# **USA IRB Submission Requirements**

All submissions to the USA IRB are made three the three thre

### IRB Review Requirement

| for: | additional guidance. |
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#### 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 Profileote: 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 IRBNetcal 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 aθω μο š • Á Z v Z ^ š Œ š t ] ὶ Œ [ ] • • ο š ] v v Á ‰ Œ } i š X ο ο } š Z Œ / Z Ē š (} Œ u • v South Alabama Institutional Review } Œ [ >] Œ Œ Ç š š Z š } ‰ } ( š Z •] P v Œ ‰ P ο ο } š Z Œ Œ ⟨ μ ] Œ } μ u v š • ο ] • š v š } • μ u ] • • ] } v Ç ο ] I]

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### New Study IRB Submission Requirements

# **Exempt Studies:**

- x Chart Reviews
  - 1. Application Pa
  - 2. Application Pattrospective Medical Records Review\*
- x Exempt, no identifying inf
  - 1. Application Pa
  - 2. Application Page mpt\*
  - 3. Recruitment n
  - 4. Information St
  - 5. Survey/Questi /Test, if applicable
- x Exempt, identifying information tained (even if coded)
  - 1. Application Pa
  - 2. Application Page empt\*
  - 3. Data Manager d Security Form\*
  - 4. Recruitment n , if applicable
  - 5. Consent Form
  - 6. Survey/Intervi

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## 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 applicableNote: 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 applicablemost 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