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Office for the Protection of Research Subjects
Institutional Review Board

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Amendments to Previously Approved Research

Version: 1.2
Date: 05/25/2012
Approved by: Human Protections Administrator, Director of OPRS, and Executive IRB Chair
AAHRPP REF#: 149
AAHRPP Elements: II.2.D.3, II.2.E.3

POLICY:

I. UIC OPRS reviews all amendment requests to previously approved research applications or exempt research to determine whether the amendment affects the risk/benefit analysis or exempt status of the research study.

II. Amendments for both federally and non-federally funded research must be approved by the convened IRB or, when the change meets the criteria of minor, by the Chair or designee using the expedited process before the investigator or their research team may implement the amendment. An investigator PI may implement a change to the approved protocol prior to IRB approval only when necessary to avoid an immediate hazard to the subject.

III. Minor changes in research previously approved by the convened IRB or expedited process is eligible for expedited review.
   A. Minor changes represent:
      1. changes not materially affecting the assessment of risk and benefit;
      2. changes not substantially changing the specific aims or design of the study;
      3. for protocols initially approved by expedited review process, the research continues to pose no more than minimal risk; and
      4. new or revised procedures are consistent with the expedited categories 1-7.
   B. Examples of minor changes include:
      1. administrative or editorial changes,
      2. minor consent form revisions (e.g., grammar corrections, change in contact information, editorial changes that clarify but do not change the material),
      3. addition of procedures that do not increase risks, such as expanding collection of information or samples already being obtained for non-research purposes,
      4. changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods,
      5. non-substantive changes to study documents such as surveys, questionnaires or brochures,

6. new study documents to be distributed to or seen by subjects that are similar in substance to those previously approved,
7. changes in the amount or process for compensating subjects that do not significantly impact the risks or benefits,
8. decrease in the number and volume of sample collections as long as they do not negatively alter the risks or benefits,
9. addition or removal of co-investigators, key personnel or performance sites (when do not adversely affect study resources),
10. increasing subject enrollment,
11. addition of template short form consents and
12. foreign language translations of materials already approved.

C. Examples changes that are not minor include:
1. new or expanded procedures (e.g., tissue biopsy, more frequent blood drawings) or changes in design (e.g., add or remove treatment arm, new study population) that increase risks or adversely impact the risk-benefit ratio,,
2. changes in eligibility criteria that impact the risk-benefit ratio (e.g., lowering or raising the age limit),
3. information concerning previously unknown risks or lack of benefit that is substantial or adversely affects the risk-benefit ratio, significant changes to materials to be given to subjects (e.g., new information about frequency or severity of adverse effects, negative outcomes from related studies), and
4. replacement of principal investigator.

IV. Protocols previously meeting the criteria for expedited review will subsequently require review by the convened IRB when the changes proposed in the amendment increase the risk level to more than minimal or involve procedures which do not fall within one or more of the seven categories eligible for expedited review (refer to UIC HSPP Policy *Expedited Review*).

PROCEDURE:

I. The investigator must submit a list of the revisions being requested and the reason for the changes using the UIC OPRS *Amendments to Previously Approved Research* form. The submission must also include an analysis as to whether the amendment changes the risk/benefit ratio. If the investigator believes that the risk/benefit analysis has changed to an extent that currently enrolled subjects and/or previously enrolled subjects must be re-consented, and subjects who have completed participation must be informed, the investigator must indicate this. The IRB or reviewer may determine on this basis that currently enrolled subjects must be re-consented and subjects who have completed participation must be informed.

A. If applicable, the PI must include a revised protocol, instruments (survey, questionnaires, etc.), informed consent, HIPAA Authorization, and /or recruitment materials that incorporate the changes.

B. The PI must also submit a marked copy of all affected documents with track changes "on" as requested in the instructions to the Amendments to Previously Approved Research application.
C. The footer version and date of any documents affected by the amendment should be revised accordingly.
D. If affected, the first page of the protocol should be revised accordingly, including the new footer version and date.
E. If affected, the original UIC OPRS Initial Review Application and any applicable appendices should be revised accordingly, including the footer version and date.

II. The IRB Assistant Director or Coordinator pre-reviews the amendment application and assesses the level of review (exempt, expedited or convened) by deciding whether the amendment constitutes a minor or more than minor change (including the addition of more than minimal risk, inclusion of prisoners, etc.).

III. The Assistant Director or Coordinator review the following documents, as applicable:
A. Review the amendment application;
B. Review, if applicable, the revised protocol, instruments (survey, questionnaires, etc.), informed consent, HIPAA Authorization, and /or recruitment materials that incorporate the changes;
C. Review the marked copy of all affected documents with track changes;
D. Review the footer version and date of any documents to ensure that any affected by the amendment were revised accordingly;
E. Ensure that, if affected, the first page of the protocol was revised accordingly, including the new footer version and date; and/or
F. Ensure that, if affected, the original UIC OPRS *Initial Review Application* and any applicable appendices were revised accordingly, including the footer version and date.

IV. Amendment submissions that include both minor and more than minor changes cannot be separated if combined into the same submission, and must be reviewed by the convened IRB in their entirety.

V. The Assistant Director and/or IRB Coordinator may consult with the IRB Chair as to whether the requested amendment constitutes a minor or more than minor change, with the IRB Chair or designee making the ultimate determination.

VI. Minor changes may be reviewed in an expedited manner. Expedited review must be documented using the UIC OPRS Amendment to Previously Approved Research Review Guide.

VII. Amendments to claims for exemption are initially assessed by the IRB designated exempt reviewer to determine if the study still qualifies for exemption. If the proposed change results in the research no longer being eligible for an exemption, the research is referred for IRB review.

VIII. An amendment involving more than minor changes to the previously approved research must be reviewed and approved at a convened IRB meeting. (Refer to the UIC HSPP Policy *IRB Review of Research by the Convened IRB* and the UIC OPRS *Amendment to Previously Approved Research* Review Guide for more information).

IX. The IRB must determine when the modifications affect one or more of the approval criteria whether the criteria for approval are still met.

X. The IRB must consider whether the changes to research activities require changes to the informed consent forms and whether currently enrolled subjects and/or previously enrolled subjects must be re-consented no matter what the level of review.

XI. The IRB must also determine as part of their review whether any significant new findings that arise from the review process and that might affect subjects' willingness to continue participation should be communicated to the participants. This determination should be based on whether new information affects the risk/benefit analysis in a way that could affect a subject's decision as to their willingness to participate or continue participation in the research study.

XII. When informed consent forms or recruitment documents are modified by the amendment, the start date for approval on the revised documents is updated to reflect the date of IRB approval of the revised documents. The expiration date remains the same. For example, if the approval period following the last continuing review approval was May 1, 2011 to May 1, 2012, the dates placed on the consent following approval of an amendment revising the consent on January 1, 2012 would be January 1, 2012 to May 1, 2012.

REFERENCES:

21 CFR 50.25(b)(5), 21 CFR 56.108(a), 21 CFR 56.108(a)(3), 21 CFR 56.110(b)(2)
45 CFR 46.103(b)(4), 45 CFR 46.103(b)(4)(ii), 45 CFR 46.110(b)(2), 45 CFR 46.116(b)(5)
OHRP Compliance Activities: Common Findings and Guidance #5, #21, #71, #71(a), #73
Guidance on Written IRB Procedures. OHRP, DHHS, July 1, 2011
Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval. US FDA, DHHS, February 2012

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 06/18/09	1.0, 10/15/08	Included language that prevents the research team from implementing amendments to

		research without IRB approval and clarified alternate IRB member language.
1.2, 05/28/12	1.1, 06/18/09	Included definition and examples of minor changes to previously approved research. Expanded amendment review procedures to include determination of approval criteria when applicable and communication with participants due to new information.