GUIDELINE FOR COORDINATING CENTER STUDIES

Federal guidelines direct the Research Subjects Review Board (RSRB) to review ‘coordinating center’ activities (i.e., administrative processes and oversight responsibility) when the University of Rochester (UR) is coordinating multi-center collaborative research. The RSRB reviews several types of multi-center studies overseen by a ‘coordinating center’. The guidance below defines these types of multi-center studies and provides information for:

- Developing protocols to include the roles and responsibilities of parties involved in coordinating center studies;
- Overseeing and conducting coordinating center activities; and
- Preparing for initial and ongoing RSRB review of coordinating center protocols.

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Definitions:

Coordinating Center – an individual or group of individuals responsible for oversight and management of the conduct of a multi-center study at all collaborating intuitions. A coordinating center may be designated by the study sponsor or by mutual agreement among participating sites.

Lead Principal Investigator (PI) – the individual with primary responsibility for oversight and management of the conduct of the study at all participating research sites.

Site PI – the individual at each site who agreed to participate in the multi-center study and is responsible for the oversight of the conduct of the study at his or her center.

Protocol Documents – materials including the study protocol (see section on The Coordinating Center Protocol), operations manual (if applicable), model consent form(s), recruitment material, and any other documents pertinent for IRB review and approval.

Research Events – an incident, experience, or outcome that occurs during the conduct of a research study that may require reporting to the IRB, Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and/or the Sponsor.
**Types of Coordinating Center Studies**

Generally, the RSRB recognizes four different types of coordinating center studies:

1. UR is the coordinating center, and the lead PI of the coordinating center is affiliated with the UR, but there is a separate UR enrolling site PI.

2. UR is the coordinating center, and the lead PI of the coordinating center is affiliated with the UR and is also the enrolling site PI.

3. UR is the coordinating center and the lead PI is un-affiliated with the UR.

4. UR acts as a data coordinating center and is responsible only for the collection and storage of data collected from enrolling sites involved in multi-center trials (the lead PI and overall coordinating center are un-affiliated with the UR).

**NOTE:** The RSRB recognizes that, in some cases, a small number of sites may conduct the same study separately and then combine the data for final analysis, with no one site acting as a coordinating center. As long as the University of Rochester site is not overseeing the conduct of the study at other institutions or managing the data collected at other institutions, the RSRB does not require that the study protocol and/or application address coordinating center activities.

**Responsibilities of a Coordinating Center**

The design of a coordinating center study may range from a minimal risk, observational study conducted at a small number of institutions to a phase III, greater than minimal risk study conducted at a large number of institutions internationally. Likewise, the role of the coordinating center may range from overseeing the entire conduct of the study (e.g., protocol development, project management, data management) to responsibility for only limited portions of study oversight (e.g., collection and storage of study data only). Therefore, depending on the nature of the study and the coordinating center’s role in the project, some oversight responsibilities addressed in this guidance may not apply. There may also be additional reporting and monitoring considerations required by the Food and Drug Administration (FDA), the study sponsor and/or international regulations that are not addressed here.

 Generally, the responsibilities of a coordinating center include working with the lead PI to complete the following:

1. **Responsibilities Prior to Study Initiation**
   - Develop and refine the protocol documents.
   - Obtain approval of protocol documents, including model consent form(s), from the coordination center IRB prior to distribution to the enrolling sites.
   - Oversee the development and design of data collection methods, e.g., case report forms.
   - Establish a method for data collection, maintenance and analysis.
• Establish subcontracts with enrolling sites, contract research organizations, central laboratories, imaging service providers, and others as appropriate.
• Assess enrolling sites to verify the site PI and study staff, as appropriate, are qualified in education, training and experience to conduct the study and to ensure the site has adequate resources (e.g., time, staff, space, etc.) to carry out study procedures.
• Develop data and safety monitoring plan to ensure the safety of study subjects
• Develop a method for supplying, handling and accounting for investigational products (drugs/devices/biologics).
• Establish a plan to monitor the conduct of the study.
• Document each enrolling site has a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP).
• Ensure each enrolling site obtains IRB approval and has an executed sub-contract prior to the initiation of subject enrollment.
• Collect all required regulatory documents (see section on Essential Study Documentation below).
• Provide enrolling site staff training on all aspects of study conduct, as applicable.

The FederalWide Assurance:

A FederalWide Assurance (FWA) is an agreement between an institution and the U.S. Department of Health and Human Services (DHHS) Office of Human Research Protection (OHRP). The assurance is the institution’s written confirmation to the federal government that it will comply with regulations and principles pertaining to the ethical treatment of human research subjects. Without this assurance, an institution cannot conduct federally-funded research. If the terms are not honored, all federally-funded research at an institution can be shut down by the government.

When the University of Rochester is acting as a coordinating center, the study team must ensure that all participating sites have a current FWA, or equivalent per sponsor requirements for non-federally funded research. A copy of the University’s most recent FWA can be found on the Office for Human Subject Protection’s homepage.

2. Responsibilities During the Conduct of the Study

• Ensure all approved, amended protocol documents are distributed to enrolling sites and approved by enrolling site IRBs prior to initiation of the changes.
• Maintain a regulatory file for the coordinating center, as well as, for each enrolling site (see section on Essential Study Documentation below).
• Monitor subject enrollment and participation.
• Ensure informed consent is obtained from each subject and consent is in compliance with federal, state and local regulations, as well as, the study protocol.
• Ensure compliance with the study protocol (including timely reporting of all research events) and data validity and integrity.
• Convey study-related information to enrolling sites, sponsors, and study-specific committees, as needed.
• Respond to enrolling site protocol inquires and questions.
• Provide enrolling site staff continued training on the conduct of the study, as necessary.

3. Responsibilities at the Time of Study Completion

• Ensure all enrolling sites are notified when, a) enrollment is complete, and b) all study-related activities are complete.
• Verify each enrolling site closes the study with their IRB.
• Ensure the data set and any stored samples are appropriately de-identified or coded and managed per the study protocol.

For additional information regarding the responsibilities of coordinating centers, please refer to the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. Note that coordinating center responsibilities are identified in this guidance document as “Sponsor” responsibilities (Section 5).

The Coordinating Center Protocol

The protocol must address how the lead PI and coordinating center will assume responsibility for the overall conduct and management of the study, including the responsibilities listed above. This information may be included within the main study protocol or provided as a separate addendum. In developing the protocol (or coordinating center specific addendum), consider the following:

• What is the organizational structure of the coordinating center? Are there separate committees responsible for administrative duties, protocol development, site monitoring, safety monitoring, data analysis, etc? Will any responsibilities be delegated to other institutions or agencies (e.g., data management or specimen storage)? If so, the responsibilities allocated to separate committees and/or entities must be clearly identified.

• What training will be provided to enrolling site staff? Will there be study meetings, teleconferences or training sessions required for staff at enrolling sites prior to protocol implementation and throughout the course of the study?

• How will the coordinating center manage and/or monitor each site’s study conduct including enrollment, research events, withdrawals and protocol deviations? How will sites report this information to the coordinating center? Will monitoring visits be conducted? If so, how often? What will the site monitoring visits entail?

• If investigational products (drugs/devices/biologics) will be used, how will they be provided to each enrolling site? How will dispensing will be monitored? What investigational product accountability procedures will be implemented?

• What are the procedures for study closures and early site terminations?

Distribution of Study Documents to Enrolling Sites and Obtaining Enrolling Site IRB Approval
Protocol documents (submitted both at the time of initial approval and via amendment) should be submitted and approved by the coordinating center’s IRB prior to distribution to enrolling sites. Once enrolling sites receive the study documents, they then must submit applications to their respective IRB for approval prior to initiation of the study at their site. Additional information regarding RSRB review of coordinating center studies is provided below.

Any changes to protocol documents requested by the enrolling site and/or their IRB should be reviewed and approved by the coordinating center prior to re-submission to the enrolling site’s IRB. Any substantive changes to study documents by the enrolling site should be appropriately justified. Every effort should be made to avoid changing the protocol for individual enrolling sites; however, in certain circumstances it may be appropriate for sites to include site-specific addendums in order to comply with their institution’s policies and procedures. Editorial changes to the consent form are also generally permissible as long as they do not change the content or intent of the document.

Once the study and/or amendment has been approved by the enrolling site IRB, a copy of the approval notification and all related approved study documents must be provided to the coordination center prior to initiation of the study at the enrolling site.

**Monitoring Coordinating Center Studies**

The purpose of monitoring is to:

- Ensure the rights and welfare of human subjects are protected;
- Ensure the study is conducted in compliance with the approved study protocol, federal regulations and sponsor requirements; and
- Ensure data validity and integrity.

Federal regulations (21 CFR Part 312 Subpart D and 812 Subpart C) require that studies conducted with an Investigational New Drug (IND) application or Investigational Device Exemption (IDE) be monitored by the sponsor. Studies not conducted under an IND or IDE should implement a monitoring plan that is appropriate to the nature and risk level of the study to ensure best practice in research, and may reference those regulations as guidance.

Per FDA guidance, the plan should address methods for monitoring the study, procedures for reviewing data and reporting research events, approaches for managing non-compliance and methods for communicating monitoring activities. The nature and extent of a monitoring plan should be based on the needs of the study. Typically, monitoring plans for large scale, greater than minimal risk studies include a combination of in-person visits to enrolling sites (prior to the start of the study, periodically throughout the course of the study and at study closure) and remote evaluations throughout the conduct of the study. Smaller scale studies may monitor in the same manner, though to a lesser extent based on the study needs.

In developing the monitoring plan, consider the study objectives, study design, endpoints, risks related to the intervention, sample size and complexity of the study population. The primary focus of the monitoring plan should be on preventing and mitigating risks and errors related to the elements of the protocol that are most crucial for achieving the study objectives. These elements may include:
• Verifying informed consent was obtained prior to initiation of study procedures using a current, IRB-approved consent document
• Assessing protocol compliance, including adherence to study eligibility requirements, enrollment rates and investigational product accountability
• Determining whether any/all research events have been reported appropriately
• Reviewing data collection tools (i.e., case report forms) for completeness, consistency and accuracy, including source verifying the data provided
• Assessing whether the enrolling site is maintaining all essential study documentation (see below)

Documentation of monitoring should be maintained by the coordinating center (e.g., a monitoring report) and include the following at minimum: the date of monitoring activities; a summary of the monitoring activities conducted; descriptions of any noncompliance, data integrity or other discrepancies identified during monitoring; and a description of any actions taken to address the aforementioned issues.

Templates for tracking IRB submissions and site set up are included in Appendix 1. Additional templates for tracking adverse events, protocol deviations, communications and training at enrolling sites are provided in the OHSP Study Documentation Tool Box. Use of these templates (aside from the “Site Regulatory Document Tracking Spreadsheet” described below) is not required by the RSRB; rather, they are provided as a resource for developing and carrying out the monitoring plan. The information that is required for initial and continuing review is discussed below under Ongoing RSRB Review of Coordinating Center Studies.

For additional information regarding monitoring, please refer to the FDA’s Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines (Sections 5 and 8).

**Essential Study Documentation**

Coordinating centers are responsible for maintaining essential documentation for the coordinating center, as well as all enrolling sites. Essential documents are those that permit the conduct of the study and demonstrate compliance with the protocol and regulatory requirements. These documents include, but are not limited to:

• Dated IRB approval notifications for all coordinating center and enrolling site protocols, informed consent forms, recruitment materials and case report forms (including initial approvals, amendments and progress reports)
• Dated regulatory/ancillary committee approvals, authorizations and notifications
• Approved versions of all protocols, informed consent forms, recruitment material and case report forms
• Signed clinical trial agreements between all involved parties
• Evidence of investigator(s) qualifications, e.g., a signed/dated curriculum vitae
• Investigational product label samples, handing instructions, shipping records and accountability records
• All versions of the Investigator’s Brochure, if applicable
• Monitoring visit reports
• Reportable research events (e.g., serious adverse event, unanticipated problem involving risk to subjects or others)
• Relevant communications between the coordinating center and participating sites

A complete list of essential documents can be found in Section 8 of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.

**RSRB Review of Coordinating Center Studies**

All coordinating center studies conducted by the University of Rochester faculty and staff must be submitted through the RSRB Online Submission System (ROSS) for review and approval. Generally, the RSRB will conduct an expedited review of coordinating center applications; however, depending on the nature of the study and risk involved, full board review may be required. In reviewing coordinating center applications, the RSRB will confirm that the protocol identifies adequate methods for addressing the following, as appropriate:

• Process to confirm that each enrolling site has an active FWA with OHRP;
• Distribution of protocol documents to enrolling sites and ensuring all sites have the most current version(s) of these documents;
• Documentation of the review and approval of enrolling site’s initial IRB approval prior to the enrollment of subjects, as well as, all amendments and re-approvals;
• Collection and management of data from each site;
• Data and safety monitoring including the review of research events and protocol deviations from all sites;
• Training site study personnel.

Consider the following when preparing the RSRB application for review and approval prior to sending the protocol documents to the enrolling sites for IRB submission:

• When the University of Rochester is acting as a coordination center, and:
  • The lead PI is affiliated with the UR and there is a separate UR enrolling site PI: The UR lead PI should submit an application to the RSRB for the coordinating center study first. The application should include all protocol documents, as well as, a description of coordinating center activities (see section on The Coordinating Center Protocol). Upon RSRB approval of the protocol documents, the materials may be distributed to each enrolling site, at which time each site PI must then submit an application to their respective IRB. The enrolling site PI at the UR will submit a separate application to the RSRB.

  • The lead PI is affiliated with the UR and is also the enrolling site PI: For smaller scale coordinating center studies, it may be acceptable to submit one RSRB application that addresses both the coordinating center and enrolling site activities to the RSRB for review and approval. The application should include all protocol documents and the University-specific documents for subject enrollment (consent and recruitment materials). In some cases, it may be appropriate to complete two
separate RSRB applications, for example, if the study involves greater than minimal risk procedures and/or several enrolling sites. In this case, the coordinating center protocol should be submitted and approved prior to submission of the UR enrolling site protocol, as above.

- **When the University of Rochester is acting as a coordinating center, and the lead PI is unaffiliated with the UR:** The same process as the first scenario above should be followed. It is preferred that the UR submit protocol materials to the RSRB and obtain approval prior to the lead PI submitting to his/her institution; however, the coordinating center should consult with the lead PI’s IRB to determine whether an alternative process is required.

- **When the University of Rochester is acting as a data coordinating center, and the lead PI and overall coordinating center are affiliated with a separate entity:** The University of Rochester PI should submit an application for the data coordinating center after the coordinating center protocol has been approved by the lead PI’s/coordinating center IRB. The application must clearly identify the UR’s responsibilities and include a study protocol that includes detail about the data coordinating center (see section on The Coordinating Center Protocol).

**Completing the Initial RSRB Application**

Completing the initial application presents a unique challenge to both the study team and the RSRB staff reviewing the application as portions of the application may not be applicable to coordinating center activities, depending on the nature of the study. In completing the initial application, keep the following points in mind:

- **Application, General:** Throughout the application, responses should be based on the roles/activities of the submitting coordination center. Depending on the responsibilities of the coordinating center, responses for any particular section of the application may vary or may not be applicable. For example, section 66 “Subject Recruitment”, item 66.2 of the application asks whether subjects will be recruited for the study in person and if so, how they will be approached:
  - If the study team is acting as a coordinating center only, it may be appropriate to state that enrolling sites will develop their own methods to recruit subjects and that template recruitment materials will be provided to them from the coordinating center to use at their discretion.
  - If the study is acting as both a coordinating center and enrolling site (and only 1 application for both entities is being completed), the response needs to address both activities (e.g., “Locally, subjects will be recruited at the time of a routine clinic visit with one of the study investigators. All other enrolling sites will develop their own methods to recruit subjects”).
  - If the study is acting as a data coordinating center, the question would not be applicable as the center will neither recruit subjects themselves nor oversee recruitment at enrolling sites (responding “N/A” is sufficient).
• **Application, Section 63 “Study Sites”:** Item 63.2 of the application requests copies of IRB approval letters for any non-UR facilities (i.e., enrolling sites). As the coordinating center application should be approved first, enrolling site IRB approvals will not be available. In lieu of providing IRB approval letters, provide a document that demonstrates how you will track enrolling site IRB submissions and approvals. This document should provide a tentative (or final, if possible) list of enrolling sites and identify fields for the following items at each enrolling site, applicable: site name, site number, principal investigator, assurance number (FWA) and expiration date, and IRB approval & expiration dates (see the “Site Regulatory Document Tracking Spreadsheet” template provided in Appendix 1 as an example). The identification of enrolling sites, allows the RSRB the ability to contact representatives of those site IRBs, as necessary to ensure the protection of human subjects.

• **Application, Section 64 “Subject Population”:** Item 64.3 of the application requests the total number of subjects expected to enroll, “for which you are responsible”. As the coordinating center is responsible for the conduct of the entire study, the total number of subjects expected to enroll in the study (at all enrolling sites) should be entered.

• **Informed Consent:** Model informed consent and assent forms must be submitted with the coordinating center application (upload into section 83 of the application). The documents should include all federally-required (and additional, as necessary) consent elements. If the application is meant to address both coordinating center and enrolling site activities, the model consent for external enrolling sites and a consent that will be utilized to enroll subjects locally should be submitted. Alternatively, if the UR is acting as a data coordinating center only, this section would not be applicable and an informed consent form does not need to be included in the submission (i.e., all responses to item 83.1 would be “no” and item 83.2 would be “not applicable”). The RSRB will provide an RSRB approved model consent template, stamped as “model consent”, for the coordination center files. The unstamped approved version(s) should be provided to enrolling sites and used as a template for the creation of their site’s consent forms. The enrolling sites should be made aware of the following information pertaining to their site’s consent:

  o Local IRB changes to the sample consent to comply with institutional requirements are permissible and editorial changes to the consent may be made as long as they do not change the information or intent. Any substantive modification of the sample consent information related to risks or alternative procedures must be appropriately justified to the coordination center.

  o Any changes requested by an enrolling site must be reviewed and approved by the coordination center prior to site IRB approval.

  o All site IRB approved consents must be received by the coordination center prior to subject enrollment at the site(s).

• **Investigational Products:** If the study involves an investigational product, documentation of either FDA approval or exemption will be required prior to RSRB approval. In the event that an IND application has been filed and the 30-day waiting period has passed without receipt of approval documentation from the FDA, a memo from the sponsor...
documenting that the 30-day waiting period has passed and that no clinical holds have been implemented by the FDA may be sufficient.

If you are unsure how to complete the application based on your coordinating center activities, please contact your RSRB Specialist.

**Ongoing RSRB Review of Coordinating Center Studies**

1. **Amending Coordinating Center Studies**

Any changes to the protocol, model informed consent form or other study documents must be submitted to the RSRB for review and approval prior to distribution to enrolling sites. It is recommended that amendments be numbered sequentially and identified by version dates to ensure proper document tracking. As with the initial review of the study, the RSRB will typically conduct an expedited review of amendments; however, depending on the nature of the modification and risk involved, full board review may be required.

In certain circumstances, administrative changes (e.g., adding enrolling sites, modifying enrolling site information on recruitment materials, updating contact information, minor editorial changes to model consent documents) may be made without RSRB approval, but these changes should be submitted with the next formal amendment. Prior to making these changes, please verify with your RSRB Specialist whether formal review and approval of the change is required.

2. **Reviewing Reportable Research Events for Coordinating Center Studies**

- Reportable research events that occur at the UR enrolling site should be reported by the UR enrolling site PI according to **Policy 801 Reporting Research Events** and **RSRB Guideline for Reporting Research Events** at the time the event occurs and by the coordination center in summary at the time of continuing review.

- Research events that occurred at non-UR sites that were reported to the external IRB of record should be reported in real time to the RSRB for acknowledgement using the ‘Reportable Event’ form in the RSRB On-line Submission System (ROSS). Note, however, that it is the responsibility of the IRB of record for the non-UR site to make review determinations for the event occurring at the respective site (e.g., determination of an unanticipated problem involving risk to subjects or others). The real-time reporting of events, allows the RSRB to communicate with the enrolling site IRB, as necessary, to ensure the protection of human subjects.

- When there is an RSRB application for the coordination center and a separate RSRB application for the UR enrolling site, non-reportable research events should be submitted in summary at the time of the coordination center continuing review (reporting across all sites) and separately at the time of the UR site continuing review (reporting just for the UR site).
• When there is one RSRB application for both the coordination center and the UR enrolling site, non-reportable research events across all sites (including UR site) should be submitted in summary at the time of the coordination center continuing review.

• When the University of Rochester is acting as a data coordinating center only: Research events do not need to be submitted at any time, unless related to the UR’s responsibilities as the data coordinating center, e.g., breach of confidentiality. In this case, the event should be reported according to Policy 801 Reporting Research Events and RSRB Guideline for Reporting Research Events at the time the event occurs.

As discussed above in Responsibilities of a Coordinating Center, while reporting research events may not require immediate notification to the RSRB, it is the coordinating center’s responsibility to ensure that events are appropriately reported to the enrolling site’s IRB, the study sponsor, and the Food and Drug Administration as needed. Depending on the nature of the event, the coordinating center may also need to determine whether any corrective or preventative action plan is required and whether all enrolling sites need to be notified of the event.

3. Submitting Progress Reports for Coordinating Center Studies

The RSRB is required to conduct continuing review at least annually. At that time, the RSRB will review the progress of the study including enrollment, subject concerns or withdrawals, findings and any reportable research events, problems and/or complications that occurred during the previous year. In completing the progress report, please keep the following points in mind:

• Section 2 “Active Study”: The Site Regulatory Document Tracking Spreadsheet originally uploaded into section 63 of the initial application must be updated with current enrolling sites, IRB approval dates, etc., and provided in item 2.7 of the progress report. Ensuring the coordination center includes an up-to-date spreadsheet of enrolling sites, allows the RSRB the ability to contact representatives of those site IRBs, as necessary, to ensure the protection of human subjects.
  o If the RSRB application is for both the coordinating center and the enrolling site, check the box appropriate for the enrollment status of the enrolling site, check 2.7 for “Multi-site Coordination Center study”, and upload the updated site regulatory spreadsheet as indicated above.

• Section 3 “Enrollment and Demographic Information”: An enrollment report identifying the total enrollment across all enrolling sites, including a breakdown of enrollment at each site, should be provided in item 3.1 of the progress report.
  o The information provided in items 3.2 – 3.5 should reflect the total enrollment across all enrolling sites at the time of the annual report.
  o If the RSRB application is for both the coordinating center and the enrolling site, an enrollment report identifying the total enrollment as stated above should be uploaded into section 3.1, and sections 3.2 – 3.5 should be specific to the site enrollment at the UR.
• Section 5 “Subject Concerns or Withdrawals”: All items should reflect information at all enrolling sites at the time of the annual report, as applicable.

• Section 7 “Documents Required for Re-approval”:
  o Last signed consent documents only need to be uploaded in item 7.2 of the progress if the application is addressing both coordinating center and enrolling site activities. The last signed consent documents provided should be that of the last subject enrolled at the University of Rochester.
  o Any DSMB reports and/or activity reports identifying (or providing a summary of) all reportable research events collected per the study protocol should be uploaded into item 7.5 of the progress report.
  o IRB approval letters for each enrolling site do not need to be uploaded into section 7.6 as long as these approvals have been documented in the site Regulatory Document Tracking Spreadsheet added to item 2.7 of the application.

4. Closing Coordinating Center Studies

A research study involving a coordinating center is considered complete when: all subjects have completed all study interventions; all protocol-defined analyses have been completed; post-study results have been communicated with subjects (if applicable); and all enrolling sites have closed the study with their respective IRBs per their IRB’s requirements.

To close a coordinating center application with the RSRB, submit a final progress report (on page 1 of the continuing review form, answer “no” to indicate the study should not remain open). Note that the Site Regulatory Document Tracking Spreadsheet uploaded in item 2.7 of the report should identify the IRB closure date of all enrolling sites.
APPENDIX 1: Sample Coordinating Center Worksheet Templates

**NOTE:** The following templates are provided for reference only and should be modified according to the needs of the study. Additional study documentation resources are available in the [OHSP Study Documentation Toolbox](#).

### Appendix 1.A: Site Regulatory Document Tracking Spreadsheet

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# Appendix 1.B: Site Initiation Checklist Template

## SITE INFORMATION

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**Additional Comments:**

## REGULATORY DOCUMENTS

**Have the following been obtained/completed?**

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**Additional Comments:**

## SITE TRAINING

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<td>Other (specify):</td>
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**Training Completed By:**

**Where the following items reviewed?**

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<tr>
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<th>NO</th>
<th>Additional Comments:</th>
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<tr>
<td>Background and Purpose</td>
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<tr>
<td>Study Procedures</td>
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<td>Eligibility Criteria</td>
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<td>Registration and Randomization Procedures</td>
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<tr>
<td>Informed Consent Procedures</td>
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<tr>
<td>Drug Administration &amp; Accountability</td>
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<td>Study Visits</td>
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<td>Adverse Event Reporting Procedures</td>
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<td>Treatment Discontinuation &amp; Study Withdrawal Procedures</td>
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<td>Data Collection &amp; Submission</td>
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**Additional Comments:**