USA IRB Submission Requirements by Project Type

Exempt:

- 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 Safety and Management 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:

- Biological Specimen Collection
 - 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 <u>in addition to</u> **Application Part B: Biological Specimens**.

- Expedited/Full Board
 - 1. Application Part A
 - 2. Application Part B: Expedited and Full Board
 - 3. Investigator's Brochure, if applicable
 - 4. Consent Form(s) in draft form
 - 5. Protocol
 - 6. Recruitment Materials