HRPP Policy Updates

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9.0 HRPP Protocol Deviations

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

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)

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– 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.

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<th>Minor Investigator Deviations</th>
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– 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.
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