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

_____ 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 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.
- 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 locatio
- 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‰} ‰ µ o š • Á Z v Z ^ š Œ š
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New Study IRB Submission Requirements

Exempt Studies:

- Chart Reviews
    1. Application Pa
    2. Application Pa etrospective Medical Records Review*
- Exempt, no identifying in n retained
    1. Application Pa
    2. Application Pa xempt*
    3. Recruitment n , if applicable (i.e. phone/email scripts, flyers, etc.)
    4. Information S
    5. Survey/Quest / Test, if applicable
- Exempt, identifying inform etained (even if coded)
    1. Application Pa
    2. Application Pa xempt*
    3. Data Manage d Security Form*
    4. Recruitment n s, if applicable
    5. Consent Form
    6. Survey/Intervi

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

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.
6. IND Acknowledgement Letter from FDA

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

x 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*

x 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*

x 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 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