USA IRB Submission Requirements

All submissions to the USA IRB are made through IRBNet. For help with general IRBNet navigation such as how to create a new project, accessing required materials, etc. please refer to our IRBNet guidance.

IRB Review Requirement

IRB review and approval is required for all non-exempt human subjects research activities in which University of South Alabama is engaged, except when necessary to eliminate apparent immediate hazards to the human subjects. See 'Does my project require IRB Review' for additional guidance. Review is required:

- Before initiating a project (initial approval)
- Before initiating any modifications to the project
- At least once each calendar year (for applicable studies) or unless not required by the regulations governing a study
- For any problems or relevant new information that develops during the research (i.e., adverse events, deviations)

New Projects - General Tips

- All new projects must include the PI's electronic signature.
- All student projects must include their faculty advisor's electronic signature.
- All study personnel listed on Application Part A must have their appropriate training certificate(s) linked to their IRBNet User Profile. Note: USA HIPAA for Research certificates are required for any individual accessing PHI.
- Individual access to a new project can be decided by the site's staff. Please note each person given Full access will receive automatic email notifications from IRBNet. **Clinical Trials Office: Please share Full access to all new clinical trials with IRB Administrator.**
- If any new project includes minors, prisoners or pregnant women/neonates, the appropriate Checklist must be included (all located in IRBNet Forms and Templates library).
- Any project using deception techniques must include the Deception Debriefing form (located in IRBNet Forms and Templates).
- Any project conducted at an unaffiliated site (e.g., local school or business) must include a signed letter of support from the proposed research location.
- Any study in which the PI and/or key personnel has a Conflict of Interest, COI information (e.g., COI disclosure and management plan) must be submitted.

The following pages summarize documents required for submission to the USA IRB, organized by submission type.

Items with an asterisk (*) are forms found in IRBNet. Application Part A auto-populates when 'Start a Wizard' is selected in a new project. All other IRBNet forms can be accessed from the 'University of South Alabama Institutional Review Board' Library at the top of the Designer page.

All other required documents listed can be added to a submission by clicking the 'Attach New Document' button at the bottom of the designer page.

New Study IRB Submission Requirements

Exempt Studies:

- Chart Reviews
    1. Application Part A*
    2. Application Part B: Retrospective Medical Records Review*
- Exempt, no identifying information retained
    1. Application Part A*
    2. Application Part B: Exempt*
    3. Recruitment materials, if applicable (i.e. phone/email scripts, flyers, etc.)
    4. Information Sheet
    5. Survey/Questionnaire/Test, if applicable
- Exempt, identifying information retained+ (even if coded)
    1. Application Part A*
    2. Application Part B: Exempt*
    3. Data Management and Security Form*
    4. Recruitment materials, if applicable
    5. Consent Form(s)
    6. Survey/Interview Questions, etc.

+Note: If identifying information is being collected or retained and participants' identities will be readily ascertainable to the investigator for an Exempt study, this goes through our Limited Review process. **Audio and/or video recording of subjects is considered identifying information**. The recording of minors will always be escalated to Expedited Review.

Expedited/Full Board Studies:

- Biobanking or Biological Specimen Collection Only
    1. Application Part A*
    2. Application Part B: Biological Specimens*
    3. Biospecimen Banking Protocol, if applicable
    4. Consent Form(s), if applicable

Note: If any activities outside the collection or banking of biospecimens will occur, **Application Part B: Expedited and Full Board** must be submitted in addition to **Application Part B: Biological Specimens**.

- Expedited/Full Board
    1. Application Part A*
    2. Application Part B: Expedited and Full Board*
    3. Application Part B: Biological Specimens* IF using a USA facility for biobanking or generating results from biospecimens
    4. Investigator's Brochure / package insert, if applicable
    5. Consent Form(s) in draft form
    6. Protocol
    7. Recruitment Materials
    8. Data collection instruments
    9. Device brochure, if applicable
    10. Pharmacy Manual, if applicable

Studies using WCG as the IRB of Record:

1. Application Part A*
2. External Review Request form*
3. WCG Boilerplate Checklist*
4. Protocol
5. Consent Form(s) in draft form
6. Confirmation from study sponsor that USA's local context language has been accepted

Studies using NCI as the IRB of Record:

1. Application Part A*
2. External Review Request form*
3. Protocol
4. Consent Form(s) in draft form
5. Handout – HIPAA – NCI CIRB*

Studies Using Another External IRB as the IRB of Record:

1. Application Part A*
2. External Review Request form*
3. Protocol
4. Consent Form(s) in draft form
5. Reliance / Authorization Agreement (or information, e.g., if utilizing SMART IRB)
6. Local recruitment materials, if applicable

Emergency / Compassionate Use Studies:

1. Application Part A*
2. Application Part B: Expedited and Full Board*
3. Consent Form(s)/Parental Permission in draft form
4. Letter of Authorization from sponsor
5. Investigator's Brochure
6. IND Acknowledgement Letter from FDA

Emergency / Compassionate Use Follow-Up Reporting (5 Day and 30 Day)

1. Emergency Use Post-Use Report Form

The following page summarizes documents required for submission to the USA IRB after initial study submission, organized by submission type.

Amendments

1. Amendment Form*
2. Change of Study Team form, if applicable*
3. Updated Part A, if applicable*
4. Any revised materials that apply to the Amendment, i.e. questionnaires, information sheets, etc.
5. All sponsor-provided materials that apply, e.g., updated IB, protocol, etc.
6. Updated ICFs, if applicable – Note: Revised ICFs are required to have any change/revision tracked from its previous USA IRB approved version.

Renewals / Continuing Review

- Next Report Due Studies (Exempt & most non-FDA Expedited studies):
    1. Annual Check-In Form*
    2. Change of Study Team form and updated Part A, if applicable*

- Full Board/Select Expedited/FDA Regulated Studies:
    1. Full Board and Expedited Continuing Review form*
    2. DSMB / safety report, if applicable – most recent report is required
    3. Change of Study Team form and updated Part A, if applicable*

- NCI, WCG & Other External IRB:
    1. Annual Check-In form*
    2. Change of Study Team form and updated Part A, if applicable*

Closures

1. Closure Form*
2. Sponsor notification of closure (for sponsored studies, excluding NCI)
3. Closure Cover Letter (if study uses USA's Data Safety Monitoring Board)

PI/Personnel Change:

1. Change of Study Team form*
2. Updated Part A*
3. Applicable training certificate(s)
4. PI Signature (for PI changes only)
5. COI Disclosure Form, if applicable

Adverse Events:

1. Adverse Event Report Form*
2. Any supplemental materials, if applicable

Protocol Deviations and Exceptions:

1. Protocol Deviation or Exception Request Form*
2. Any supplemental materials, if applicable