

NIH/NIDA-FSPHP Research Study: Imaging Biomarker for Addiction Treatment Outcome Guidelines for Appropriate Dissemination of Study Information and FAQs

The goal of this memorandum is to offer guidance to PHP and Treatment Center staff on appropriate means of disseminating study information to prospective participants to mitigate implicit coercion.

IRB APPROVED MATERIALS

****Note: Only NIH IRB Approved Study Materials Should Be Disseminated****

- The IRB approved [Study Flyer](#) can be posted throughout physical PHP/Treatment Center space, posted online on PHP or Treatment Center websites or patient/participant portals, sent via electronic mass communication (e.g., email)
- Use these IRB approved scripts for disseminating study information
 - [Script for Treatment Centers](#)
 - [Script for PHP](#)

APPROVED METHODS OF DISSEMINATING STUDY INFORMATION

Do	Don't
Have the provided IRB approved flyer displayed in public places	Hand a flyer to a specific participant
Talk about the study in general gatherings	Approach an individual participant to talk about participating in the study
Distribute study flyer to ALL PHP members through non-targeted mechanisms (e.g. meetings, mass email distributions; online forums, etc.)	Email, mail, or otherwise distribute flyers and fact sheets to individuals
Answer general questions about the study and encourage participants who have specific questions to call Dr. Salmeron directly	Ask who wants to participate
In all study-related communications, assure potential participants that their participation is completely voluntary, not part of their treatment and does not provide any direct benefit. Whether or not they participate will not have any impact on their status at PHP or future treatment.	Be vague about the voluntary nature of participation in the study
Disseminate only NIH IRB approved recruiting materials	Create your own recruiting materials, modify the approved materials, or use excerpts only from the approved materials (<i>including using the NIH or NIDA logos</i>)

Frequently Asked Questions

Q1: How can PHPs and Treatment Centers (TCs) advertise for the study?

The NIDA study team will provide flyers that can be displayed in public places. Flyers and fact sheets can be disseminated through general distributions (email, newsletter, web page) that target the whole PHP/TC. In addition, study information can be shared informally by FSPHP Research Coordinator(s), PHP directors, or the NIDA study team during participant gatherings. The IRB approved scripts should be used when sharing information about the study to participants/patients.

Q2: Will the PHP or TC know if an individual is participating in the study?

Yes. There are several reasons that the PHP or TC need to be informed of participation. These reasons include the requirement for PHPs and TCs to provide drug testing results and for TCs to provide intake evaluation and H&P records, a private room for online sessions, approval to travel to NIDA and arrange substance screening following study visit (if necessary). No information collected by the NIDA study team will be disclosed to the PHP or TC. Only in the case of a life-threatening situation, the participant's PHP or TC will be informed for the sake of the participant's safety.

Q3: Will PHPs or TCs share information from participants' records with the NIDA study team?

Yes. If a participant joins the study and signs a release of information, PHPs and TCs will be asked to release certain information from participant records. The records will be used to determine participants' eligibility and abstinence status. TCs will be asked to share the initial evaluation/intake record, drug testing and medication records, and a discharge or transfer summary. PHPs will be asked to share drug testing results and a brief summary of progress. It is vital that records are received promptly, especially from the TCs, as those who participate in the longitudinal arm must still be in the initial phase of treatment. NIDA will reimburse PHPs and TCs for administrative costs pertaining to releasing records.

Q4: Will the NIDA study team share participants' research records with their PHP or TC?

No. Any information collected by the NIDA study team will not be disclosed to the participants' PHP or TC. In the case of a life-threatening situation, the participant's PHP or TC will be informed for the participant's safety.

Q5: Can participants share their experience with others at their PHP or TC?

Yes. PHP and TC should allow participants who have completed the study to share their experience with their groups at PHPs and TCs. However, PHP or TC staff should leave the room when a participant shares their experience with the study.

Q6: Who should participants contact if they are interested?

Anyone who is interested can contact Dr. Betty Jo Salmeron at BSalmeron@nih.gov (preferred) or (443) 740-2651. Interested individuals need not identify themselves to PHP or TC administration. If participants appear eligible after the phone screen, the study team will have participants sign a Release of Information for the PHP and/or TC and request the necessary records for eligibility determination.

Q7: Do participants need to currently be in treatment at a TC?

No; the study includes participants that are currently in treatment (longitudinal group), as well as those that have completed treatment within the last 5 years (cross-sectional group).

Q8: Where does the study take place?

Main study visits will be at the NIDA-IRP in Baltimore, Maryland. The characterization arm is done online.

Q9: Who is funding this study?

This study is funded by the Intramural Research Program of the National Institute on Drug Abuse (NIDA-IRP), which is a part of the National Institutes of Health.