PENNINGTON BIOMEDICAL RESEARCH CENTER
LSU

HRPP Policy Updates

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9.0 HRPP Protocol Deviations

Policy is available at
www.pbrc.edu/hrpp/policies

Deviation Model

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Participant vs. Investigator Deviations

9.5.1 Participant Initiated Deviations (Major)

9.5.1 Participant Initiated Deviations

- Are due to a study participant's non-adherence to the protocol.

Major Participant Deviations	• May impact participant safety • May alter the risks to participants • If the deviation affects participant safety or if a pattern of the protocol departure indicates a need for a change in the protocol or informed consent

- Decision on whether the deviation is a major participant initiated deviation or a minor participant initiated deviation is left to the discretion of the investigator.
- **All major deviations need to be reported to the IRB within 7 days.**

9.5.1 Participant Initiated Deviations (Minor)

9.5.1 Participant Initiated Deviations

– Are due to a study participant's non-adherence to the protocol.

Minor Participant Deviations	• **Does not** impact on participant safety • **Does not** alter the risks to participants • **Does not** affect the participant's willingness to participate

– **Does not have to be reported to the IRB.** Participant deviations need to be recorded in the participant record.

9.5.2 Investigator Initiated Deviations (Major)

9.5.2 Investigator Initiated Deviations

- Are the result of the investigator, research staff or other party involved in the conduct of the research intentionally or unintentionally deviating from the approved protocol.

Major Investigator Deviations	• May impact participant safety • May alter the risks to participants • May affect the participant's willingness to participate

- **All major deviations need to be reported to the IRB within 7 days.**

9.5.2 Investigator Initiated Deviations (Minor)

9.5.2 Investigator Initiated Deviations

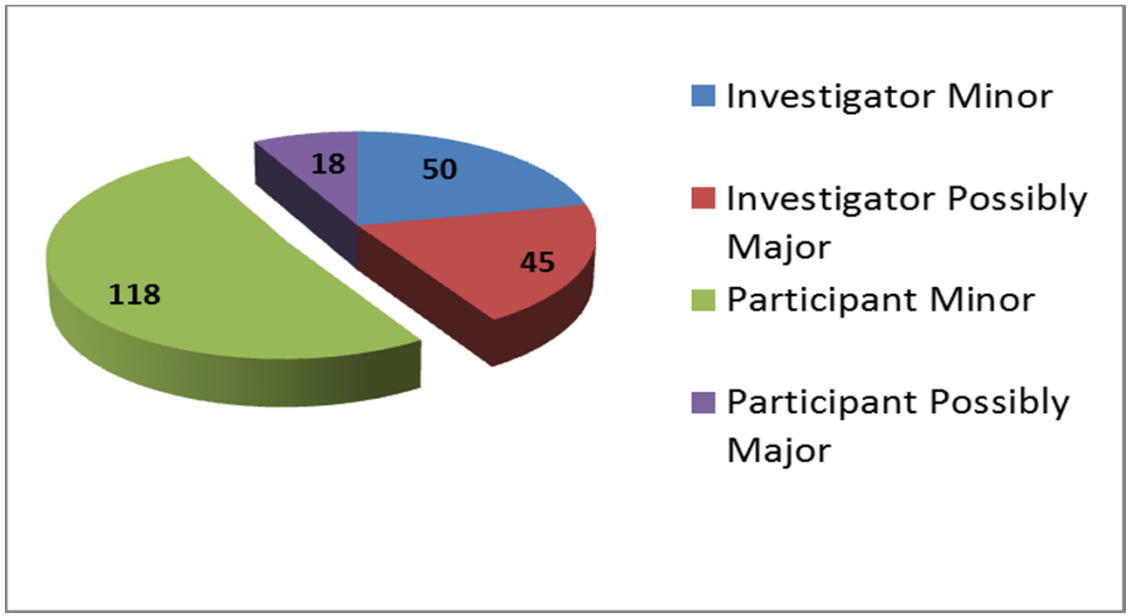
- Are the result of the investigator, research staff or other party involved in the conduct of the research intentionally or unintentionally deviating from the approved protocol.

Minor Investigator Deviations	• **Does not** impact on participant safety • **Does not** alter the risks to participants • **Does not** affect the participant's willingness to participate

- **All minor deviations need to be reported to the IRB within 14 days.**

Percentage of Deviations

Deviations from March 2013- May 2014



Participant Minor (**Do not Report**) – 51%
Participant Possibly Major (Report in 7 Days) – 8%
Investigator Minor (Report in 14 days) – 22 %
Investigator Possibly Major (Report in 7 days) – 19%

19.0 Deception or Incomplete Disclosure in Research

Policy is available at
www.pbrc.edu/hrpp/policies

19.0 Deception or Incomplete Disclosure in Research

- 19.2.1 Deception

  Deception occurs when an investigator gives false information to subjects and intentionally misleads them about some key aspect of the research. A key aspect includes but is not limited to a primary endpoint.

- 19.2.2 Incomplete Disclosure

  Incomplete disclosure occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research.

When To Use Deception

- There must be a justification
- Cannot deceive participants about research that is expected to cause physical pain or severe emotional distress
- Must let participants know at the earliest convenience about the deception

Waiver or Alteration of the Informed Consent

- The research cannot be more than a minimal risk
- The waiver or alteration does not adversely affect the rights and welfare of the participant
- Whenever appropriate, the participant will be provided additional information after participation

Deception De-Briefing Goals

- To repair the breach of informed consent entailed by the deception
- To remove any confusions or defuse any tensions that might have been generated by the deception
- To make it clear especially to younger participants that deception is permissible only in exceptional circumstances
- To repair (as much as possible) the breach of trust that has occurred not only between the investigator and the participant, but (potentially) between all researchers and all participants.

Debriefing Guidelines

- The de-briefing opportunity must be prompt and the researcher must take reasonable steps to correct any misconceptions the participant may have.
- If scientific or humane values justify delaying or withholding this information, the researcher take reasonable measures to reduce the risk of harm.
- When researchers become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

Examples of Deception

Deception Examples

- Participants complete a quiz, and are falsely told that they did very poorly, regardless of their performance.
- Participants (who don't know they are in a research study) are observed to see how they behave when they find a large amount of cash in a public location.
- In a study of anxiety, participants are told to expect mild pain during the course of the study, but no painful procedures are administered.

Examples of Incomplete Disclosure

- Participants are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance.
- Subjects are told they are completing study questionnaires to evaluate their satisfaction, when the true purpose of the study is to correlate psychiatric symptoms with subject satisfaction.

Future HRPP Initiatives

- Privacy Board will be absorbed by the IRB
- Data and Bio-specimen Use Policy
- Social Networking Policy

Next HRPP Training

Conducting Research in Children and Conducting School Research

Tuesday, July 29, 2014

1 PM – 2 PM

Reilly Auditorium

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