

INFORMED CONSENT IN RESEARCH WITH DRUG USERS: ADDRESSING ETHICAL CONCERNS

Sherry Deren, Ph.D.

Angela Banfield, M.P.H.

**Center for Drug Use and HIV Research
NYU College of Nursing**

COMPONENTS OF TODAY'S PRESENTATION

- Principles of research relevant to informed consent
- Concerns in doing research with drug users
- Issues to address in all consent forms
- Methods to enhance validity of informed consent in research with drug users
- Example: the GALT project, a biobehavioral study of injection drug users
- Potential research questions to address



WHAT PRINCIPLES UNDERLIE RESEARCH WITH HUMAN SUBJECTS ?

- Belmont Report: 3 ethical principles and their applications
 - Respect for persons - informed consent
 - Beneficence - risks/benefits assessment
 - Justice - selection of subjects for research



INFORMED CONSENT ISSUES FOR DRUG USERS: THREE COMPONENTS

- Disclosure – information about the study must be disclosed, in a way that is comprehended by the participant
- Capacity – the participant must have the ability to understand the information and understand the consequences of participating
- Voluntary – the participant must be able to freely make his/her decision about participation without undue pressure



EACH COMPONENT OF INFORMED CONSENT MAY BE QUESTIONED IN STUDIES OF DRUG USERS

- Researcher can provide detailed information about a study – but is it in language that is understood by the potential participant?
- In studies that recruit individuals who are currently using drugs or alcohol – do they fully understand the procedures of the study?
- Does the offer of money for research participation to active drug users reduce the “voluntariness” of participation?



SOME ISSUES MUST BE ADDRESSED IN ALL CONSENT FORMS (CFR TITLE 45, PART 46)

- Description of the research and what participation entails
- Potential risks (e.g., loss of confidentiality) and protections against those risks
- Potential benefits
- Disclosure of alternative procedures or treatments
- Confidentiality of data
- Explanation of whether any compensation is available in the event of injury
- Contacts for questions about the research and about rights as a research participant
- Statement that participation is voluntary, no penalty for refusal



OTHER DECISIONS TO BE MADE BY IRB

- Need for documentation of informed consent
- Risk level determination and risk/benefit ratio



METHODS USED TO ADDRESS INFORMED CONSENT CONCERNS

- Disclosure: describe study using lay language; brief checklist of key items
- Capacity: assess participant's ability to understand consent; use methods to maintain attention: coffee, break, candy. If necessary, reschedule
- Voluntariness: ensure that potential participant understands what is described and makes decision freely, without coercion
- After the consent process: provide opportunity for participants to review the consent, ask additional questions, and change their minds (provide copy of consent and contact numbers)



THE GALT STUDY: CORRELATES AND CONSEQUENCES OF INCREASED IMMUNE ACTIVATION IN INJECTION DRUG USERS (FUNDED BY NIDA)

- Principal Investigator: Martin Markowitz, MD, Aaron Diamond AIDS Research Center
- Co-Investigators: Sherry Deren, PhD, NYU College of Nursing; Saurabh Mehandru, MD, Mt Sinai School of Medicine
- Research Scientist: Angela Banfield, MPH, NYU College of Nursing

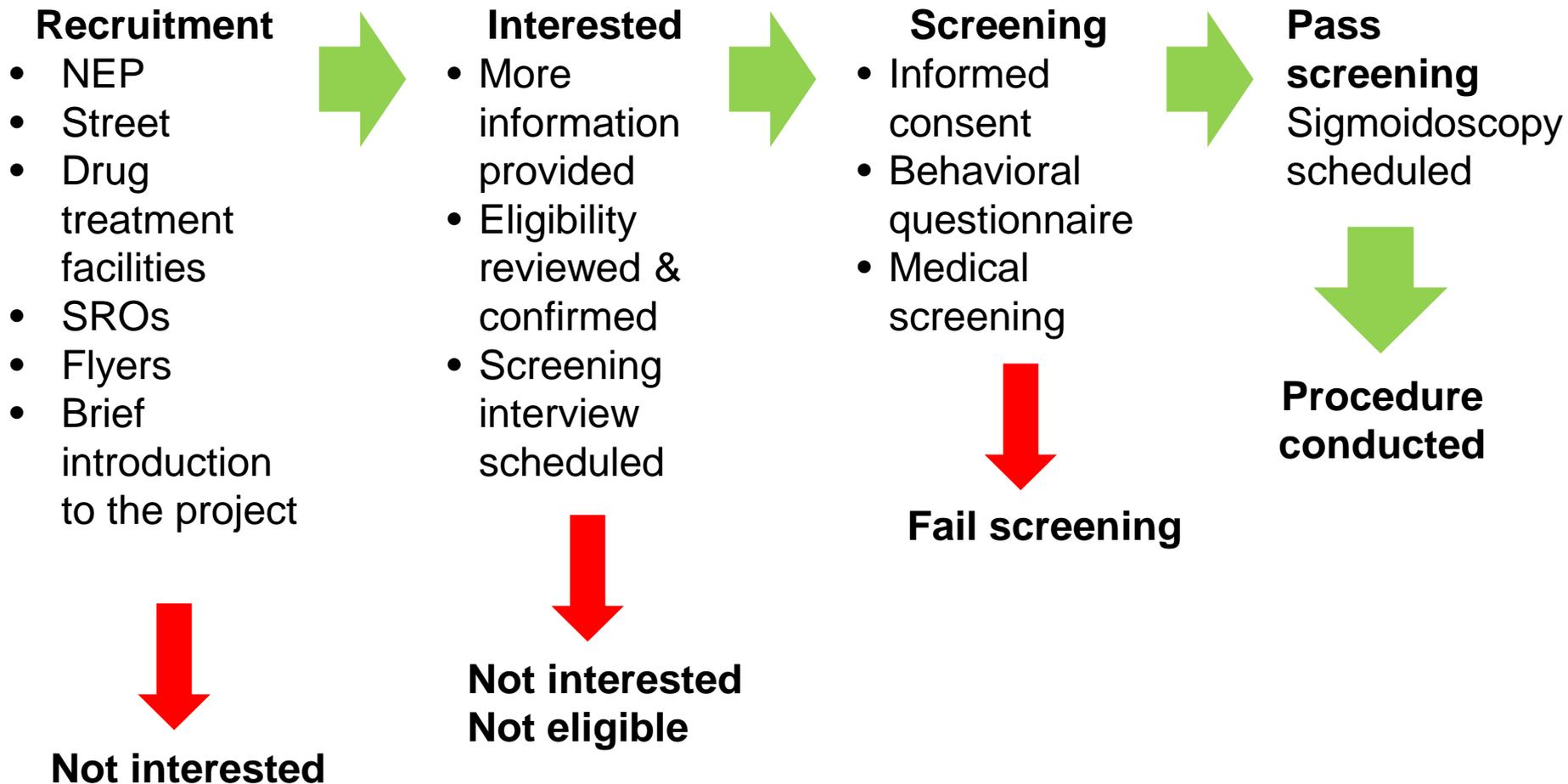


GALT STUDY AIM AND METHODS

- Aim: To understand the impact of injection drug use on immune activation in IDUs, in blood and gut-associated lymphoid tissue (GALT).
- Methods: Active IDUs were recruited, HIV-infected and – uninfected, along with non-injecting controls.
 - Participants were recruited from the community and screened at Rockefeller University Hospital. Those that meet eligibility requirements are interviewed for the collection of behavioral data and undergo a complete physical examination.
 - Those who meet clinical criteria are given an appointment for a flexible sigmoidoscopy with biopsy.
 - Participants receive a \$50 patient incentive for the screening interview and \$150 for the procedure (with a metrocard at each visit).



GALT PROJECT: RECRUITMENT TO COMPLETION



RECRUITMENT CHALLENGES

- Need for participants to know the type of procedure to be done
- Need for recruiters to be comfortable talking about the study
- Important to exclude those who will not qualify



INFORMED CONSENT CHALLENGES

- Insuring that participants
 - Understand the study and the procedures
 - Have an opportunity to ask any questions or concerns they may have



INCREASING VALIDITY OF THE CONSENT PROCESS IN THE GALT STUDY

- Specific information about the study was conveyed during recruitment
- Because minorities and drug users are under-represented in medical studies, an introductory information session preceding the informed consent was conducted



INTRODUCTORY SESSION: IMPORTANCE OF MINORITY AND DRUG USER PARTICIPATION IN MEDICAL RESEARCH

- Under-representation in the past
- Description of medical research
- Elicit potential participants' questions and concerns
- Describe required protections



ADMINISTERING THE IRB-APPROVED INFORMED CONSENT (APPROVED BY RUH, NYU AND MSH)

- While waiting for the screening to begin, participant given the consent to read
- With interviewer, participant listens to audio recording of consent, played while participants read along. They are encouraged to ask questions.
- Recording is stopped at various stages and participant is asked to explain in their own words what they understood. Four areas of focus are: description of groups, procedures, risk, confidentiality



ADDRESSING INATTENTION OR NODDING OFF

- The consent procedure is stopped and participant is offered a refreshment (e.g., water, candy) or a break from the procedure.
- If inattention continues, interview is terminated and rescheduled



INFORMED CONSENT OUTCOMES

- Most who refuse do so in the field or on the telephone, minimizing participants coming who may not participate
- Over the course of 2 studies and approximately 100 participants who were administered the informed consent: 3- interview was terminated because participant was inattentive; 1-decided during the consent that he did not want to participate. One additional participant came for the sigmoidoscopy and decided not to participate.
- Participants were generally very favorable about the entire study after completion; several have assisted in further recruitment.



POTENTIAL RESEARCH QUESTIONS

- How do we know that participants actually understand the study? How can we determine that?
- Does engaging them in discussions in the introduction, about minority/drug user participation, encourage questions to be asked during the consent process?
- Does asking more questions (by the participant) mean there is enhanced understanding of the study?
- Others?



ACKNOWLEDGMENTS

- GALT project – NIDA
 - P30DA011041-12S1
 - R01DA033777
- Thanks to Marya Gwadz, PhD, NYU College of Nursing and Angela Banfield, MPH, NYU College of Nursing, for developing the procedures to enhance validity of informed consent



The Aaron Diamond AIDS Research Center
Affiliate of The Rockefeller University

