

## *Purview & Roles of IRBs*

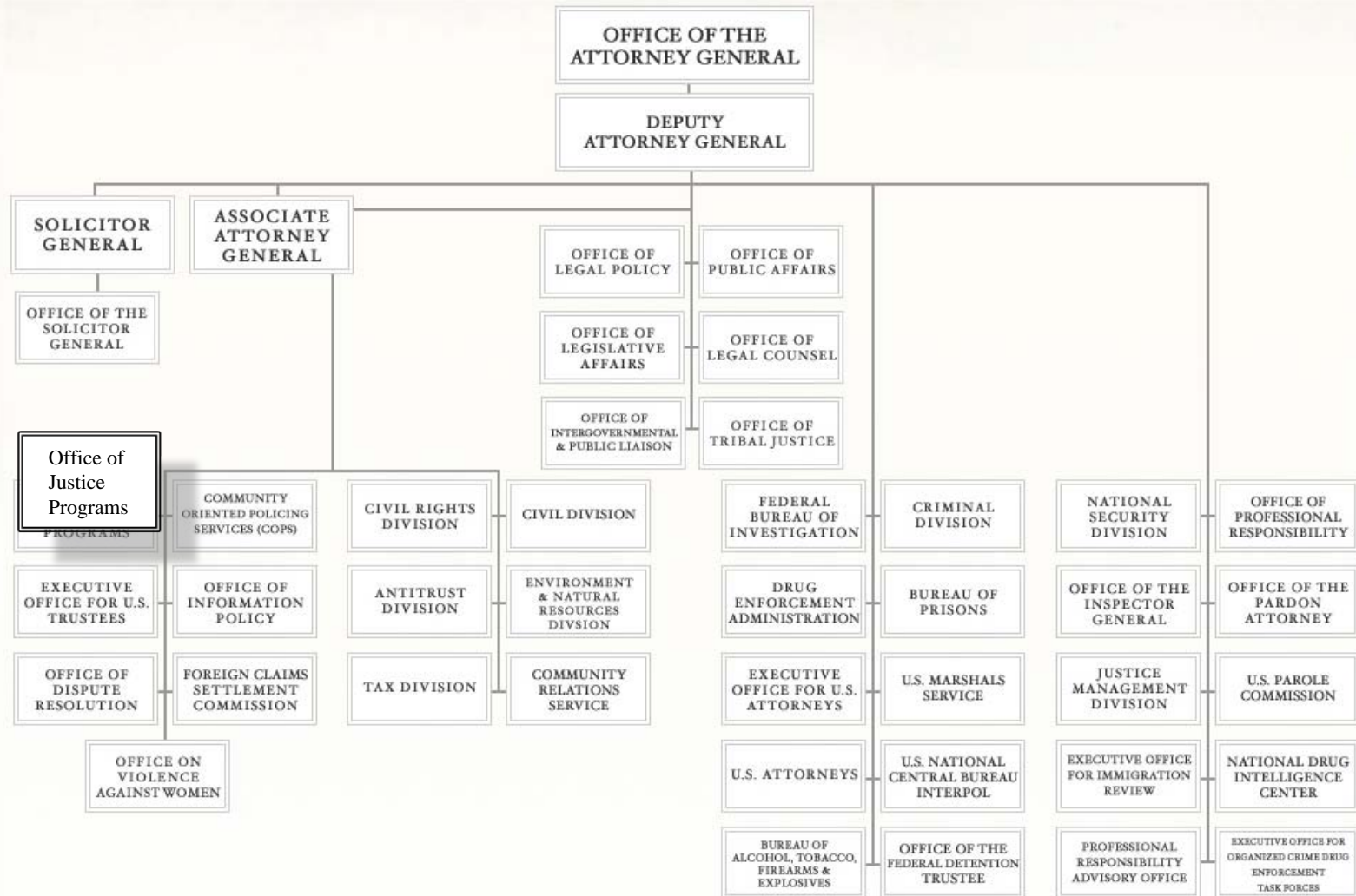
*NAS Workshop on Proposed Revisions to the  
Common Rule in Relation to  
the Behavioral and Social Sciences*

**Cheryl Crawford Watson**  
**Human Subjects Protection Officer, NIJ**  
**[cheryl.crawford.watson@usdoj.gov](mailto:cheryl.crawford.watson@usdoj.gov)**

## *NIJ's Mission*

The National Institute of Justice — the research, development and evaluation agency of the U.S. Department of Justice — is dedicated to improving knowledge and understanding of crime and justice issues through science.

# *NIJ's Location Within the Department*



## *Office of Justice Programs*

- National Institute of Justice
- Office for Victims of Crime
- Bureau of Justice Assistance
- Bureau of Justice Statistics
- Office of Juvenile Justice & Delinquency Prevention
- Office of Sex Offender Monitoring, Apprehending, Registering & Tracking

## *OJP Funding*

- Over the past 10 years, OJP has provided 52,000 funding awards to the criminal justice community totaling more than \$26 billion.
- In Fiscal Year (FY) 2009, OJP awarded 4,900 grants totaling more than \$2.5 billion. In FY 2009, OJP also awarded an additional 3,883 Recovery Act grants totaling more than \$2.74 billion to state and local and tribal law enforcement and community organizations.
- Most of OJP's funding programs are highly competitive; hundreds of grant proposals are received & processed for the same funding opportunities

## *Where do IRBs come in?*

Through grants, cooperative agreements, and contracts, NIJ/OJP funds:

- Extramural research – reviewed by a grantee's own IRB or commercial IRB
- Intramural research – reviewed by OJP IRB

## *Duties of NIJ HSPO*

- To review research awards, adding & removing special withholding conditions to ensure compliance
- To train/educate in-house research staff
- To consult with NIJ-funded researchers & IRBs
- To serve as co-chair on OJP IRB
- Plus a myriad of other things HSP-related!

## *Laws and Regs. re: DOJ-funded Research*

- Confidentiality of Information (42 USC §3789g)
- Confidentiality of Identifiable Research and Statistical Information (28 Code of Federal Regulations (CFR) Part 22)
- Protection of Human Subjects (28 CFR Part 46)  
[The Common Rule]
  - DOJ adopted only the Common Rule, not Subparts



# CONGRATULATIONS!

You've received and accepted an award from NIJ.

## **Now what?**

Read all of the award conditions.

If the award has special conditions for human subjects protection and/or privacy, please note that these conditions withhold funds until regulatory compliance is achieved.

## **To get the funds released, you must submit the following to NIJ for approval:**

- 1. Human Subjects Protection Form
  - IRB Approval, if applicable
    - IRB-approved informed consent docs
    - IRB-approved instruments
- 2. DOJ Privacy Certificate

**\*\*Cite the DOJ regulatory citations in your IRB application & ask IRB to use them!**

## *Common issues in HSPO review of Grantee HSP-related documents*

- Forms not signed or dated, nor proof-read
- PI's attempt to self-exempt
  - (ANPRM “excused” as new category)
- IRBs unaware of DOJ regulations

## *Common issues, continued*

- IRBs confused by DOJ regulations
- PI's anxious to start HS research; must wait for funds release
- Complexity of consent process

## *FAQs by PIs & IRBs*

- Can I get a CoC from DOJ?
- What is the difference between CoCs & PCs?
- Are there exceptions to confidentiality?
- What about mandatory reporting?



*Department of Justice Confidentiality Statute  
(42 USC §3789g)*

“No officer or employee of the Federal Government, and no recipient of assistance...shall use or reveal any research or statistical information furnished...by any person and identifiable to any specific private person other than the purpose for which it was obtained. **Such information ...shall be immune from legal process, and shall not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any...judicial, legislative or administrative proceedings.**”

## *Privacy/Confidentiality Regs (28 CFR Part 22)*

All DOJ awardees collecting PII must submit a Privacy Certificate (PC):

- describing the research,
- **assuring** that the applicant will comply with the requirements, and
- describing the procedures that will be used to protect the confidentiality of the identifiable information collected as part of the research.

## *Elements of the Privacy Certificate*

### *(28 CFR §22.23)*

- Brief description of project
- Procedures to notify subjects (informed consent)
- Justification for the collection and maintenance of identifiable information and assurance to preserve confidentiality
- Administrative and physical security of identifiable data, to include removal of identifiers, locked file cabinets, password protection, etc.
- Access to data limited to persons w/ need-to-know and who agree to comply
- Information transfer agreements - limitations and authority
- Final disposition of data in identified form & data archiving



## *Notification (Inform + Consent)*

- All research subjects must give their consent to participate and be told:
  - the information they provide will be used for research and statistical purposes only;
  - compliance with the request for information is voluntary and can be terminated at any time;
  - study risks and benefits;
  - how the data will be securely maintained; and
  - how data will be archived/disposed of post-study.
- Study funder should be identified.

## *Are there exceptions to confidentiality?*

- No. Confidentiality can only be broken with the subject's consent. Identifiable data collected can only be used for research purposes and no other purpose without the subject's consent.
- 28 CFR Part 22.20 (c): The regulations do not apply to information gained regarding future criminal conduct.

## *CoC vs. PC*

- Both allow voluntary disclosure by subjects.
- Both protect against compelling disclosure.
  - They allow the researcher to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- They differ with respect to other voluntary disclosures.

## *What About Mandatory Reporting?*

- CoCs do not prevent researchers from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened harm to self or others, while DOJ confidentiality statute & regs. do.
- Federal law supersedes State law, thus need for 2 consent forms: consent to participate & consent to allow reporting
- Self-report is strongly encouraged and resources can be provided to all study subjects.

## *Bright Line of Confidentiality*

- Researchers using DOJ funds cannot report suspected abuse of subjects, unless they obtain subjects assent/consent to
  - 1) participate in the research **AND**
  - 2) allow the PI to report if abuse alleged or suspected
- DOJ is le agency; few would participate in DOJ-funded research without protections on identifiable data

*If NIJ-funded PI or their IRB needs or wants to report:*

- Flexibility to use combined form or two forms
- If combined form, must clearly state and subject must sign to participate & to allow mandatory reporting
- Subject must be fully informed of & acknowledge awareness of circumstances when confidentiality can be broken.
- Subject should be encouraged to self-report.

## *Penalties*

- Any person violating the provisions of 42 USC §3789g or 28CFR Part 22 is subject to a fine of \$10,000 in addition to any other penalties imposed by law.
- DOJ has the right to terminate funding and initiate appropriate legal action for violations of the statute or the regulation.

# *Resources*

- NIJ on the Web at NIJ.GOV
- NIJ Webpages on Human Subjects Protection  
<http://www.nij.gov/nij/funding/humansubjects/welcome.htm>
- Contact: Cheryl Crawford Watson  
Human Subjects Protection Officer  
National Institute of Justice  
Office of Justice Programs  
U.S. Department of Justice  
E-mail: [cheryl.crawford.watson@usdoj.gov](mailto:cheryl.crawford.watson@usdoj.gov)