

Human Research Protections Newsletter

Comment Period for Draft SOPs

The IRB continues to revise and re-organize the 'Guidelines' to 'HRPP Operating Procedures'. Although NDSU's overall policy for protection of human research participants is not changing, the new SOP format will enhance access to information, provide additional operational details, and advance NDSU's compliance with federal standards.

The latest drafts are posted on the *IRB Updates* BB course for comments from the research community prior to implementation:

- 12.1 QA Audits—Random
- 12.2 Directed Audits of Research
- 12.3 Complaints or Allegations of Non-compliance
- 12.4 Reporting
- 7.5 Protocol Amendments
- 7.7 Unanticipated Problems

HRPP Operating Procedures at: ndsu.edu/research/irb

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Survey Monkey Users

If Survey Monkey or another online survey vendor is utilized in your department or unit, the IRB would like your input! As online survey methods become widely used, there is a need to establish consistent campus-wide guidance for protecting confidentiality of research participants' data. Contact Teri Grosz at 231-8908.

Your Questions:

Who is a research participant?



All research participants are entitled to rights and protections, in accordance with federal regulations and NDSU policy.



The terms 'research participant' and 'human subject' are used interchangeably. Federal regulations (45CFR46.102) define 'human subject' as *'...a living individual about whom an investigator ...conducting research obtains: 1) data through intervention or interaction with the individual, or [emphasis added] 2) identifiable private information.'*

Note that this definition would include those participants who may provide information only anonymously, be exposed to little or no risks, or have no direct interaction with researchers.

NDSU extends the definition to include some participants whose de-identified existing data, documents, records or specimens are obtained for research purposes. Refer to SOPs 11.1, 11.2 and 11.3.

For examples of ways in which individuals become research participants, see FAQ #1 on the IRB website.

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Questions or comments? E-mail us at ndsu.irb@ndsu.edu, or call 701-231-8908

Visit the *IRB Updates listserv* course on Blackboard to self-enroll or change your status on this list.