C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

NCI Choose 1

REVIEWER WORKSHEET

CIRB REVIEW FOR INCLUSION OF INCARCERATE PARTICIPANTS

OMB #0925-0753 Expiration Date: 07/31/2021

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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1. I have reviewed the following documents (check all that apply):

- ☐ Protocol
- ☐ Consent Form
- ☐ Summary of site request for inclusion of incarcerated participants
- ☐ Letter from Local Context approving individual inclusion of prisoner
- ☐ Other (specify): _____

2. Are there any possible advantages to the prisoner through his or her participation in the research, when compared to the general living conditions (i.e. medical care, quality of food, amenities and opportunity for earnings in the prison) that may influence his or her ability to weigh the risks against the benefits of the study given of such advantages and in the limited choice environment of the prison?

- ☐ N/A – Incarcerated participants are not a targeted population. Participants will not be considering these advantages during time of enrollment. Only those participants who become incarcerated participants after enrollment on the study will be eligible.

☐ Yes
☐ No

3. Are the risks involved in the research commensurate with risks that would be accepted by non-incarcerated volunteers?

☐ Yes
☐ No

4. Are the procedures for the selection of subjects within the prison fair to all incarcerated participants and immune from arbitrary intervention by prison authorities or incarcerated participants?

☐ N/A – Incarcerated participants are not a targeted population. Participants will be selected per the protocol eligibility criteria prior to becoming incarcerated.
☐ Yes
☐ No

5. Is the Informed Consent Document presented in language understandable to the population?

☐ Yes
☐ No

6. Does adequate assurance exist that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole?

☐ N/A – Incarcerated participants are not a targeted population. Facilities may vary when a participant become incarcerated and the use of parole boards will be unknown.
☐ Yes
☐ No

7. Is there need for follow-up examination or care of participants after participation?

☐ Yes – proceed to question 7(a)
☐ No – proceed to question 8

a. Have adequate provisions been made for care of this population taking into account the varying lengths of incarcerated participants' sentences?

☐ Yes
☐ No

8. Confirm the study qualifies for one of the following 6 categories of research:

a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

☐ N/A – Incarcerated participants are not targeted as a study population. Study will only allow those currently enrolled who become incarcerated to continue participation.
☐ Yes
☐ No

b. Study of prisons as institutional structures or of incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

☐ N/A – Incarcerated participants are not targeted as a study population. Study will only allow those currently enrolled who become incarcerated to continue participation.
☐ Yes
☐ No

c. Research on conditions particularly affecting incarcerated participants as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

☐ N/A – Incarcerated participants are not targeted as a study population. Study will only allow those currently enrolled who become incarcerated to continue participation.
☐ Yes
☐ No

d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of incarcerated participants in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

Note that incarcerated participants are not targeted as a study population. Study will only allow those currently enrolled who become incarcerated while already on study to continue participation. The CIRB must determine the following:

i. Do the study practices have a reasonable probability of improving the health or well-bring of the subject?

☐ Yes
☐ No

If No, the study may not involve incarcerated participant utilizing this category.

ii. Are there situations, such as a control arm, where participants may not benefit directly from the study practices?

☐ Yes
☐ No

If Yes, the study may not involve incarcerated participants utilizing this category.

9. Questions for the Study Team

Questions included below will considered for discussion with the Study Chair during the CIRB meeting.

10. Topics for CIRB Discussion

List below any topics requiring discussion among the CIRB members prior to a final assessment of the study.

11. Proposed Stipulations

Changes or additional information that the CIRB requires before the study can be approved should be listed below. The changes or requested information must pertain to the regulatory criteria for approval or have a direct impact on the protection of study participants.

12. Recommendation to the CIRB

☐ **Approve**
Inclusion of incarcerated participants on the protocol may be allowed. The request meets the regulatory and CIRB SOP requirements for approval

☐ **Approve Pending Modifications**
There are required changes to allow for the inclusion of incarcerated participants (per question 11).

☐ **Table**
There is insufficient information available to make a determination or substantive changes are required which warrant re-review by the convened CIRB.

☐ **Disapprove**
Inclusion of incarcerated participants on the protocol may not be allowed. The submitted material does not meet the regulatory and CIRB SOP requirements for approval.