Reidy, Dennis (CDC/ONDIEH/NCIPC)

To: Noel, HarmoniJoie

Subject: RE: IRB submission approved for project IPV METRIC (project number 01410.104/B&P

number 85684)

From: padii@air.org [mailto:padii@air.org]

Sent: Wednesday, February 08, 2017 9:48 AM

To: Scardaville, Melissa <mscardaville@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

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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:

This re-review covers changes to the study's access to identifiable information about the incarcerated participants and also changes to the consent form for that population made following OMB review. The IRB finds that the change in information management provides further protections for the participants. Changes to the consent form are consistent and acceptable. Documentation of consent is not required because the conditions stipulated in 45 CFR §46.117(c) are met. 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 <u>IRB Administrator</u> or <u>IRB Chair</u>.