

Ethical Issues in Substance Abuse Research

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Immediate Motivation

Request from NIDA to develop an Ethics Guidance Document for NIDA grantees involved in HIV/AIDS research with drug users

Enduring Motivation

Confronted thorny ethical dilemmas in conducting field based HIV prevention research in US and in international settings

NIDA Funded HIV/AIDS Research

- Prevention and Treatment
- From Biomedical to ethnographic
- Observational and interventional
- Domestic and international
- Adults and children
- Out of treatment and in-treatment samples
- Active drug users versus those in recovery

Where to begin?

Step 1) Identify an ethical framework

International Ethical Guidelines for Biomedical
Research Involving Human Subject

Committee for International Organization of Medical Sciences (CIOMS)

Overarching Guiding Principles for Ethical Conduct of Research

1. **Respect for persons**

(ensuring voluntary & informed consent)

2. **Beneficence/non-maleficence**

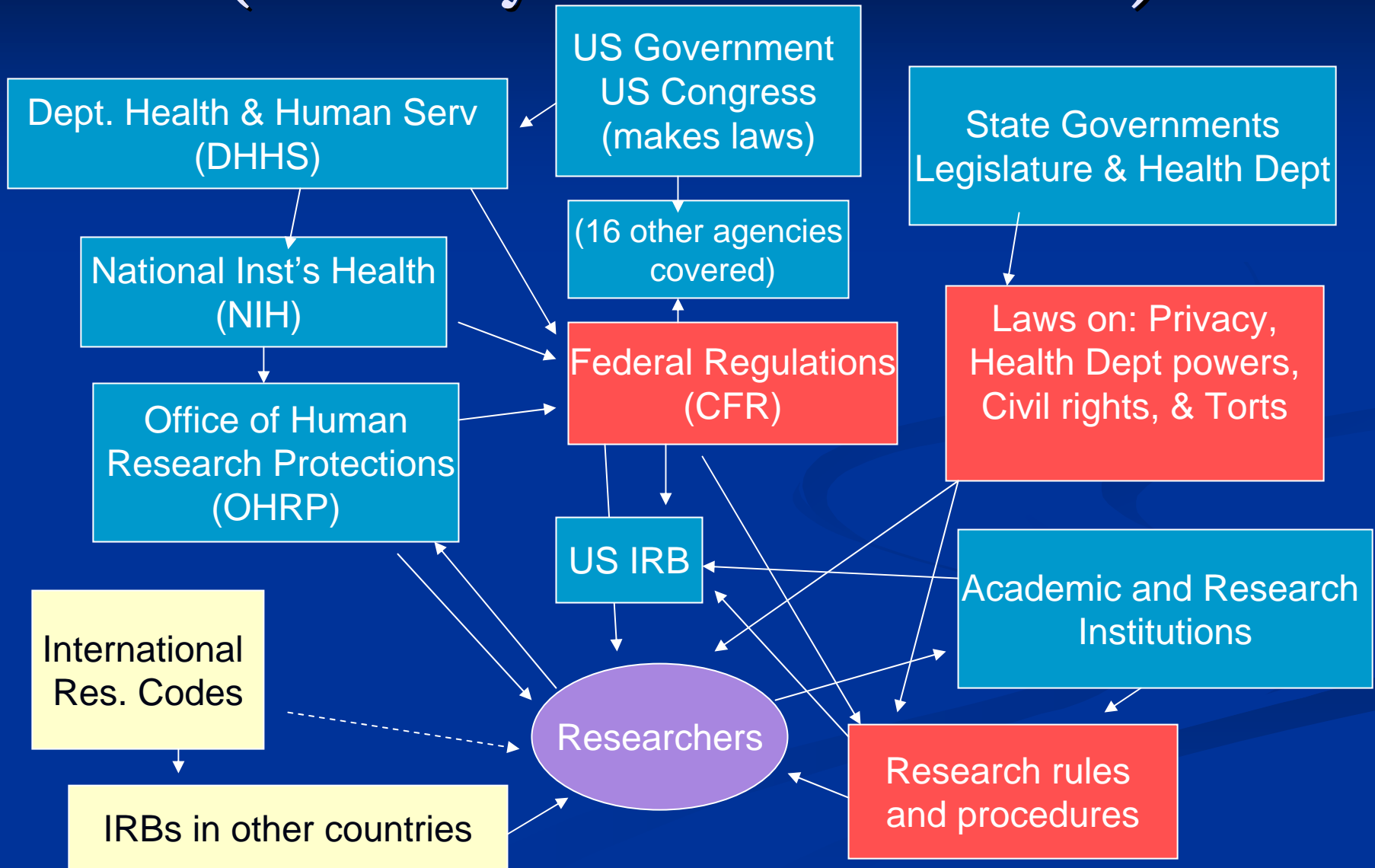
(do good, minimize harm)

3. **{Distributive} Justice**

(fair distribution of benefits & risks)

Step 2) (Try to) Understand
the Regulation of Research

Regulation of US-Based Research (courtesy of Zita Lazzarini)



**Step 3) identify “generic”
ethical issues in drug use
research**

“Generic” Ethical Dilemmas in Drug Use Research

- Illegal nature of drug use and related activities can result in a variety of risks to subjects and staff
- Stigma attached to illicit drug use
- Drug use is a highly personal and emotionally charged behavior
- Vulnerability of drug users creates potential for their exploitation in research

Selected Ethical Dilemmas: Study Participants

- Risk of arrest and incarceration
- *Achieving Informed Consent and “voluntary participation” under desperate circumstances*
- Rise of unrealistic expectations from the researchers
- Unforseeable challenges resulting from field-based research

Do You Use

Cocaine Clinic Research Study

Yale University
School of Medicine
Inpatient

Non-Treatment Seeking
Volunteers

\$\$ Paid Participation \$\$

COCAINE?



For more information call Seth (860) 545-7802

All information held confidential

(HIC #10856, #13995, #12993, #27688)

Should We Pay Drug Users for Participation in Research?

Does paying drug
users undermine
informed consent?

Does Payment to drug users for participation in research constitute “coercion” or “undue influence”?

Is money special?

What about offer of free and/or immediate access to drug treatment?

Informed Consent: Coercion or undue influence

“An investigator shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate *and that minimize the possibility of coercion or undue influence*”
(emphasis added)

US Common Rule for Protection of Human Subjects (1991)

Another concern:

**Does monetary
compensation transform
the research subject into
a commodity?**

What is the purpose of research?

Should we view research in terms of a “market place” where people pay and get paid for their work and/or for the risks they take?

Purpose of Research?

- “a systematic investigation, ... designed to develop or contribute to generalizable knowledge.”

[45 CFR 46.102(d)]

- To alleviate suffering ?
- To address inequities?
- To promote justice?

**Additional ethical
concerns associated with
field staff**

Selected Ethical Dilemmas: Study Staff (1)

- Risk of physical harm or arrest
- Stigma of working with “Junkies”
- Assisting participants in procuring or using drugs
- Risk of relapse for former IDUs
- Blurring of personal/professional boundaries

Selected Ethical Dilemmas: Study Staff (2)

- Observing a significant risk behavior by study participant (e.g., sharing syringes between discordant persons)
- Learning of study participant's intention to hurt herself or others
- Damage to social relationships and social standing of staff in the community due to unanticipated problems in the study

Additional Ethical Challenges in Drug Use Research in International Settings

- No or little tradition of research with drug users.
- No or inexperienced IRBs.
- No or limited medical (including drug treatment) and social service resources.
- Extremely punitive law enforcement against drug use.
- Competing agendas of funders, researchers, participants, local IRBs and partners.

Is there any help out there for
researchers to resolve these
ethical dilemmas?!

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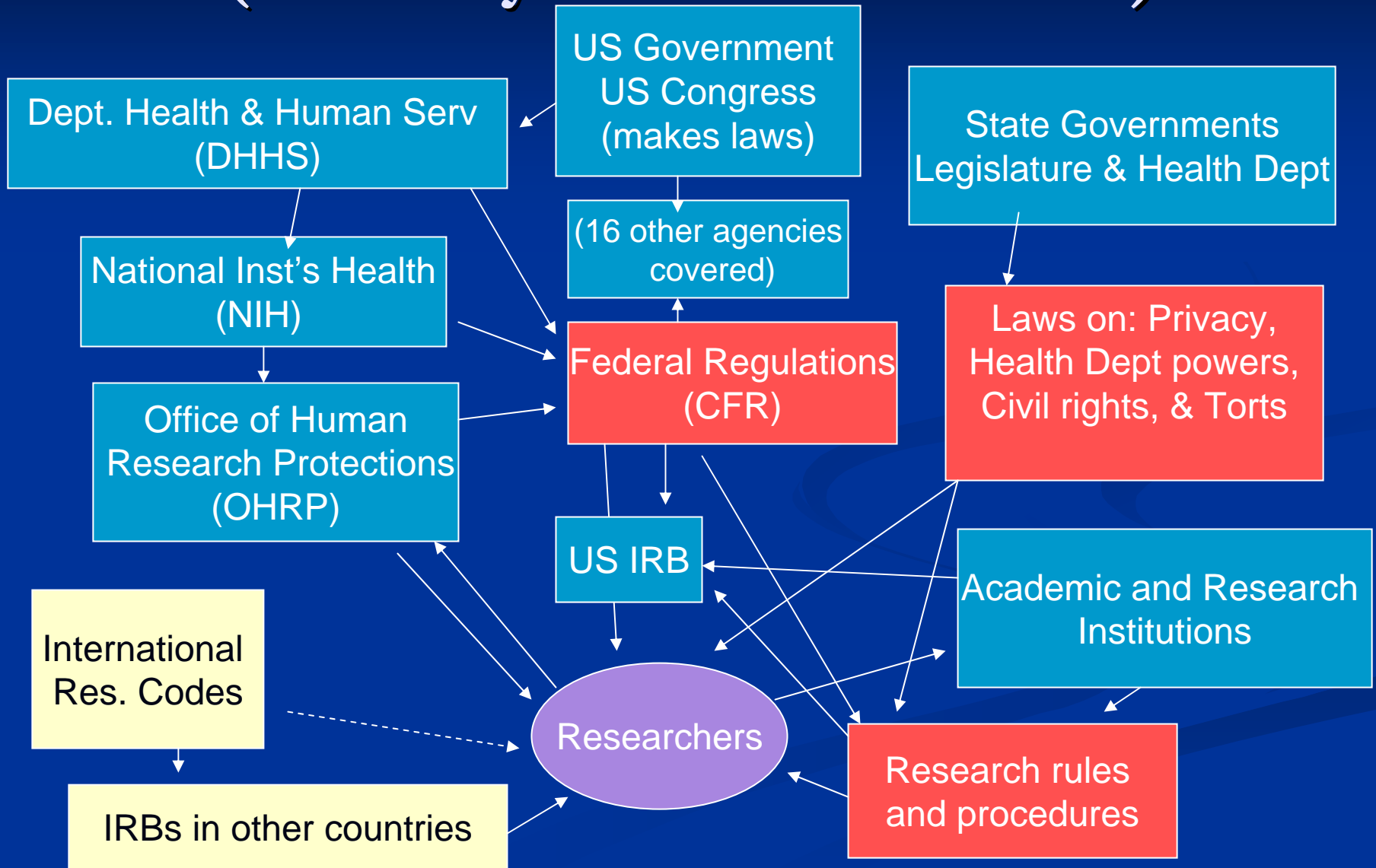
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Regulation of US-Based Research (courtesy of Zita Lazzarini)



Ethical principles and
regulations primarily
focus on protection of
individual human
subjects

But what about the context of research?

HIV/AIDS Research involving drug users often occurs in context of poverty and lack of adequate health care

Broadening the ethical discourse

- Focus on issues beyond individual human subjects and on the community
- Investigate the experience of research

Asking new questions about research

(1)

- What actually happens in research and how are ethical dilemmas negotiated and resolved?
- What are researchers' experiences with local NGOs, police, government officials, IRBs and general community?
- How is the adequacy of informed consent ensured?
- How is material inducement (incentive) for participation in research determined and negotiated?

Asking new questions about research (2)

- How do investigators deal with lack of essential social and medical resources to refer drug users to?
- What are programmatic and policy implications of the research?
- Are there significant “adverse events” in the research setting (i.e, local partners, local community) beyond individual research participants?

The Way Forward: Researchers

- Assemble multidisciplinary teams that includes ethicists and social scientists.
- Develop community consultations in setting local standards
- Report and publish research experiences and best practices, not only outcomes.
- Build capacity of both US based and international IRBs in reviewing drug use research.
- Consider programmatic and policy implications of research; before, during and after your study.

The Way Forward: *IRBs*

- Seek resources to increase the capacity to review protocols involving field-based research with active drug users in international settings.
- Identify and actively recruit individuals with expertise in this area to serve as permanent or ad-hoc members of your IRBs.

The Way Forward:

Funders/Regulatory agencies

- Encourage researchers to share their experiences with thorny ethical challenges with the larger scientific community.
- Remove disincentives for researchers to openly discuss ethical challenges they encounter in their work.
- Provide funding to increase the capacity of *both* US and international IRBs to review research protocols involving active drug users.

The Way Forward: *Editors/Organizations*

- Create venues (special issue of Journals, conferences, websites, etc.) for researchers to document their research experiences and discuss the ethical issues encountered and how they responded to or resolved them.
- Consider the creation of an International Harm Reduction Research Ethics Committee that can serve as a clearing house and resource to offer technical assistance.

**“We’re good enough to
study but not good
enough to care for”**

Haitian Woman with AIDS