1. Research Question

2. Research Objectives

3. Hypothesis

4. Study Design

5. Research Study Protocol

6. Data Collection Methods

7. Data Analysis Plan

1. Where is the data coming from?

2. List ALL identifiers, even if you plan to de-identify data.

3. Will you receive Protected Health Information (PHI)?
a. How will you anonymize the data?
b. Can you re-identify subjects with the data?
c. Are you signing a DUA or MTA (please provide documentation if yes)?

4. Where will you store the data? Who will have access to the data?

5. What are the data retention and destruction timelines?

1. Describe how the research involves minimal risk to participants.
2. Describe how the waiver will not adversely affect the rights and welfare of subjects.
3. Describe how the research could not be carried out without the waiver.
4. Is the data publicly available?
5. Describe the restrictions that apply to the data source.
6. Research participant information.
7. Total sample size and rationale.
8. Confidentiality and security plan: describe how you will protect the confidentiality of subjects and security of data. Describe where data will be stored, who has access, and data retention/destruction timeline.

1. Does the research obtain, use, or disclose PHI?
2. Type of authorization requested: **a.** Obtain partial authorization for PHI.
b. Waiver or alteration of HIPAA authorization.
c. Partial waiver for subject identification or recruitment.
3. Health Information Use Request.
4. List ALL HIPAA-defined identifiers recorded from patient medical records or other sources.
5. Attach list of data collected about subjects from medical records
6. Describe the destruction plan and timelines.

The IRB may deny application, ask for further information to review in consideration of approval, or approve application outright.