**DO NOT COMPLETE THIS FORM. THIS IS ONLY A GUIDANCE DOCUMENT.**

**PLEASE USE THE IRA TEMPLATE**

This guidance document is only to be used in conjunction with the Non-Therapeutic JCTO or Chart Review protocol templates to assist with the preparation of the IRB Review Application – SBER and Records.

**Do not use this document to complete an IRB Review Application.**

Guidance language provided throughout is not meant to replace the guidance language provided throughout the IRB Review Application.

First time users of this form are encouraged to set-up a walkthrough [consultation with the IRB](https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0).

|  |  |
| --- | --- |
| Title: |  |
| Version Date: |  |
| Funding Source(s): |  |
| Principal Investigator: |  |
| Study Sponsor: |  |
| Participating Sites/Collaborators: |  |
| **IRB (WRG number):** |  |

*All above information should be identical to the information provided on page 1 of the Non-Therapeutic or the Chart Review JCTO protocol templates.*

## Background/Purpose/Study Aims:

*All information provided here should be written in lay terms, assuming an unfamiliar audience. This will likely require rewording of the information from Sections 1, 1.1, and 2 of the Non-Therapeutic or Chart Review JCTO protocol templates. Please only provide a concise summary, do not copy/paste the information from the JCTO protocol template.*

## Adequacy of Resources/Qualifications:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Study Population:

*Using section 4.1, 4.2, and 4.3 of the Non-Therapeutic JCTO protocol template or Section 2.3 of the Chart Review JCTO protocol template, please provide detailed information to describe the participant population. For the Non-Therapeutic JCTO protocol template, this may require rewording as the protocol prompts for a general description. All exclusion criteria require a justification, rather than a simple listing, for the IRB Review Application.*

## Vulnerable Populations:

*Confirm the details provided here are in line with the information provided in portions of section 4.4 of the Non-Therapeutic JCTO protocol template. You may need to expand upon the described safeguards to be sure it includes steps taken in regard to the consent process. See IRB policies for guidance as needed. There is no corresponding section of the Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information as applicable.*

## Recruitment Process:

*You may use portions of section 4.4 of the Non-Therapeutic JCTO protocol template or section 2.3 of the Chart Review JCTO protocol template as a guide, but please expand your response to include when you will identify potential participants/data/sources. Overall, this section must provide a detailed plan of how all participants will be approached/recruited where applicable. Note, all advertising/recruitment materials should be described and included with your IRB application also when applicable.*

## Screening Procedures:

*Only screening numbers are included in section 4.4 of the Non-Therapeutic JCTO protocol template. You will need to expand on this following the guidance provided in the IRB Review Application. There is no corresponding section of the Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information if applicable.*

## Informed Consent Process:

*Do not copy/paste section 7.2.3 of the Non-Therapeutic JCTO protocol template. You will need to provide additional information, as prompted, in the IRB Review Application to address all regulatory requirements. The information required here cannot be found in the Non-Therapeutic JCTO protocol template.*

***Note, informed consent is not automatically waived for chart/tissue review studies. Please review the waiver criteria cited in the IRB Review Application. These criteria must be satisfied, otherwise informed consent is required.***

## HIPAA Authorization:

*The information required here cannot be found in one area of the Non-Therapeutic JCTO protocol template. Although some information may be included in subsections throughout the protocol template, additional information is required for IRB Review. Please address all prompted information in the IRB Review Application to address regulatory requirements.*

*Also, there is no corresponding section of the Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Data Collection Procedures:

*You may use information from section 3 of the Non-Therapeutic JCTO protocol template or section 2.1 of the Chart Review JCTO protocol template as a guide, but rewording may be required to provide lay terms, assuming an unfamiliar audience. Please summarize the information provided in this section. Include a concise and clear description of study activities/procedures or data collection methods addressing the previously mentioned study objectives, describing how data will be captured. Note, less information is required in the IRB Review Application than the Non-Therapeutic JCTO protocol template; however, this summary must include all project procedures, interventions, assessment, and participant activities. All documents/surveys/etc. utilized will need to be included with your IRB application. If you will be receiving/sending data to and from another institution, indicate which institution.*

## Study Duration/ Study Timeline:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Study Locations:

*Contrary to the Non-Therapeutic JCTO protocol template, this section must include more than a list of sites enrolling participants, number of sites, or sites for recruitment. Please refer to the IRB Review Application for specific guidance. You may use section 5.2 of the Chart Review JCTO protocol template as a guide.*

## International Research:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Participant Compensation:

*You may use portions of section 4.4 of the Non-Therapeutic JCTO protocol template to complete this section.*

*There is no corresponding section of the Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information if applicable.*

## Risk to Participants:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Benefits to Participants:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Privacy of Participants:

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Data Management and Confidentiality:

*Do not copy/paste section 7 of the Non-Therapeutic JCTO protocol template or sections 3.3/3.4 from the Chart Review JCTO Protocol Template as a significant amount of additional information is needed per regulatory requirements. Closely follow the guidance provided on the IRB Review Application.*

**Data Banking**

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Withdrawal of Participants

*There is no corresponding section of the Non-Therapeutic or Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## Sample Size:

*Summarize the information partially provided in sections 4.4 and 8 of the Non-Therapeutic JCTO protocol template or section 2.4 of the Chart Review JCTO protocol template to address this section of the IRB Review Application. An explanation of how you arrived at this number should be written in lay terms, assuming an unfamiliar audience. This may require rewording.*

## Approach to Analysis:

*Revise section 8 of the Non-Therapeutic JCTO protocol template to provide a concise summary in lay terms to describe what and how you plan to analyze the data you collect.*

*There is no corresponding section of the Chart Review JCTO protocol template to assist with this portion of the IRB Review Application. Please provide the prompted information.*

## References:

*Only list the references cited within the IRB Review Application. It is not necessary to add all references listed in Section 9 of the Non-Therapeutic JCTO protocol template.*