OUR COMMITMENT

As a partner in the human research endeavor, the USC Institutional Review Board is committed to protecting the rights and welfare of all human research participants and facilitating research efforts undertaken by USC faculty, staff, and students, and members of the LAC+USC community. This is accomplished by ensuring that the principles of the Belmont Report and federal, state, and local laws and regulations, as well as USC policies are adhered to by all study personnel.

To ensure all submissions to the USC IRBs are reviewed efficiently and thoroughly, we offer the following guidelines. Follow them carefully. Submissions that do not adhere to the basic guidelines described below will be returned without review. For questions and clarifications to the guidance, please contact the IRB.

NEW STUDIES

Submissions that do not adhere to the basic guidelines described below will be returned without review. For questions and clarifications to the guidance, please contact the IRB via email (irb@usc.edu).

1) Plan Ahead
   a) It is the responsibility of the researcher/study team to submit their application with adequate time to allow the application to wait in queue, be assigned to a staff member, respond to contingencies, etc.
   b) Check the “Current IRB Wait Time” table on the OPRS homepage to see the estimated time to assignment to an IRB analyst.
   c) Frequently check the “Tip of the Week” on the OPRS/IRB website to see if there is any new information that might facilitate your submission.

2) Protocol
   a) A protocol is required with each new study submission and must be uploaded at #5.2 in the iStar application. (Please note that a grant application cannot serve as the protocol.)
   b) Use the appropriate protocol template (Social Behavioral, Biomedical or Secondary Analysis Protocol) located on the “Forms and Template” section of the OPRS/IRB website. Use of an incorrect protocol will result in the application being returned as incomplete.
   c) When feasible, the protocol should be written in language that reviewers from various disciplines will understand. The IRB encompasses a wide breadth of reviewers in various disciplines, and not all reviewers are scientists or experts in the investigator’s field of expertise.
   d) The protocol must include sufficient information for the IRB to determine the type of study review needed.
   e) Complete all relevant sections of the protocol template to ensure sufficient information is provided to the IRB. Incomplete protocols will be returned.
   f) Remove template instructions from the protocol.
   g) Fully describe all research activities.
      i) Include calendars (e.g., a schedule of events) and/or tables to visually represent timing and frequency of research activities, especially for biomedical studies.
      ii) When the study involves an intervention(s), clearly delineate if the intervention is a research activity or would occur irrespective of research participation.
   h) Ensure inclusion/exclusion criteria are explicit.

3) iStar Application
a) Make sure the names of all documents are consistent in the protocol and iStar application. (e.g., use “Quality_of_life_questionnaire V5_pdf” in the protocol as well as the iStar application). The document name should be representative of the document contents.

b) Submit your application to the appropriate IRB. Qualitative studies should be submitted to the Social Behavioral IRB and Quantitative studies that involve drugs or devices should be submitted to the Biomedical IRB.

c) Submit all materials required for IRB review (e.g., intervention materials, investigator brochures for device or drugs, instruments, protocol, informed consent).

d) Use the appropriate informed consent template (expedited and full board studies only). For multicenter industry sponsored studies please follow the sponsor’s informed consent template and not the USC informed consent template. Refer to the “Forms and Template” guidance on the OPRS/IRB website.

e) Ensure all applicable certifications (e.g., Human Subjects, GCP, Research HIPAA) are current for all study personnel. New applications with certifications that are missing, expired, or due to expire within 30 days will not be allowed to submit. Final approval will not be issued until all study personnel are compliant with the certification requirements and all contingencies are confirmed by the IRB Analyst (IRBA) as being fulfilled.

**AMENDMENTS**

Follow the guidelines provided below carefully to facilitate an expedient and successful amendment submission. Failure to do so will result in delays in review and approval. **Submissions that do not adhere to the basic guidelines described below will be returned without review.** For questions and clarifications to the guidance, please contact the IRB via email at irb@usc.edu.

1) **Plan ahead**
   a. It is the responsibility of the researcher/study team to submit their amendment in adequate time to allow the application to wait in queue, allow the staff member time to review and for the investigator to respond to contingencies, etc.
   b. Check the OPRS/IRB website for the “Tip of the Week” to see if there is any new information that might facilitate your submission.

2) **iStar Application**
   a. Name the changes or additions in the amendment title (e.g., Revised ICF +Site Addition).
   b. Use track changes when revising any document (e.g., consent, survey instrument, recruitment documents, protocol).
   c. When making changes to the study procedures and/or protocol, include a summary or explanation of the most significant changes and the rationale for the changes at iStar item AM8.
   d. Highlight changes that affect risk to participants or study design.
   e. Do not refer or redirect the reviewer to another document (e.g., a summary of change or the track changed protocol) instead of providing a summary.
f. For industry studies, do not copy and paste a list of itemized changes to the protocol sections. Do upload a summary of change document if provided by the sponsor.

g. Ensure all applicable certifications (e.g., Human Subjects, GCP, Research HIPAA) are current for all study personnel. Amendments with certifications that are missing, expired, or due to expire within 30 days will not be allowed to submit. Final approval will not be issued until all study personnel are compliant with the certification requirements and all contingencies are confirmed by the IRB Analyst (IRBA) as being fulfilled.

3) Informed Consent

a. When making changes to the informed consent document, include a summary or explanation of the most significant changes in the response to iStar item AM5.

b. If revising the informed consent for industry sponsored studies, do not cut and paste large blocks of text into your informed consent. The consent must be carefully edited line by line so the IRB can quickly identify and verify the changes. This is especially important when updating the risk section.

c. For industry sponsored studies, upload the sponsor’s revised Informed Consent template (with track changes) at iStar #5.3.

SIMPLE AMENDMENTS

Simple amendments are iStar amendments that involve changes that are not complex in nature and can be reviewed quickly. If there are no more than two “simple” changes in a single amendment, the IRBA may pull it from the queue (within 3 business days) for quick approval. Submissions that do not adhere to the basic guidelines described below will be returned without review. For questions and clarifications to the guidance, please contact the IRB via email (irb@usc.edu).

➢ The number of simple amendments will be limited to one simple amendment per study within any 15-day window.

➢ Abuses of this simple amendment process will result in this privilege being rescinded for the study team.

➢ The IRBA will make the final decision as to what qualifies as a simple amendment.

Examples of simple amendments include, but are not limited to:

1) Changing:
   • Sample size/target accrual.
   • Funding source, where no additional changes to the application are needed.
   • Survey instruments where the changes are minor (e.g., revising pagination, adding a single item that does not affect risk level of the study).
   • Interview protocols where the changes are minor (adding a question or two that do not affect the risk level of the study).
   • Study personnel (i.e., PI, FA, nonaffiliates, outside collaborators).
     o If the only change is removing study personnel, an amendment is not required. Instead utilize the “edit study personnel” function in iStar.

2) Adding:
• Simple patient diaries and/or similar materials.
• Sites/locations.
• Updated Investigator’s Brochure that does not require protocol and/or informed consent changes.

Reasons why an amendment would not be deemed simple include:
• More than two simple changes are combined in a single amendment.
• The survey instrument has multiple (>4) changes to the items or changes the risk level of the study.
• The interview protocol has multiple (>4) changes to the questions or alters the risk level of the study.
• Changes require revisions in multiple sections of the application and/or documents.

To submit a simple amendment, name the changes or additions in the amendment title (e.g., Simple Amendment: Revised Patient Diary + Site Addition), indicate “yes” in iStar section AM1.7. Amendments that do not indicate changes or additions in the title will remain in queue and be reviewed in the order received.

For questions related to the simple amendment, please reach out to the IRBA assigned to the application and provide the IRB number (UP-**-00*** or HS-**-00***). The IRB number and IRBA contact information is provided in the home page of the iStar study application.

RESPONSE TO CONTINGENCIES

When contingencies are issued by the IRB, the investigator’s response to contingencies will be reviewed within 3 business days only if:

1) A complete point-by-point response addressing each contingency is provided, and
2) The response is submitted to the IRB within 3 business days of the contingencies being issued.

An incomplete or inadequate response to contingencies will be returned without review and the subsequent response will be reviewed in the order received.

URGENT REVIEW

Urgent Review procedures may be requested only under limited circumstances. These are when:

• A federal or state agency, foundation, or funder requires IRB approval prior to issuing a funding award,
• A federal or state agency, foundation or funder has imposed a deadline by which funds must be expended or data collection activities must be completed,
• Data collection must be undertaken immediately because the opportunity is ephemeral.

See the OPRS website for additional information about Urgent Review requests.

If an Urgent Review (UR) is required, check “yes” in section 4.1.1 of the iStar application, complete the justification and attach the support document. Applications that do not meet the UR requirements, or do not include adequate support documents, will be returned with instructions to provide documentation according
to the guidelines or remove the UR request in iStar and return the application. Applications with the UR request removed will be placed in the queue according to the original submission date.

CEDED REVIEW

Investigators with industry-sponsored multisite clinical trials where a central IRB has been identified by the sponsor are highly encouraged to submit a ceded review application to the USC IRB. **Submissions that do not adhere to the basic guidelines described below will be returned without review.** For questions and clarifications to the guidance, please contact the IRB via email (irb@usc.edu).

- All sections of the iStar ceded application should be completed.
- The USC study activities should be fully described in the study application. State if any of the study activities at USC differ from what is described in the approved protocol.
- All documents requested in the ceded application should be uploaded (reliance agreement, external IRB approval, approved protocol, approved consent template (if applicable), USC consent (if applicable).
- Use the external IRB approved consent template to create the USC consent by adding the USC PI contact information and required USC language using tracked changes.

REPORTABLE/ADVERSE EVENTS

- Provide a concise description of the event (e.g., failure to gain signature on informed consent, breach of data, death of participant), the investigator’s assessment of relatedness to the study, and what actions were taken by the study team.
- Indicate whether the study drug or intervention was interrupted, discontinued, etc. and indicate the outcome of the event.
- Describe the measures that have been taken to reduce the likelihood that similar deviations or errors will occur in the future.
- For biomedical studies, do not provide excess information from the electronic medical record.

CONTINUING REVIEWS

- **Plan ahead.** It is the responsibility of the researcher/study team to submit their continuing review application two months prior to the study expiration date to allow adequate time for the IRB review.
- Ensure all applicable certifications (e.g., Human Subjects, GCP, Research HIPAA) are current for all study personnel. Continuing reviews will be returned without review if certifications are due to expire within 30 days during the review process (prior to the IRB expiration date).

NOT HUMAN SUBJECTS RESEARCH

Not-human subjects research (NHSR) studies are studies that do not meet the definition of research and the definition of human subjects, which includes coded data/specimens, secondary analysis and contract/grant
determinations. Before you determine whether a study meets the definition of human subjects research, you should first determine whether the study meets the definition of research. HHS and FDA have different definitions. The FDA has created a comparison of the FDA and HHS Human Subjects Protection Regulations document.

USC policy allows researchers to make an NHSR determination themselves if a project does not meet the regulatory definition of human subjects and/or research.

For studies involving survey and interview procedures, some publishers and funders will require an official NHSR determination notice by the IRB. Please follow the guidelines below to request a NHSR determination prior to starting any activities. Determination notices will not be provided retroactively.

Note: An NHSR determination cannot be made on any FDA regulated research, including studies involving secondary analysis on de-identified data/specimens. Currently, all FDA regulated studies involving de-identified data/specimens require a non-exempt human subjects application.

Please visit the NHSR page for detailed guidance.

If a researcher requires an NHSR determination letter from the IRB, the researcher will need to submit an exempt human subjects application in iStar. The short study title should include “NHSR Determination Request.”

If the analyst determines the project is NHSR, a NHSR determination letter will be issued. If the analyst determines the application qualifies for exemption and all relevant information pertaining to an exempt determination is included, an exemption determination letter will be issued.

If additional information is required, for example a fully developed protocol, data collection form, survey and/or interview instruments to make the determination, the application will be returned with a request for changes.

If you have any questions, please contact the IRB via email (irb@usc.edu).

**CODED DATA/SPECIMENS**

The term “coded data” applies to both data and specimens. To meet the regulatory definition of coded data/specimens, the items must have been collected for one purpose, will be analyzed for a completely different purpose, and the researchers conducting the secondary analysis cannot readily ascertain the identity of the person from whom the data/specimen were collected.

A fully completed coded data/specimen application must be submitted. Below are sections that require additional considerations for coded data applications:

- Section 1.1—check “Research Protocol or Study on Human Subjects.”
• Section 1.5—check the appropriate IRB.
• Section 5.1—check “Coded Specimens/Data.”
  o Section 5.2—A fully developed protocol must be uploaded utilizing the template Secondary Analysis Protocol. The template is available on the OPRS/IRB (HSPP) website.
• Fully complete the remainder of the application.
• Section 42–If data from a Clinical Data Warehouse will be procured, this section must be fully completed.

Data and/or specimens requiring procurement may require a Material Transfer Agreement (MTAs) and/or a Data Use Agreement from Stevens Center for Innovation and/or may require review by USC’s Business Services department. The executed agreement and/or proof of purchase documents are not required to be submitted to the IRB.

**SECONDARY DATA ANALYSIS**

Similar to coded data, secondary research is conducted on data/specimens that have been collected for one purpose and are being analyzed for another purpose. The main differences between coded specimens/data and secondary data analysis are the ability to have access to identifiers. The review/risk category is dependent upon whether the data/specimens exist at the time the application is submitted to the IRB and whether investigators have access to or record identifiable information.

Secondary analysis conducted on data/specimens collected from another research study will require explicit consent from the participant in the original study and the IRB may require a copy of the approved Informed Consent form, or a copy of the Information Sheet provided to the research participant to be submitted with the IRB application.

A fully completed iStar application must be submitted. Below are sections that require additional considerations for secondary analysis applications:

• Section 1.1 - check “Research Protocol or Study on Human Subjects.”
• Section 1.5 – choose the appropriate IRB (Biomedical or Social Behavioral).
• Section 5.1- check the appropriate review type.
  o If identifiers are accessed and not being recorded, the study may qualify for exemption.
  o If identifiers are being recorded, the study may qualify for expedited review and a waiver of consent will be required (section 24).
    ▪ For guidance review the Levels of IRB Review.
• Section 5.2 - Upload a fully developed protocol, the template protocol for Secondary Analysis Protocol must be utilized. The template is available on the OPRS/IRB (HSPP) website.
• Section 9.1 - indicate whether the data/specimens have already been collected/generated for non-research purposes and/or whether the data/specimens have already been collected/generated for another research purposes.
  o Data collected for non-research purposes typically include medical records, school records, census data, social media data, etc.
Data collected for other research purposes typically include data sets collected for initial research purposes.

- Section 13.2—If utilizing medical, employment or school records, upload a copy of the data collection form.
  - A data collection form can be a word or excel spreadsheet with a listing of all data points being recorded from the source data.
  - A data collection form is not required when accessing artifacts, publicly available data.
- Section 35.1: When applicable, the iStar application must include the waiver request, and all study personnel listed in section 2.1 of the iStar application must be compliant with the Research HIPAA educational requirement available on the CITI website.

Data and/or specimens requiring procurement may require a Material Transfer Agreement (MTAs) or a Data Use Agreement from Stevens Center for Innovation or may require review by USC’s Business Services department. The executed agreement and/or proof of purchase documents are not required to be submitted to the IRB.

**CONTRACTS AND GRANTS ONLY SUBMISSIONS (CG APPLICATIONS)**

Contracts and Grants (CG) Only submissions are projects that lack definite plans for involvement of human participants. When necessary to satisfy a funding sponsor, the researcher may submit a grant/contract application through iStar. The CG application is not approval to conduct research involving humans, it is an acknowledgement of the grant application.

There are generally two types of CG applications:

- Applications for approval of Center, Training or Program Project Grants, where the application outlines the administrative core requirements and does not include a plan for the involvement of humans.
- Applications requesting approval for development purposes only, under 45 CFR 46.118 and 46.119, where the proposals lack definite plans for the inclusion of human subjects.

Both types of submissions will require a separate application for the project(s) involving humans.

A fully completed Grant/Contract application must be submitted. Below are sections that require specific considerations for CG applications:

- Section 1.1—check “Grant/Contract Only.”
- Section G1.5—Upload a copy of the grant application/proposal/contract submitted to the funding agency, including the budget information (individual salary information may be redacted).
- Section G1.6—if the CG application is linked to a human research application, upload the relevant study/studies by clicking on the three dots, and selecting the relevant study/studies.

The human research application must be submitted as a new application and a fully developed protocol must be uploaded. The IRB will not accept a copy of the grant application in lieu of a fully developed protocol. In
in addition, all relevant documentation must be submitted with the human research application, for example, survey and interview instruments, recruitment tools, consent documents.

Amending the CG application will result in the application being returned with the request to withdraw the amendment and submit a human research application.