

**GPC (Greater Plains Collaborative)
Institutional Review Board (IRB)
Standard Operating Procedures (SOPs)**

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GPC IRB Consortium SOP #1: Reliance Review Process

This document describes the procedures to be followed by GPIC POCs when reviewing requests to use GPIC and associated study materials. This SOP does not address the reliance decision process itself, which is unique to each institution and should be addressed by institution-specific policies and procedures.

1. Studies must be reviewed and approved by the GPC governance body to be eligible to use the GPIC process. A copy of the GPC's governance body's signoff must be provided by the study team with the request to use GPIC, as described below.

2. Lead study team will submit a GPIC request form, GPC governance signoff, study protocol, template consent/authorization form(s), and list of key personnel from each site to GPC Administration via the GPIC website.

2.1 Only 1 GPIC request should be submitted for each study.

2.2 Study teams completing a GPIC request will be asked to indicate which institution they think should serve as IRB of record for the study.

2.3 The GPIC request form will ask study teams to identify a single point person for the request who will serve as the primary point of contact for GPC Administration and the lead GPIC POC.

3. Upon receipt of a GPIC request, GPC Administration will proceed as follows:

3.1 GPC Administration will upload copies of the GPIC request form and supporting materials to the secure area of the GPIC website following the SOP for GPIC Document Management.

3.2 After the documents have been uploaded, GPC Administration will then notify the GPIC POC for the proposed IRB of record that a request has been received and materials are available on the GPIC website for his/her review.

3.3 Except in unusual circumstances, GPC Administration will upload documents and notify the appropriate GPIC POC within 3 business days of receipt of the request.

4. Upon notification that a request has been received and materials are available on the GPIC website for review, the POC for the likely IRB of record (hereafter referred to as lead GPIC POC) will proceed as follows:

4.1 The lead GPIC POC will check the documents for completeness within 3-5 business days of notification of the request. Incomplete materials will be returned by the lead POC to the lead study team for revision and without further review.

4.2 The lead GPIC POC also will review the documents to determine that the study is one for which his/her institution can serve as IRB of record in accordance with that institution's policies and procedures. In addition, the following criteria will help determine whether a GPC institution can serve as IRB of record for a study:

4.2.1 The IRB of record will typically be the institution of the lead PI for the study or the grant holder. If the study team proposes a different IRB of record, justification must be provided by the study team.

4.2.2 The IRB of record must be from a GPC institution that is engaged in human subjects research for the study.

4.2.3 Final decisions about whether a study can be reviewed by a single IRB and which IRB will serve as IRB of record are at the sole discretion of the GPC institutions engaged in human subjects research.

4.3 If the lead GPIC POC determines that her/his institution cannot serve as IRB of record for the study, she/he will notify GPC Administration of this decision. GPC Administration and the lead GPIC POC will then discuss next steps that may include a conference call with the POCs from all the institutions engaged in human subjects research for the study to determine the appropriate course of action.

5. When the lead GPIC POC determines the materials appear complete and the lead institution can serve as IRB of record for the study, she/he will proceed as follows:

5.1 The lead GPIC POC will email the GPIC POCs at the other institutions potentially engaged in human subjects research for the study to notify them that a request to use GPIC has been received and documents are ready for review on the GPIC website.

5.2 The lead GPIC POC will email the lead study team POC to notify her/him that the request and supporting materials are being reviewed by the IRBs from each institution. The lead study team POC is responsible for notifying study team POCs at other sites of the status of the GPIC review.

6. Upon notification from the lead GPIC POC regarding the new request, the GPIC POCs from the other sites will review the documents to determine whether their institution will defer IRB review to the proposed IRB of record. POCs unable to conduct a preliminary review of the documents within 3-5 business days will notify the lead GPIC POC by email of their time frame for review.

7. After reviewing the request form and supporting documents, the GPIC POC for each site may ask for additional information from the study team if such information is critical in order for the site to decide whether it can defer IRB review. If additional information is requested, the following will occur:

7.1 Unless otherwise agreed upon by all the involved GPIC POCs, requests for additional information will be emailed to the lead GPIC POC.

7.2 The lead GPIC POC will obtain the additional requested information via email to the lead study team POC.

7.3 The lead study team is responsible for obtaining the requested information from study teams at other participating sites, as appropriate, and emailing the information to the lead GPIC POC within 3-5 business days of receipt of the request.

7.4 The lead GPIC POC will convey any study team responses for additional information to the appropriate GPIC POC via email.

8. If no additional information is required to make a decision to rely on the IRB of record or if all relevant concerns have been addressed, the GPIC POCs from the relying institutions will proceed as follows:

8.1 GPIC POCs will ensure either that their local institutional requirements have been identified prior to deferring IRB review to the IRB of record and that any outstanding requirements are communicated in the reliance checklist to the IRB of record.

8.2 GPIC POCs will complete a GPIC reliance checklist documenting any outstanding concerns or requirements to be addressed before the study is approved by the IRB of record.

9. After the above steps are completed, reliance decisions will be communicated as follows:

9.1 POCs from relying institutions will email the lead GPIC POC indicating deferral of IRB oversight to the proposed IRB of record. A copy of the reliance checklist will be attached to this email.

9.2 Upon receipt of the email, the lead GPIC POC will review the reliance checklist and note any outstanding items that may require additional action before the study can be approved by the IRB of record.

9.3 The lead GPIC POC will then reply by email to the POC from the relying institution, indicating that the IRB of record is willing to accept IRB oversight for the relying institution.

Upon completion of these steps, the reliance process for each institution will be considered to be complete.

10. Any institution that determines it cannot defer IRB oversight for the study to the proposed IRB of record will notify the lead GPIC POC, lead study team POC, and GPC Administration of this decision by email. A brief rationale for the decision not to rely on the proposed IRB of record should be provided as well as guidance for obtaining IRB approval for the study at that site.

11. After all involved GPC institutions have provided the lead GPIC POC with a decision about reliance and the reliance process has been completed, the lead GPIC POC will notify the lead study team POC and GPC Administration that an IRB application can be submitted to the IRB of record for review.

12. Inquiries from any site's study team regarding the status of a pending GPIC request should be forwarded to the lead GPIC POC.

GPC IRB Consortium SOP #2: Point of Contact Roles and Responsibilities

The purpose of this SOP is to describe the overall roles and responsibilities for Greater Plains Collaborative IRB Consortium (GPIC) points of contact (POCs). Specific procedures to be followed by POCs at various stages in the review process are outlined in other GPIC SOPs.

1. Each GPC IRB will designate a POC and an alternate POC for its institution. A list of POCs and alternates will be maintained by GPC Administration on the GPIC website. Each GPC IRB will be responsible for notifying GPC Administration of any changes to its POC or alternate.
2. The primary role of POCs is to serve as the single point of contact for their respective institution's IRB for GPC. This includes serving as point of contact for GPC Administration for IRB-related issues as well as review of GPC studies submitted for consideration through the GPIC process.
3. General POC responsibilities include (but are not limited to) the following:
 - 3.1 Responding to communication from GPC Administration and GPIC POCs in a timely fashion.
 - 3.2 Adhering to GPIC SOPs and participating in preparation and review thereof.
 - 3.3 Serving as a resource for researchers at their institution about the GPIC review process and requirements.
 - 3.4 Regularly attending and/or participating in GPC and GPIC meetings.
4. POC responsibilities during the GPIC review process include the following:
 - 4.1 Communicating with POCs at other GPC institutions to determine, on a protocol-by-protocol basis, which institutions choose to rely on a single GPC IRB and to identify the IRB that will serve as IRB of record.
 - 4.2 Upon receipt, promptly reviewing GPC study protocols and any supporting materials to determine whether reliance on a single IRB of record is appropriate in accordance with the each institution's policies and procedures.
 - 4.3 Identifying any questions or concerns about a GPC study that require resolution in order for the POC's IRB to determine whether deferral of IRB review is appropriate. POCs are responsible for communicating these concerns to the POC of the proposed IRB of record in accordance with GPIC procedures.
 - 4.4 Consulting as needed with individuals and resources (e.g., other IRB staff, legal counsel) at the POC's institution regarding deferring IRB review or accepting IRB oversight for a particular GPC study.
 - 4.5 Addressing any questions from the study team at the POC's institution regarding the GPIC review process and status of the GPIC request.
 - 4.5 Ensuring that institutional requirements are met and documented prior to deferring IRB review, per that institution's policies and procedures.
 - 4.6 Communicating IRB reliance and IRB of record decisions in accordance with GPIC procedures.
5. After the GPIC review process is complete and 1 or more GPC institutions have agreed to rely on a single IRB of record, the POC for the IRB of record is responsible for the following:

5.1 Notifying GPC Administration, the lead PI and relying PIs, and POCs from relying institutions regarding final IRB of record and reliance decisions for a GPC study. This will be communicated using the GPIC Reliance Checklist.

5.2 Coordinating and hosting a conference call with the lead and relying study teams to review the GPIC Reliance Summary and address any questions about the IRB review process.

5.3 Following IRB approval, uploading IRB documentation to the GPIC website and notifying POCs from relying institutions when these documents are available.

6. After the GPIC review process is complete and 1 or more GPC institutions have agreed to rely on a single IRB of record, the POC(s) for the relying IRB(s) is responsible for the following:

6.1 Responding promptly to any requests for assistance or information from the POC for the IRB of record (e.g., assistance with gathering information regarding reportable events occurring at the relying site).

6.2 Notifying the IRB of record's POC regarding events that occur at the relying site that may alter the IRB of record's decision to accept IRB oversight for the relying site or the relying site's decision to defer, such as misconduct investigations or suspension of PI privileges. This notification would be limited to events that might not otherwise be reported to the IRB of record by the study team.

GPC IRB Consortium SOP #3: Study Team and Study Team Points of Contact Responsibilities

The purpose of this SOP is to describe the responsibilities for study teams at all sites utilizing the GPIC review process. This also includes specific responsibilities for study teams from relying sites as well as the lead study team. In the event that a study team(s) does not or is unable to fulfill these responsibilities, the GPC IRBs involved in the study may determine that the study is no longer eligible for oversight by a single IRB of record.

1. **Study Team Responsibilities:** Study team responsibilities from all sites participating in a GPC study include (but are not limited to) the following:

- 1.1 Each GPC institution has its own policies governing human subjects research, including responsibilities of PIs and key personnel at that site. Study teams participating in a GPC study must adhere to their own institutions policies governing human subjects research, in addition to the policies of the IRB of record.
- 1.2 Ensuring that all study team members complete and maintain current human subjects research training certification as required by their institution.
- 1.3 Adhere to the requirements of any ancillary committees (e.g., conflict of interest, biosafety) at each study team's institution, as applicable. If ancillary committee review is required, this may need to be completed before IRB oversight can be deferred to another IRB.
- 1.4 Ensuring that all budgetary and contractual issues relevant to the conduct of the study are resolved before starting the research.
- 1.5 Ensuring required agreements for data or sample/specimen transfer (e.g., data use agreements, material transfer agreements, etc.) are in place prior to receiving or transferring samples/specimens.
- 1.6 Providing the sponsored programs office at the study team's institution with documentation that IRB oversight for a study has been deferred to and approved by an IRB external to their institution.
- 1.7 Study teams cannot begin any research activities for a study deferred to a single GPC IRB until the IRB of record has formally agreed to assume IRB oversight for that site and the IRB of record has approved the site's involvement in the research. In addition, all local institutional requirements must be met for each site before research activities can commence.
- 1.8 After the IRB of record has approved a site's involvement in a study, the study team at that site must adhere to the IRB of record's decisions and determinations, including using only those study documents (e.g., consent and authorization documents) approved by the IRB of record.
- 1.9 Reporting to the IRB of record any changes (including funding changes and personnel changes), reportable events, and continuing review progress reports in accordance with the IRB of record's policies and procedures.

2. **Responsibilities of Study Teams from Relying Sites:** Study teams from sites which decide to rely on a single IRB of record for a GPC study have responsibilities that include (but are not limited to) the following:

- 2.1 Each relying site's study team will designate a single point of contact (POC). The primary role of the POCs is to serve as the single point of contact for their study team throughout the GPIC review process and after the study has been approved by the IRB of record.
- 2.2 Promptly responding to questions or requests for information from the lead study team as well as any GPC IRBs.
- 2.3 Each relying site's study team will be responsible for drafting consent documents using the IRB of record's template and including the applicable institutionally required language (e.g., compensation for injury, who to contact with questions) from that relying site.
- 2.3 Participating in GPIC conference calls regarding a study as requested. Typically only the study team's POC will need to participate in such calls.
- 2.4 Upon request, provide access to study records for audit by the relying site's institution, the IRB of record's institution, and other regulatory or monitoring entities.
- 2.5 Following applicable GPC IRB Consortium policies and procedures regarding the reliance review process.
- 2.6 Reporting to the lead study team any changes (including funding changes and personnel changes), reportable events, and information applicable for continuing review progress reports in accordance with the IRB of record's policies and procedures.

3. Responsibilities of the Lead Study Team: The lead study team will typically be the study team affiliated with the institution serving as IRB of record for a GPC study. In addition to the responsibilities noted above, the lead study team's responsibilities include (but are not limited to) the following:

- 3.1 If no other coordinating center is identified for the study, the lead study team will be expected to serve this role. This includes coordinating communication across sites throughout the course of the study and ensuring that all participating sites are provided with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- 3.2 The lead study team will designate a single point of contact (POC) whose responsibilities will include promptly responding to questions or requests for information from the study teams at relying sites as well as any GPC IRBs.
- 3.3 Assist study teams from relying sites in ensuring consent documents use the IRB of record's template form and including the applicable institutionally required language (e.g., compensation for injury, who to contact with questions) from each relying site.
- 3.4 Notify other study team POCs of all IRB of record determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
- 3.5 Participating in GPIC conference calls regarding a study as requested. Typically only the study team's POC will need to participate in such calls.
- 3.6 Upon request, provide access to study records for audit by the relying site's institution, the IRB of record's institution, and other regulatory or monitoring entities.

3.7 Obtain information from relying sites regarding local variations in study conduct, such as in regard to recruitment materials and process, consent process, and subject identification processes.

GPC IRB Consortium SOP #4: Access to IRB and Study Documents

This document describes the procedures to be followed regarding access to IRB and study documents after the reliance decisions have been finalized and a GPC study has been approved by the IRB of record.

1. Access to Documents Upon Request: In accordance with the GPC IAA, the IRB of record will provide access to the relying site(s) to any IRB documentation and study documents upon request by the relying site(s) within a reasonable timeframe.
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GPC IRB Consortium SOP #5: Review of Initial Review Applications and Consent and Authorization Documents

This document describes the procedures to be followed regarding review of initial applications for new studies as well as consent and authorization documents.

1. **Initial review**: The IRB of record will conduct review of initial applications for new studies in accordance with the GPC IAA and its own policies and procedures. Unless an issue is discovered in the course of review of the application that requires input from the relying IRBs, the IRB of record will not provide any direct communication to the relying IRBs regarding the initial review of the application except as described below:

1.1 Upon approval of the study, the lead GPIC point of contact (POC) will email the GPIC POCs from the relying sites to inform them that the study has been approved

2. **Consent documents**

2.1 **Overview**: A GPC study for which a consent document is required will use the consent template of the IRB of record for all relying sites for that study. The approved consent documents will be stamped by the IRB of record using its stamp. The IRB of record will determine the content of the consent document except for those sections for which relying sites must provide their institutionally-required language. These sections are:

- Compensation for injury
- Costs
- Who to contact with questions about the study

Each GPIC institution will provide its required language for these sections via a document uploaded to the GPIC website. Each GPIC institution is responsible for ensuring its required language is kept current and for notifying other GPIC POCs if its required language has been updated.

2.2 **Responsibilities for Drafting Consent Documents**: The lead study team for a GPC study is responsible for assisting the study team for each relying site in drafting a consent document that meets the requirements for that site.

2.3 **Reviewing for Locally Required Language**: The IRB of record is responsible for ensuring that the locally required language for each relying site is incorporated into each site's consent document. The IRB of record will rely on the language provided by each site that is available on the GPIC website. Relying sites will not review the consent document(s) for their sites unless specifically requested in the reliance checklist.

4. **Authorization Documents**: The IRB of record will utilize the GPC authorization template for all sites.

GPC IRB Consortium SOP #6: Reportable Events, Suspensions, Terminations, and Other Notifications

This document describes the procedures to be followed regarding review of reportable events (e.g., noncompliance, unanticipated problems), suspensions, and terminations after the reliance decisions have been finalized and a GPC study has been approved by the IRB of record. It also includes other notifications (e.g., scientific misconduct, suspension of FWA) required by the GPC IRB authorization agreement (IAA). The IRB of record will conduct reviews of reportable events, suspensions, and terminations in accordance with the GPC IAA and its own policies and procedures. The communication process between the IRB of record and a relying institution regarding these types of events is described below.

NOTE: Policies and procedures regarding reportable event vary across GPC institutions. For the purposes of the GPC IAA, study teams from sites electing to rely on a single IRB of record for a study will follow the IRB of record's policies and procedures for reportable events unless otherwise indicated by the relying institution(s) in the reliance checklist.

1. **Noncompliance and Unanticipated Problems**: Reports of noncompliance and unanticipated problems for GPC studies will be submitted to and reviewed by the designated IRB of record in accordance with its own policies and procedures. Upon becoming aware of such a report, the IRB of record will notify and work with any relying institution(s) involved in or affected by the report as follows:

- 1.1 The lead GPIC POC will promptly inform the GPIC POC(s) from relying institution(s) of reports of noncompliance and unanticipated problems occurring at or involving that institution, even if information gathering by the IRB of record regarding the report is ongoing.
- 1.2 As needed, the lead GPIC POC may request assistance from the relying institution's GPIC POC in gathering information about the reported event.
- 1.3 The lead GPIC POC will notify the POC(s) from the affected relying institution(s) of the IRB of record's determination regarding the reportable event, including any plans for reporting to regulatory bodies (e.g., OHRP, FDA).
- 1.4 In the event that reporting to regulatory bodies is required, the IRB of record will provide the relying institution(s) with opportunity to review and provide input on such reports before they are sent to any regulatory body.
- 1.5 The relying IRB(s) remains responsible for ensuring that any additional actions regarding the reportable event are taken as required by that institution's policies and procedures.

2. **Serious Adverse Events, Deviations, Subject Complaints, and Other Types of Reportable Events**: Reports of serious adverse events, deviations, subjects complaints and other events for GPC studies will be submitted to and reviewed by the designated IRB of record in accordance with its own policies and procedures. If such a report is found to potentially constitute noncompliance or an anticipated problem, the IRB of record will notify and work with any relying institution(s) involved in or affected by the report as described in point 1 above.

3. Suspensions and Terminations: The IRB of record will suspend or terminate studies in accordance with the GPC IAA and its own policies and procedures. The IRB of record will notify by email all relying IRBs within 1 business day of any suspensions or terminations. In the event of a suspension, the IRB of record will determine whether it can continue to accept IRB oversight for the relying institutions and will notify those institutions of its decision. If the IRB of record agrees to retain oversight, each relying institution will then determine whether it will continue to defer IRB oversight for the study.

4. Additional Notifications Required by the GPC IRB Authorization Agreement (GPC IAA): In addition to the events described above, the GPC IAA requires the IRB of record and the relying IRBs to provide additional notifications regarding specific events as described below. In each of these cases, the GPIC POC will facilitate the required notifications in consultation with the appropriate individuals at his/her institution. Due to variations in administrative personnel and structures across GPC institutions, the precise process for conducting these notifications will remain at the discretion of the affected institutions.

4.1 Scientific Misconduct: Both the IRB of record and relying institutions are responsible for immediate notification regarding allegation of scientific misconduct. For the purposes of this SOP, immediate may be understood to mean within 1 business day.

Immediate notification is required as follows:

4.1.1. The IRB of record will immediately notify the relying institution(s) of any allegations of scientific misconduct involving the relying institution(s) investigator or study team members.

4.1.2 The relying institution(s) will immediately notify the IRB of record of any allegations of scientific misconduct involving its investigators or study team members that may potentially affect the safety of subjects in the study for which the IRB of record is providing IRB oversight.

4.2 FWA/Accreditation Status and Other Legal Issues: Both the IRB of record and relying institutions are responsible for notifications regarding changes to FWA or accreditation status as well as legal actions related to the research as follows:

4.2.1 The IRB of record will immediately notify the relying institution(s) of any changes to the IRB of record's FWA or accreditation status.

4.2.2 The relying institution(s) will promptly notify the IRB of record of any events or actions affecting the relying institution(s) compliance, such as FWA or accreditation status.

4.2.3 Both the IRB of record and relying institutions are responsible for notifying each other regarding legal actions related to the study for which the IRB of record is providing IRB oversight.

4.3 Suspension or Restriction of Principal Investigator: The relying institution(s) is responsible for immediately notifying the IRB of record of suspension or restriction of principal investigator status to conduct human subjects research at the relying institution.

4.4 Change in Acceptance of Reliance: Relying institutions are responsible for notifying the IRB of record if they no longer wish to rely on the IRB of record for review of a study.

5. Change in Study Team Member Conflicts of Interest Related to the Study: Relying institutions are responsible for notifying the IRB of record of changes in study team member conflicts of interest that are not already being reported to the IRB of record via a protocol amendment or other process. The IRB of record and relying institution(s) reporting the change in conflict of interest will then consult regarding next steps on managing the new conflict of interest (including reverting IRB oversight for the relying institution back to that institution).

GPC IRB Consortium SOP #7: Review of Continuing Reviews and Amendments

This document describes the procedures to be followed regarding continuing reviews and amendments after the reliance decisions have been finalized and a GPC study has been approved by the IRB of record.

1. Continuing review: The IRB of record will conduct continuing reviews in accordance with the GPC IAA and its own policies and procedures. Unless a reportable event is discovered in the course of review of the continuing review, the IRB of record will not provide any direct communication to the relying IRBs regarding the continuing review except as described below:

1.1 In the event a continuing review is submitted after IRB approval for the study expires, the lead GPIC POC will notify all GPIC POCs from the relying sites via email of the lapse in IRB approval and any corrective action plans.

2. Amendments: The IRB of record will conduct reviews of amendments in accordance with the GPC IAA and its own policies and procedures. Unless a reportable event is discovered in the course of review of the amendment, the IRB of record will not provide any direct communication to the relying IRBs regarding the amendment except as described below:

2.1 If any changes are made to the PI or key personnel from a relying site, the lead GPIC POC will contact the GPIC POC from that site to ensure these personnel meet the institutional requirements for the relying sites before the amendment is approved.

2.2 If any changes are made that appear to affect any state law or local context issues a relying site noted in its reliance checklist, the lead GPIC POC will contact the GPIC POC from that site for consultation on these issues as needed before the amendment is approved.

2.3 If any changes are made that indicate a new, potential conflict of interest, the lead GPIC POC will contact the appropriate GPIC POC(s) from the relying site(s) for consultation.

2.4 If a new GPC site(s) is being added via amendment, the GPIC reliance review process will be followed.