

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to review all requests for amendments to previously approved research applications or claims for exemption to determine if a change in the risk/benefit ratio of the study has occurred.

II. Authority

A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

A. 45 CFR 46

B. 21 CFR 50 and 56

C. OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004

IV. Definitions

A. Amendment: Any change to an IRB-approved study protocol regardless of the level of review it receives initially.

B. Major Amendment: A proposed change in research related activities that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

C. Minor Amendment: A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

V. Procedures

A. Change Must be Approved by the IRB

For previously approved Claims for Exemption, all planned changes in the conduct of a study and/or changes to the informed consent document (ICD) must be approved by the IRB prior to initiation.

1. Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB. When there are numerous changes to the research protocol, a summary of the changes should also be submitted.
2. Modifications to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects

already enrolled in the study. The latter may be addressed using an addendum to the initial ICD or, less preferably, by re-consenting the subject using the modified ICD.

3. The Investigator may make a modification to research activities to avoid an immediate hazard to the participant but must report this to the IRB within 10 working days.

B. Minor Amendments

Minor changes proposed for previously approved research may be reviewed in an expedited manner. Examples of minor modifications may include, but are not limited to, the following:

1. The addition of research activities that would be considered exempt or expedited if considered independently from the main research protocol;
2. An increase or decrease in proposed human research subjects' enrollment;
3. Narrowing the range of the inclusion criteria;
4. Broadening the range of the exclusion criteria;
5. Alterations in the dosage form (e.g., tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant;
6. Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations;
7. An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring;
8. A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;
9. Alterations in human research participant payment or liberalization of the payment schedule with proper justification;
10. Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
11. The addition or deletion of qualified Investigators;
12. The addition of study sites (which may require a Federal Wide Assurance

(FWA) and appropriate IRB approval) or the deletion of study sites; or

13. Minor changes specifically requested by the IRB or individuals with jurisdiction over the research.

C. Major Amendments

When a proposed change in a research study is not minor, then the IRB must review and approve changes at a convened meeting before changes can be implemented. Examples of major modifications may include, but are not limited to, the following:

1. Broadening the range of inclusion criteria;
2. Narrowing the range of exclusion criteria;
3. Alterations in the dosage or route of administration of an administered drug;
4. Extending substantially the duration of exposure to the test material or intervention;
5. The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
6. The addition of serious unexpected adverse events or other significant risks to the Informed Consent Document; or
7. Changes, which, in the opinion of the IRB chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

D. Re-consent/Notification of Participants

The IRB will render a determination of whether the changes to the research activities require a change in the ICDs and therefore warrant re-consenting of currently enrolled participants or notification of participants who have completed research interventions.

E. Exempt Research

Any proposed or anticipated changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review. For Claims for Exemption that were approved more than one year before the amendment was submitted, the Investigator must submit a new "Claim for Exemption" incorporating the proposed change.

VI. History Notes

This is a new policy. The Office of Statewide Research, Ethics and Human Research Protections Program are responsible for this policy.

VII. Signature Block with Effective Date



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Secretary, Department of Health

06/29/05

Date