



MRSEC Education Coordinator's Meeting

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Reminder: Institutional Review of Human Subjects Research Is Required

All projects involving human subjects must either

- (1) have approval from the organization's Institutional Review Board (IRB) before issuance of an NSF award,

Or

- (2) must affirm that the IRB or an appropriate knowledgeable authority previously designated by the organization (not the Principal Investigator) has declared the research exempt from IRB review.



<http://www.nsf.gov/bfa/dias/policy/docs/45cfr690.pdf>

Human Subjects Research

Does the research involve human subjects?

According to the Dept of Health and Human Services (HHS), a human subject is: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (pg. 4 from 45cfr690.doc).

Is this a research activity?

According to HHS, research is defined as:

A systematic investigation... designed to develop or contribute to generalizable knowledge (pg. 3 from 45cfr690.doc). (*Do you want to present or publish these results? If yes, then it's research.*)

What about Quality Improvement, and Program Evaluation Studies? Is it human subjects research?

- ❑ Depends upon why the study is being conducted...
- ❑ **Is generalizable knowledge the goal?**
- ❑ Is it being done to improve a procedure or practice in a particular setting?
- ❑ **Are results likely to be published or presented at professional meetings?**



Human Subjects Research

Multiple Sites

When research is conducted at multiple sites, there are several forms that IRB approval may assume:

- One lead IRB reviews all sites where human subjects will be conducted.
- A central (i.e., commercial) IRB may be used to review all sites.
- Each site may review its own research.
- One IRB may be designated as “lead,” but still rely upon reviews of other IRBs.



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Human Subjects Research

SIX Categories for “Exempt” Research as Defined by 45 CFR 46:

- (1) Research conducted in educational settings
- (2-3) Tests, surveys, interviews, or public observation
- (4) Research on existing public or anonymous data or specimens.
- (5) Federal demonstration projects designed to study or evaluate
- (6) Taste and food quality evaluation & consumer acceptance studies

Bottom line – based on the level of activity of this working group, if you have not done so already, - get an exemption from your IRB!



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Questions?

