

Reidy, Dennis (CDC/ONDIEH/NCIPC)

From: Scardaville, Melissa <mcardaville@air.org>
Sent: Wednesday, November 09, 2016 9:33 AM
To: Reidy, Dennis (CDC/ONDIEH/NCIPC); McIntosh, Wendy LiKamWa (CDC/ONDIEH/NCIPC)
Subject: FW: IRB submission approved for project IPV METRIC (project number 01410.104/B&P number 85684)

From: padii@air.org [mailto:padii@air.org]
Sent: Tuesday, November 08, 2016 12:47 PM
To: Scardaville, Melissa <mcardaville@air.org>
Cc: Padiisupport <Padiisupport@air.org>; Huang, Alison <ahuang@air.org>; Humphrey, Erica <ehumphrey@air.org>; Noel, HarmoniJoie <hnoel@air.org>; Goodson, Andrea <agoodson@air.org>; Kendziora, Kimberly <KKendziora@air.org>; Morrison, Erin (Wallace) <emorrison@air.org>; Keovilay, Suriya (Donald) <skeovilay@air.org>
Subject: IRB submission approved for project IPV METRIC (project number 01410.104/B&P number 85684)

Dear Applicant,

The IRB has completed its review of your PADII submission for the project (project number 01410.104/B&P number 85684) and has granted approval. Please keep in mind these directives made by the IRB Reviewer:

On the basis of this review, the IRB has determined that the project, as described in the materials submitted, is research and does involve human research participants. The research is approved because the selection of participants is equitable and the risks to the participants are minimized and are reasonable in relation to the knowledge that may reasonably be expected to result. Because this research project involves (in part) participants who are prisoners, the IRB has made findings for each of the relevant requirements under Subpart C. These are as follows: 1. Category of permissible research The IRB finds that this research fits into category (iii) the study of on conditions particularly affecting prisoners as a class. As is required under 45 CFR §46.306(a)(2), we find that the study presents no more than minimal risk, and no more than minor inconvenience to the subjects. Approval requires the study may proceed only after the Secretary of Health and Human Services and her designee has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research. 2. Advantages to the prisoner do not impair the ability to weigh risks There are no direct advantages to the incarcerated persons for taking the survey. These include no changes in living conditions, medical care, quality of food, amenities, or opportunity for earnings. There are small monetary incentives and access to snacks during the survey administration session. 3. Risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers We find that this is minimal risk research, which for prisoners means that the probability and magnitude of physical or psychological harm involved in participating in the interview is no greater than what is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. 4. Procedures for the selection of participants are fair The incarcerated participants will be purposively selected from the incarcerated populations at participating facilities. 5. Understandable language Only English-speaking participants will be included in the interviews 6. Parole boards will not take research participation into account The consent form specifies the following: "Please know that taking this survey will not affect your case. It will neither help nor hurt your case in any way." 7. Need for follow-up or care of participants addressed We find that there is no reasonable expectation that follow-up or care will be required following participation in the survey. Given these findings, and the approval of AIR's prisoner advocate who also has carefully reviewed this project, the IRB makes this

determination of approval. Data collection may proceed.

If you have questions about this determination, please check with the primary reviewer for this submission, KENDZIORA, KIMBERLY T.. The next IRB review for this project is set for 10/08/2017. Please submit an IRB Progress/Final Report before that time.

Thank you,

PADII Support,
padiisupport@air.org

Any material changes made to the study or the study procedures require the submission of an updated IRB package.

Any unanticipated problems or adverse events must be promptly reported to the [IRB Administrator](#) or [IRB Chair](#).