USC Office of Research Office for the Protection of Research Subjects *Institutional Review Board*	Authorized by: Version date: 10/12/2021

Basic Submission Guidelines for Researchers

OUR COMMITMENT

As a partner in the human subjects 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 faculty, staff, 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**
- **Amendments**
- **Simple Amendments**
- **Response to Contingencies**
- **Urgent Review**
- **Ceded Review**
- **Reportable /Adverse Events**
- **Continuing Reviews**

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.

1) Plan Ahead

a) It is the responsibility of the researcher/study team to submit their application in 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 IRB review.

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 and must be uploaded at iStar #5.2 in each 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 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. 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 reflective of the document contents.
b) Submit your application to the appropriate IRB (Social Behavioral or Biomedical).
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 industry sponsored studies please follow the sponsor's template and not the USC template. Refer to the "Forms and Template" guidance on the OPRS/IRB website.
e) Ensure all certifications (e.g., Human Subjects, GCP, HIPAA) are current for all study personnel. New applications with missing or expired certificates will be issued contingencies. 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.

1) **Plan ahead.** It is the responsibility of the researcher/study team to submit their amendment in adequate time to allow the application to wait in queue, be assigned to a staff member, respond to contingencies, etc.
2) Check the OPRS/IRB website for the "Tip of the Week" to see if there is any new information that might facilitate your submission.
3) Name the changes or additions in the amendment title (e.g., Revised ICF +Site Addition).
4) Use track changes when revising any document (e.g., consent, survey instrument, recruitment documents, protocol).
5) When making changes to Procedures and/or Protocol, include a summary or explanation of the most significant changes and the rationale for the changes at iStar item AM8.

a. Describe the ***nature*** and ***rationale*** for the changes. A rationale for the changes must be included.
b. Highlight changes that affect risk to participants or study design.
c. 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.
d. 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.

6) 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.
   a. If revising the informed consent for industry sponsored studies, do not simply 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.
   b. For industry sponsored studies, upload the sponsor's revised informed consent template (with track changes) at iStar #5.3.
7) Ensure all certifications (e.g., Human Subjects, GCP, HIPAA) are current for all study personnel. Amendments with missing or expired certificates will be issued contingencies. 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.

SIMPLE AMENDMENTS

Simple amendments are 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.

- 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 question 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)
    - 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 materials
- Sites/locations
- Updated Investigator's Brochure that does not require protocol and/or informed consent changes

Reasons why an amendment <u>would not be deemed simple</u> 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***). 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 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.

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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.

- All sections of the 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 in order to allow adequate time for the IRB review.
- Ensure all certifications (e.g., Human Subjects, GCP, 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).