

IRB PROTOCOL REVIEW

Study Title: _____
PRINCIPAL INVESTIGATOR: _____
PI ADVISOR: _____
FIRST REVIEWER: _____
SECOND REVIEWER: _____

Please comment only if changes are requested. Changes should only be related to the protection of human subjects.

TYPE of REVIEW Full Board Expedited Exempt

Background and Rationale: Justification for conducting the study; results of similar or pilot data; current literature cited – include references and in-text citations.

Present/Acceptable Present/ Changes Requested Absent

Comment: _____

Purpose of the Study / Objectives: Clearly stated purpose of the study.

Present/Acceptable Present/ Changes Requested Absent

Comment: _____

Design: Clearly articulated and described for either research or EBP.

Present/Acceptable Present/ Changes Requested Absent

Comment: _____

Inclusion/Exclusion Criteria

Present/Acceptable Present/ Changes Requested Absent

Comment: _____

Tools and/or Metrics

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

Recruitment Plan (flyers, scripts, sample size justification)

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

Risks and Benefits

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

Informed Consent Form/Readability Score: The Regis IRB recommends that the reading level of the informed consent document should be no higher than an 8th grade level. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an 8th grade reading level. The comprehension level of the consent document must be verified to ensure it is consistent with the comprehension level of the participants. Please use the Flesch-Kincaid Grade Level.

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

Data Collection (data collection process, Qualtrics, Survey Monkey, etc., and analysis tools)

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

Data Safety and Participant Privacy (anonymity, confidentiality, password protected/secured)

Present/Acceptable

Present/ Changes Requested

Absent

Comment:

All permissions included? Yes No

All signatures included? Yes No

All documents included? (i.e., AI Pledge, CITI training, Site Permission letters, outside IRB approval letters)

Yes No (if no, please list which document is missing)

Please list all required changes below in a numerical list.

Please list all suggested changes below in a numerical list – if none, please leave blank.