB members, as appropriate.

7. The OIRB staff maintains documentation in the database and the study file of the local regulatory issues and the measures taken to ensure sufficient IRB knowledge of that context.

8. The IRB includes the name and contact information for an IRB contact in the consent document for non-local IRB review or designates an individual at the research site to serve as the contact to relay reports to the IRB.

9. In the minutes of the meeting during which non-local research review occurs, OIRB staff document the procedures used to ensure that the IRB adequately considered community attitudes.

III. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)