



Reporting of New Findings to the IRB

1. SCOPE

- 1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

- 2.1. None

3. PROCEDURE BODY

Purpose is to provide guidance on disclosure of new findings to study participants, as well as a policy for IRB review of these findings.

3.1. Background

- a. Federal regulations (45 CFR 46.116(b)(5) and 21 CFR 50.25 (b)(5)) require that, when appropriate, a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- b. Examples may include but are not limited to:
 - Results from IRB-approved research
 - One drug on a blinded study is found to be more effective than the other so subjects are to be unblinded and crossed-over
 - Alternative treatments for the same disease/disorder become FDA approved or become standard of care during the course of the research.
 - Findings of new potential risks to subjects

3.2. Process

- a. Significant new findings that could potentially affect a subject's willingness to continue participation in approved research should be reported to the IRB as soon as possible, but no later than 5 working days of the research staff becoming aware of the finding.
- b. If the new finding meets the criteria for an "Unanticipated Problem", it must be reported to the IRB according to the policy, "Unanticipated Problems Reporting and Review of".
- c. If the new finding does not meet the criteria for "Unanticipated Problem", it must be reported to the IRB on a Change or Update to Original Submission form". The update will be processed via expedited or convened IRB review as allowed by regulation.
- d. Findings may not be communicated to subjects prior to IRB review and approval, except where providing information in real time is necessary to eliminate an apparent immediate hazard to subjects.

- e. If findings are communicated to subjects prior to IRB approval (as described in (d) above, they must be reported to the IRB within five business days of the first notification and it must be clearly explained what was told to subjects and in what manner.

4. ADDITIONAL RESOURCES

- 4.1. References:
- none
- 4.2. IRB Submission Form:
- Change or Update to Original Submission Form

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #689.3 Updated IRB Submission form Title from ARU to Change & Update form. Formatting changes due to document control system.
2.0	
3.0	

6. DOCUMENT PROPERTIES

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