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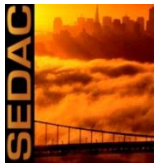

Scientific Data Management for the Protection of Human Subjects

Robert R. Downs
NASA Socioeconomic Data and Applications Center (SEDAC)
Center for International Earth Science Information Network (CIESIN)
The Earth Institute, Columbia University

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Basic Ethical Principles from the Belmont Report (1976)

- **Respect for persons** "as autonomous agents"
  - "give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others".
  - "Respect for the immature and the incapacitated may require protecting them … even to the point of excluding them from activities which may harm them".
- **Beneficence "**by making efforts to secure their well-being"
  - "complementary expressions of beneficent actions … (1) do not harm and (2) maximize possible benefits and minimize possible harms".
  - "investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation"
- **Justice** – "ways to distribute burdens and benefits"
  - **" (1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit".
  - **"**determine whether some classes … are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied".

Minimize Risks to Subjects

- When designing a research study that involves human subjects, the risk to the subjects should be minimized.

- Title 45 of the Code of Federal Regulations (CFR) Part 46, Protection of Human Subjects, offers policy, which can be considered a starting point for the protection of human subjects.

- The design of social science research should go even further than the minimum requirements to protect human subjects by minimizing potential risks to any subjects that will be participating in the research.

45 CFR 46.111
Criteria for IRB Approval of Research

1 "Risks to subjects are minimized …"
- Do the risks exceed those normally encountered in daily life?
- In some research, the potential loss of confidentiality poses the greatest risk. How can data management minimize such risk?

2 "Risks to subjects are reasonable in relation to anticipated benefits …"
- What risks will the subjects be exposed to by participating?
- What benefits will result from the research?

3 "Selection of subjects is equitable. …"
- What are the criteria for the selection of subjects?
- Are the selection criteria justified by the research purpose?

Available from: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

45 CFR 46.111 (continued) Criteria for IRB Approval of Research

4 "Informed consent will be sought from each prospective subject or the subject's legally authorized representative …"

- Are all the elements of informed consent present?
- Will the subjects understand the language of informed consent?
- Is there any potential for coercion during the consent process? How will informed consent be administered?

5 "Informed consent will be appropriately documented …"

- Will the informed consent be documented with a signed form?
- Since the signed informed consent form could identify research subjects, should a waiver of documentation of informed consent be requested?

45 CFR 46.111 (continued) Criteria for IRB Approval of Research

6 "When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."

- How will the data be protected from the time they are collected, during transportation and processing?
- Where will the data be stored? Who will have access?

7 "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

- Are the data being collected in a way that exposes subjects to potential risks?
- Will the data contain individual identifiers of subjects and, if so, is there a plan to de-identify the data?
- Are any identifier codes secured separately from the data?