Reviewer Checklist

This purpose of this form is to serve as a guide for IRB members when reviewing protocols.

What is your recommendation?
- Approve as submitted
- Conditionally approve, pending minor modifications
- Defer
- Disapprove

Is continuing review needed?
- Yes, continuing review is needed.
- No, continuing review is not needed.

Note any issues involving the following and raise as discussion points during the IRB review:

Does this study involve **vulnerable populations** (such as minors, prisoners, those with diminished capacity to consent)?
- If yes, is there no greater than minimal risk involved?
- Are there adequate provisions in place for appropriate consent and assent procedures?
- Are there adequate additional safeguards to protect the rights and welfare of vulnerable populations?

Is **subject population** appropriate (number, characteristics)?

Are **recruitment procedures** adequate? Recruitment documents included?
- If no, what changes are needed?

Are procedures to maintain **confidentiality** appropriate?

Are there any outstanding issues?

Are **participants compensated**?
- If yes, is the compensation appropriate?

Are **data to be collected and is exactly what participation will involve** adequately explained?

Is there appropriate detail regarding **risks and benefits**?

Documentation of 45CFR46.111 requirements:
i. Risks to subjects are minimized.
ii. Risks to subjects are reasonable in relation to anticipated benefits.
iii. Selection of subjects is equitable.
iv. Informed consent is sought OR Waiver sought, appropriately.
v. Informed consent is appropriately documented OR Waiver sought.
vi. Research plan makes adequate provisions to monitor data collection to ensure subject safety (**not applicable to minimal risk studies)**
vii. Adequate provisions to protect subjects' privacy and maintain confidentiality of data.

The elements of consent to watch for:
- Identified as a UW-Madison research project
- Clear description of what participation in the study involves
- Address any risks, and steps to mitigate those risks
- Benefits (typically there are no direct benefits in minimal risk research)
- How confidentiality of data will be ensured?
- Any compensation?
- Participation is voluntary; subjects can withdraw at any time and refuse to answer any questions
- Contact information (PI, IRB office and a local contact if it is international).