Project Title:

Principal Investigator:

1. Are Human Subjects Involved? Y / N
    a. Please see IRB Guidelines statement below
2. Is this study exempt from Federal Regulations? Y / N
    a. If yes, what is the exemption number?
    b. If no, is the IRB review pending? Y / N
        i. IRB Approval Date (please attach IRB approval):
3. Clinical Trial Questionnaire
    a. Does the study involve human participants? Y / N
    b. Are the participants prospectively assigned to an intervention? Y / N
    c. Is the study designed to evaluate the effect of the intervention on the participants? Y / N
    d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Y / N
    e. Provide the ClinicalTrials.gov identifier (e.g. NCT87654321) for this trial, if applicable:

4. Are Vertebrate Animals Used? Y / N
    a. If YES to Vertebrate Animals Is the IACUC review pending? Y / N
        i. IACUC Approval Date (please attach IACUC approval):

Guidelines

All projects involving human subjects research are required to receive IRB approval before funding is released. Some projects may be required to use a single IRB (sIRB). Some projects may also be required to undergo the NCATS human subject prior approval process. Once established, each applicant/team is required to meet all established IRB deadlines and comply with all information requests. Failure to meet deadlines or respond to information requests in a timely manner may result in the administrative removal of the non-compliant institution from the project team.