Analyst Checklist
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19-40
test
Initial Submission

RERC/Analyst Checklist

Pre-Review Section
Type of Submission (check all that apply)

Pre-Review 1
For all submission types:

1) Confirm that the activity is Human Research or Not Regulated Research Status

Pre-Review 2
For all submission types:

2) The research investigators & key personnel have completed the Human Subjects Protection Training.

Pre-Review
For all submission types:

Note any missing materials necessary for review.

Select all that apply & RETURN the submission to the PI to provide what is missing

What level of review was this IRB Protocol submission determined to be?

Decision Charts

1. Inform the Principal Investigator and Faculty Advisor, (if Student Investigator) of the determination
2. Assign Primary Reviewers
3. Add to Meeting Agenda
4. Assign the PI a meeting appointment time

Assign Reviewers

Research Ethics Review Coordinator to review the protocol and prepare the authorization letter or notify the Principal Investigator of any changes needed

Add any additional comments

REGS Check the Regulations!
45 CFR 46.111 Criteria for IRB Approval of Research

- a1: Minimization of risks
- a2: Risk-benefit relationship
- a3: Equitable selection
- a4: Consent process
- a5: Consent documentation
- a6: Data monitoring
- a7: Privacy/confidentiality
- a8: Vulnerable population/subjects

Are the qualifications of the investigator(s) appropriate for the proposed research?

Is the purpose clear in terms of what the research could add to existing knowledge?

Are the methods clear and appropriate
(methods are smaller parts of the procedure or the step-by-step followed to accomplish the procedure)

Are the procedures clear and appropriate?
Risks to the subjects are minimized [45 CFR 46.111(a)(1)]

1. The Investigator provides a description of procedures the IRB would need in order to make the determination under 45 CFR 46.111(a)(1), (2), and (4).
2. The Investigator provides clarifying information needed to assess the risks to subjects that the IRB would need in order to make the determination under 45 CFR 46.111(a)(1) and (2).
3. The Investigator provides clarifying information regarding the timing and circumstances under which the informed consent of prospective subjects will be sought, that the IRB would need in order to make the determinations under 45 CFR 46.111(a)(4).
4. The Investigator provides a plan to implement additional subject monitoring in order to reduce risks to subjects, that the IRB would need in order to make the determination under 45 CFR 46.111(a)(1), (2), and (4)).

Information Security
With respect to data collection, handling, storage, reporting, and destruction of research data and consent forms.

If you were not able to check off all of the boxes above in the Information Security Section, please enter in your comments and justification.

Are the criteria for subject selection equitable in terms of the purpose of the proposed research?

Are the criteria for subject rejection equitable in terms of the purpose of the proposed research?

Are the research subjects from any of the following vulnerable populations?

- Children and minors (under 18 years of age)
- Incarcerated persons
- Institutionalized or hospitalized persons
- Pregnant women
- Mentally-disabled or cognitively-impaired persons
- Elderly/aged persons
- Economically- or educationally-disadvantaged persons
- Students in the classroom
- Ethnic/racial minority persons
- Employees in their workplace
- Other __________________

Does the research protocol clearly describe the provisions for managing any adverse reactions, physical or emotional, as a result of the subject’s participation in the research?

Please rate the potential risks to subjects of the proposed research
Physical risk (injury, illness, etc.)

Please rate the potential risks to subjects of the proposed research
Risk of criminal or civil liability if data disclosed

Please rate the potential risks to subjects of the proposed research
Financial or employment risk if data disclosed

Please rate the potential risks to subjects of the proposed research
Risk to family or personal reputation if data disclosed

Please rate the potential risks to subjects of the proposed research


Psychological or emotional risk (anxiety, frustration, stress)

Other risks

Summary of Risk Analysis
Select your overall risk category

Summary of Benefit Analysis
Select your overall Benefit Category

Potential benefits of the proposed research to the research subject him/herself

Potential benefits of the proposed research to the subject population as a generalized group

Potential benefits of the proposed research to scientific knowledge

Potential benefits of the proposed research to society of humankind in general

Other benefits
Select the statement that best summarizes your assessment:

Will there be a signed written Informed Consent Form?

NOTE: the Online Information Sheet section is below

If you were not able to check off all of the boxes in the Informed Consent Form Section, please enter your comments and justification

Other Reviewer comments

Information regarding whom to contact with questions about the research activity (the Principal Investigator's contact information) is present

Information regarding whom to contact with questions about the research subject's rights (the Research Ethics Review Coordinator's contact information) is present

Information regarding whom to contact with questions about any research-related injuries or emotional traumas
The Principal Investigator will need to make a revision to the protocol to add this required information.

Reviewer comments

If a waiver of written consent is requested:

- The proposed research involves only minimal risk to human subjects
- The alteration or waiver does not adversely affect the rights and welfare of the human subjects
- The proposed research cannot be practicably carried out without the waiver of consent
- The subjects will be given additional pertinent information after their participation in the research

Is there a request for oral or online consent?

Note any missing materials/inappropriately answered sections:
Select all that apply and return the protocol back to the Principal Investigator to correct the item(s)

Recommended Action
select one of the following options

NOTE: Reviewer comments are located in the protocol document