Protection of Human Subjects in Research at NIST

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Outline

- Definition of research involving human subjects
- Procedures – non-use of human subjects, exemptions, IRB review, NIST institutional review
- Role of IRB
- IRB Review process
- Investigator responsibilities
- Informed consent
- Questions

Research Involving Human Subjects - I

- Definition:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

1) Data through intervention or interaction with the individual, or
2) Identifiable private information (15 CFR 27.102(f))

Research Involving Human Subjects - II

- Defined very broadly
- Encompasses all areas of research, including:
  - Study of human behavior, reactions and thought processes
  - Study of human body, tissues, organs, cells, cell lines, DNA, etc.

What procedures must be followed when using human subjects in research?

- Research involving human subjects is governed by 15 CFR Part 27, the Common Rule.
- NIST procedures are set forth in Administrative Manual Subchapter 14.01.

What at NIST is covered by the Common Rule?

- All research involving human subjects **“conducted or supported”** by NIST, including research conducted by:
  - NIST employees, contractors and funding recipients
  - Guest Researchers
  - Outside parties using NIST facilities
  - Shared facilities, e.g., CARB, JILA
  - CRADA partners, e.g. ADA

“Protected Classes”

- Children, prisoners, pregnant women, human fetuses, and neonates
- Protocol and informed consent form must be approved by a qualified Institutional Review Board (IRB) with a federal-wide assurance from Department of Health and Human Services (DHHS)
- NIST IRB is not authorized to review research involving Protected Classes.

Non-Use of Human Subjects

- When investigator conducting a research project supported or conducted by NIST and/or their direct collaborator(s) on the project DOES NOT have access to identifiers (for example, purchases of cell lines from vendors).
- Div. Chief determines whether research involves human subjects and documents this in a memo to the NIST IRB Chairperson through the NIST Counsel.

Exemptions - Procedure

- In general, available when the research does not involve prisoners or children, and fits within one of the exemption categories listed in 15 CFR 27.101(b).
- The Laboratory/OU Director determines whether research is exempt and documents this in a memo to the NIST IRB Chairperson with concurrence by NIST Counsel. (See Admin Manual Subchapter 14.01, App. A.)

Exemptions - Examples

- Surveys, interviews and questionnaires, observations of public behavior are often exempt.
- Existing records/specimens when publicly available or not identifiable with a particular subject. (may not be research involving human subjects)
- Exemptions only permitted in limited circumstances for research involving children and not permitted for prisoners .

NIST IRB Review -When

- If the research involves human subjects and
  - does not involve a Protected Class,
  - is determined not to be exempt, and
  - is to be conducted at NIST by NIST employees.

NIST IRB Purposes

- Protect physical and psychological well-being of human subjects participating in research
- Ensure NIST research using human subjects is designed and conducted in a manner that minimizes the risk to the subjects.
- Serve as safeguard to protect NIST from errors in ethical judgment

IRB Review of Research - I

- "Expedited Review"
  - When research involves no more than minimal risk and falls within one of the DHHS expedited review categories
  - When there are minor changes in previously approved research within one year
  - Done by IRB Chair, who may request that experts and/or other IRB members review, as well.

IRB Review of Research - II

- IRB Review
  - When expedited review not acceptable
  - Formal meeting convened
  - Majority of IRB present, including at least one member from non-scientific area
  - Majority vote rules
  - Provides feedback to PI, if necessary

Criteria for IRB Approval of Research

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Informed consent sought and documented
- Adequate provisions protecting privacy of subjects
- Adequate provisions maintaining confidentiality of data
- Importance of knowledge to be gained

IRB Process

- Memo from OU Director to IRB Chair summarizing human subjects research protocol, with full documentation and recommendation
- IRB Chair decides if expedited review acceptable, or if full IRB review necessary
- IRB consideration and vote
- IRB may request changes to protocol and informed consent documents
- IRB approval document goes through NIST Counsel to NIST Deputy Director for approval
- PI notified by IRB Chair
- Approval must be renewed annually (within 365 days)

IRB Membership

- All members appointed by NIST Director
- Broad range of expertise and experience
- At least one member not affiliated with NIST
- NIST Counsel and ATP Human and Animal Subjects Advisor designated as ex-officio members

Current IRB Membership

- Alan Cookson, EEEL (Chair)
- Lisa Karam, PL (Vice-Chair)
- Jeanice Brown Thomas, CSTL
- Joseph Antonucci, MSEL
- Cynthia Reed, BFRL
- Walter Liggett, ITL
- Victor Nedzelnitsky, MEL
- John Nail, ATP
- Barbara Lambis, ATP
- Cynthia Snipes, OD
- Maureen E. Power, NIH
- Mike Rubin, NIST Counsel, (ex-officio)
- Melissa Lieberman, NIST Counsel, (ex-officio)
- Larry Uhteg, ATP, (ex-officio)

Investigator Responsibilities - I

- Primary responsibility for protecting rights and welfare of human subjects research
- Knowledgeable about Federal regulations, NIST policies and procedures for protection of human subjects
- Training requirements
- Conduct research according to IRB- approved protocol and using IRB-approved documents

Investigator Responsibilities - II

- Ensure that each potential subject understands nature of research and their participation
- Provide and keep a copy of signed IRB-approved informed consent form for each subject

Investigator Responsibilities - III

- Promptly report proposed changes in activities to IRB - do not initiate until approved by IRB
- Report progress to IRB as prescribed
- Promptly report to IRB incidents of unanticipated problems involving risks to subjects and others

Informed Consent

- Basic Concepts of consent process include:
  - Full disclosure of nature of research and subject's participation
  - Adequate comprehension on part of potential subject
  - Subject's voluntary choice to participate and withdraw without loss of benefits to which the subject is otherwise entitled
- Specific requirements for informed consent set forth in Common Rule (15 CFR 27.116) and NIST Admin Manual Subchapter 14.01, App.C

Consent Process

- Informed consent obtained prospectively from subject or legal representative
- Information in understandable language
- Subjects given opportunity to consider
- Consent must be given without coercion or undue influence
- Subjects must not give up legal rights or be given impression that they are being asked to do so

Elements of Informed Consent - I

- Federal regulations detail specific elements of information provided to each subject:
  - Description of research and subject's participation, incl. experimental procedures
  - Description of reasonably foreseeable risks
  - Description of expected benefits to the subject or others
  - Potentially advantageous alternatives to participation

Elements of Informed Consent - II

- Explanation of extent to which records and subjects' identities will be kept confidential
- Explanation of compensation for injuries
- Whom to contact with questions
- Explanation that participation is voluntary

NIST Institutional Review of NIST-Supported External Research - I

- If the research
  - is to be funded or supported by NIST but conducted outside NIST, **or**
  - is to be conducted at NIST by an outside organization; **and**
  - is determined not to be exempt

NIST Institutional Review of NIST-Supported External Research – II

- Protocol and informed consent form must be approved by a **qualified external IRB**
- Approved protocol, informed consent form, and external IRB approval documentation must be approved by the NIST Deputy Director

Human Subjects Research

- All uses of human subjects must be approved **IN ADVANCE!**
- No retroactive approvals!
- No exceptions!
- If there is any doubt, **ask!**

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- IRB Website
  http://www.nist.gov/director/IRB