Study Coordinator
Checklist for Study Submission to the IRB

Pre-Submission Requirements

All study personnel to be listed on the study must have IRB+ accounts. To obtain an IRB+ account, the following items are required. If you need assistance with this process, please contact the IRB Office.

1. Certification of Human Subject Protection Training by completing the Biomedical Research Basic/Refresher course offered by CITI. Each individual must create an account, affiliate with INTEGRIS Health and complete the training. Please note that while we strongly encourage everyone to complete the Good Clinical Practices course, it is not a requirement at this time. The following link may be used to access the CITI website: https://www.citiprogram.org/

2. Request an IRB+ account by completing the form at the following link: http://integrisok.com/institutional-review-board/registration-form.

IRB+ Application Considerations

1. **Paperless IRB:** The INTEGRIS Health IRB (IH IRB) is paperless. We utilize IRB+ to handle all study applications, study-related documents, approval letters, etc.

2. **Consent Form Requirements:** If your study has a consent form(s), it is your responsibility to submit it/them to Legal Counsel for review and approval. Any changes requested by Legal Counsel will need to be reviewed/approved by the study Sponsor. It is your responsibility to oversee this process. Once the consent form(s) receive final approval from both Legal Counsel and the Sponsor, a clean copy must be uploaded to IRB+. Please note that if it is necessary to submit a study to IRB+ prior to receiving final approval of the consent form(s), please notify the IRB Office. The IRB Coordinators will be happy to work with you to process the study request and upload the consent form(s) when they are approved. All Consent forms should be uploaded as Word documents.

3. **Uploading Documents/Forms:** As part of the study application process, you will be required to upload various documents and forms to IRB+. For each new study application and continuing review request, you must upload a signed PI Certification form and completed/signed Conflict of Interest forms. Blank copies of these forms are available within IRB+. If you encounter any problems either uploading items to IRB+ or obtaining blank copies of forms, please contact the IRB Office.

4. **Study Closures:** When a study is completed, please use the Continuing Review request to submit study closure information.

5. **Type of Review Being Requested:** At this time there are three types of Initial Study applications and Continuing Review requests: review by INTEGRIS Health IRB, ratification of a study approved by a Central IRB; ratification of a study approved by the

NCI CIRB. Please note that any study going to a Central IRB (CIRB) or the NCI CIRB **must have** received permission from the IRB prior to being submitted to an outside entity. Please refer to the *Central IRB* policy (SYS-IRB-102) or the *National Cancer Institute Central IRB* Policy (SYS-IRB-101) for additional information. If you are unsure which type of application you need to submit, please contact the IRB Office.

Items Required for Initial Applications Going to IH IRB for Approval

1. New study application completed within IRB+
2. Protocol uploaded to IRB+
3. Consent form(s) uploaded to IRB+
4. Consent process uploaded to IRB+
5. Conflict of Interest forms for the Principal Investigator and all Sub-Investigators uploaded to IRB+
6. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators is optional)
7. Investigator Brochure (for pharmaceutical studies) uploaded to IRB+
8. Instructions for Use (for device studies) uploaded to IRB+
9. 1572 (if applicable)
10. Additional study-specific documents such as marketing materials, appointment reminder cards, etc.
11. Minor Assent (if applicable)
12. Revocation of Authorization of Informed Consent (if applicable)

Items Required for Initial Applications of Studies Approval by a CIRB or NCI CIRB

1. New study application completed within IRB+
2. Protocol approved by the CIRB/NCI CIRB uploaded to IRB+
3. Consent form(s) approved by the CIRB/NCI CIRB uploaded to IRB+
4. Conflict of Interest forms for the Principal Investigator and all Sub-Investigators uploaded to IRB+
5. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators is optional)
6. Approval Letter issued by CIRB/NCI CIRB uploaded to IRB+
7. Minor Assent (if applicable)
8. Revocation of Authorization of Informed Consent (if applicable)

Items Required for Continuing Review of Study Previously Approved by IH IRB

1. Continuing Review request completed within IRB+
2. Clean, unstamped Consent form(s) uploaded to IRB+
3. Current signed and stamped Consent form(s) (de-identified) uploaded to IRB+
4. Conflict of Interest forms for the Principal Investigator and all Sub-Investigators uploaded to IRB+
5. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators is optional)

Items Required for Continuing Review of Study Previously Approved by CIRB/NCI CIRB

1. Continuing Review request completed within IRB+
2. Consent form(s) approved by the CIRB/NCI CIRB uploaded to IRB+
3. Conflict of Interest forms for the Principal Investigator and all Sub-Investigators uploaded to IRB+
4. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators is optional)
5. Approval Letter issued by CIRB/NCI CIRB uploaded to IRB+

Items Required for Amendment to Study Previously Approved by IH IRB

1. Amendment application completed within IRB+
2. If change is requested by Sponsor, summary of changes list and documents changed (i.e. Consent form(s), Protocol, Advertising material, etc.) uploaded to IRB+
3. If change is to list of Investigators, Conflict of Interest forms for the investigators being added uploaded to IRB+
4. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)

NOTE: You do not have to submit amendment information for studies approved by CIRB/ NCI CIRB. Any amendments will be handled by the CIRB/NCI CIRB.

Items Required for UPIRSOs (Unanticipated Problems Involving Risk to Subjects or Others)

1. Adverse Event application completed within IRB+
2. If external UPIRSO, report from Sponsor uploaded to IRB+
3. If internal UPIRSO, report to Sponsor uploaded to IRB+
4. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)

NOTE: For studies approved by CIRB/NCI CIRB, internal UPIRSOs must be reported to the IH IRB; however, it is not necessary to report external UPIRSOs.

Items Required for Protocol Deviation to Study Previously Approved by IH IRB

1. Unanticipated Problems application completed within IRB+
2. Report to Sponsor uploaded to IRB+
3. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)

NOTE: You do not have to submit protocol deviation information for studies approved by CIRB/ NCI CIRB. Any protocol deviations will be handled by the CIRB/NCI CIRB.

Items Required for Informational Item to Study Previously Approved by IH IRB

1. Informational Items encompass Data Safety Monitoring reports, SUSAR reports, Annual reports and any informational items from the Sponsor. These are items that need to be reviewed and acknowledged by the IH IRB, but do not need approval from the IH IRB. I
2. Unanticipated Problems application completed within IRB+
3. Report/Document/Item from Sponsor uploaded to IRB+
4. Principal Investigator certification form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)

NOTE: You do not have to submit informational items for studies approved by CIRB/ NCI CIRB. Any informational items will be handled by the CIRB/NCI CIRB.

Items Required for Study Closure of Study Previously Approved by IH IRB

1. Continuing Review application with study closure date completed within IRB+
2. Final reports and/or publications, if any, uploaded to IRB+
3. Principal Investigator study closure form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)

Items Required for Study Closure of Study Previously Approved by CIRB/NCI CIRB

1. Continuing Review application with study closure date completed within IRB+
2. Final reports and/or publications, if any, uploaded to IRB+
3. Principal Investigator study closure form uploaded to IRB+ (signatures from Sub-Investigators are not necessary)
4. Study Closure Approval Letter issued by CIRB/NCI CIRB uploaded to IRB+

If you have any questions or need additional information, please contact the IRB Office at 405.949.4184 or 405.713.7762 or via e-mail at irb@integrisok.com