RESEARCH ETHICS

Tools

Forms Included:

Human subject and information protection protocol
Draft informed consent form (only for persons with knowledge of drug use)
Human Subject and Information Protection Protocol

Purposes:

- To summarize procedures to protect the safety and identity of human subjects in this research;
- To ensure that information is collected accurately, attributed correctly (when applicable), and protected from unintended disclosure;
- To ensure that national and international standards for research ethics are met and appropriate documentation maintained to establish compliance.

Human Subject Protection Protocol and Protecting Information and Identities:

Key principles:

- consent of subjects to participate;
- protection of confidentiality;
- limited disclosure with attribution when specifically permitted;
- anonymity of subjects and records where highly sensitive information is collected.

Process:

Observe the following requirements while collecting data from research subjects in the RPAR.

1. All subjects must give voluntary informed consent to participate.

2. Recruited subjects will be told that participation is fully voluntary and interviews or groups participation can be ended at any time without any penalty or adverse consequences to the subject’s medical care, psychological services, or participation in other programs.

3. Informed consent must be documented for every participant, but participants who are not system or interactor interviewees will use initials or pseudonyms only on their consent forms and on all other documentation.

4. System and interactor informants will be informed that unless they object their names will be recorded and they may be quoted by name unless they specifically object. Interviewers will clearly note that informant has or has not given permission to use his or her name.

5. Any informant possibly engaged in illegal or otherwise sensitive activities will remain anonymous in the recorded data from the interview.
6. Any form (such as a list of potential key informants) that contains names should not designate people by status (such as “injection drug user”) but instead indicate areas of expertise (e.g., “has information about drug use”).

7. Research data and informed consent forms will be kept in a locked office, file cabinet, or on password protected computers.

8. Research team personnel will refrain from talking about interviews or focus group results in public in any way that could reveal the identities of participants who have not given such permission (researchers should be particularly careful of discussions in restaurants, institutional settings, elevators or on the street).

9. Research team personnel will protect participants from being identified as part of the project unless the participant has given permission for such identification.

10. Research team personnel who know subjects from other settings will not identify them as subjects without their permission.

**Monitoring of the project**

The investigators are responsible for ensuring that research subjects are protected from harm and that the subject and information protection protocol is followed. The following steps should be undertaken to monitor compliance with subject protection.

1. All researchers, staff and field workers should be trained about the details of this plan and the means to protect subjects.

2. The primary investigator should review the data collection, recording and storage techniques of staff and fieldworkers throughout the RPAR.

3. The U.S. investigators will inspect data collection and storage methods on at least annual visits to each site.
Informed Consent Forms

Attached is a sample form to be used in interviewing people who have knowledge of injection drug use. (This form has been approved by UCHC and modified slightly for ethical review in Poland.) A complete set of forms will be provided after final approval and translation.
Consent Form
Client interviews

Study Title: Rapid Assessment of Drug Law & Policy in the CEE & FSU

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Co-PI's: Scott Burris (Temple University) & Patricia Case (Harvard Medical Schools)

Purpose of the Study:
You are being asked to participate in this study in order to share your experience and knowledge about the epidemics of drug use and HIV in Poland, Ukraine, and Russia. The study will use a new investigative process, the Rapid Policy Assessment and Response (RPAR), to help the local community document and respond to barriers to HIV prevention among injection drug users (IDUs) in Central and Eastern Europe and the Former Soviet Union. Approximately 14 client interviews will take place in each country.

Procedures:

The only procedures in this study will be collecting information from you on your knowledge of, and experience with, the criminal justice and public health systems as they are responding to the epidemics of drug use and HIV. After you agree to participate and sign an informed consent form, the investigators will collect information from you during an interview. The interview will last one to two hours. All sessions will be audio-taped and transcribed.

If you agree to participate in this study you will be interviewed individually and asked a series of semi-structured questions in four domains: 1) legal; 2) criminal justice; 3) injection drug use and public health response; and 4) HIV/AIDS and other communicable diseases. Specific questions address:

- enforcement of drug, syringe, and prostitution laws;
• any provisions criminalizing homosexuality and HIV exposure or transmission;
• operation of courts and prisons;
• drug policy politics;
• risk reduction and public health interventions;
• advocacy resources;
• epidemiologic data on HIV and drug use;
• criminal justice data

Emphasis within the interviews will vary based on your specific knowledge and experience. The RPAR research tools include screening questions for each topic area that allow you to skip any area in which you have no background or experience.

Potential Risks:

Risks to you are expected to be minimal, even if you have engaged in drug use or other illegal activities. You may become embarrassed, feel discomfort, or become afraid in the interview when asked to describe your drug use, other activities, or your engagement with law enforcement and other institutions of authority. The most serious risk, though still small, is loss of confidentiality. If your status as drug user became known, it could result in a number of harms, among them stigma, loss of employment or housing, arrest, or forced treatment for drug abuse. In addition, the process of reflecting on your drug use, may increase your desire to find referrals for drug treatment. Every effort will be made to protect your confidentiality and to provide you with referrals for drug treatment or medical care, if it is available.

Required disclosures:

The following persons may review the records of this project for compliance with informed consent and other federal requirements and may therefore have access to information you provide, although no personally identifiable information about you will be collected:
• Institutional Review Boards of University of Connecticut, Temple University, and Harvard Medical School in the United States (U.S.);
• National Institute for Drug Abuse, U.S.;
• Research Ethics Boards in Ukraine, Poland, and Russia.

Measures to reduce potential risks and assure confidentiality

Reducing Potential Risks:

Local investigators and field workers will be trained to respond to any participant who becomes uncomfortable during the interview by offering to take a break, skipping that set of questions, moving on to a different domain of the questions, or simply stopping the interview. You have the right to decline to answer any part of the interview or stop at any time.

The primary risks (although small) to subjects will be potential breaches of confidentiality, addressed below.

Confidentiality:

All investigators and staff will also be trained about the importance of confidentiality and the steps the project will take to protect confidentiality.

For interviews with injection drug users, or other informants who might have engaged in illegal acts, all interview tapes will be retained, but no personally identifying information will appear on transcripts, or summaries. All tapes, transcripts and summaries will be coded using unique codes, and signed consent forms will be unlinked to other materials. Interviews with IDUs will be completely anonymous and no identifying information will be kept on the tape, transcript or any other field materials. In addition, exact locations of venues and street scenes where IDUs congregate will not be published, only general neighborhood designations. Databases will be password protected in all sites, and data transmittal will occur by courier to the US.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state,
or local civil, criminal, administrative, legislative, or other proceedings in the United States. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The local lead investigator and the US PI will monitor adherence by field workers and staff to project confidentiality policies and procedures. The US PI or co-PI’s will review and inspect the confidentiality practices of the foreign sites during periodic visits.

**Potential Benefits from this Study:**

This project will provide no direct benefit to individual participants, but the process may provide other benefits to participants and the community. The collective work of the CAB, focus group, system, interactor and IDU participants may benefit the community by identifying ways to improve HIV prevention locally, and participants may benefit from the increased sense of community involvement that their participation generates.

Participants will receive US$10.00 for their time and transportation expense for each meeting or interview in which they participate. IDUs will also benefit from receiving safe sex and injection supplies (no syringes), information and referrals to any locally available care and services. These benefits, though modest, balance the slight risks to individual subjects.

**Costs to Participants**

There will be no costs to participants for participation in this study.
Additional Information or Questions about this Study:

The interviewer and the investigators in this study are willing to answer any questions you may have about the study or about participation in research in general.

If you have further questions you can contact your local Principal Investigator:

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Polish AIDS Society
ul. Arkonska4
71-455 Szczecin, Poland
korkiniec@fol-plast.pl
+48 91 431 62 42

Or the overall Principal Investigator for the study:

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For additional information on your rights as a research subject, you can also contact the office of the IRB at University of Connecticut Health Center at 860-679-3054 or email: chasse@adp.uchc.edu.

Voluntary Participation:

Your participation in this study is voluntary and you may choose NOT to participate or to end your participation at any time without any penalty.

By signing below you agree to participate in this study and confirm that you have read or had explained to you the details of this
study contained in this form, had the opportunity to ask questions and have them answered to your satisfaction, and received a copy of this consent form.

__________________________________________________
participant (initials or pseudonym please) date

__________________________________________________
investigator date