REQUESTING A MODIFICATION TO A PROTOCOL PREVIOUSLY APPROVED BY THE IRB

A modification is a change in a protocol originally approved by the Institutional Review Board (IRB). Modifications include, but are not limited to:

- Substantive changes in questions asked in surveys or interviews (if unsure whether changes qualify as substantive, check with the Research Integrity Services office)
- changes in personnel conducting the research
- changes in number or populations of subjects
- changes in procedures, or
- addition of instruments

The IRB must review and issue written unconditional approval of all requests for modifications to previously approved research protocols PRIOR to implementation. Though seemingly benign, modifications may alter the risk to participants in a research project, and therefore must be reviewed and approved by the IRB. (Changes in researcher information, such as mailing address or phone number, should be conveyed to the Research Integrity Services office, but do not necessarily need to undergo review by the IRB.)

All modification requests must be reviewed and approved at the initial review level (see study approval letter for this information); for example, changes in protocols initially reviewed at the Full board level must be reviewed at a regularly scheduled meeting of the IRB. Therefore, investigators must plan accordingly and allow adequate time for review and approval of modifications before implementation. For Full board protocols, modification requests must be received by the IRB by the submission deadline for the next meeting (visit http://unh.edu/research/irb-meeting-schedule for this information); modifications to protocols originally approved at the Expedited or Exempt level are reviewed on an ongoing basis. Allow a minimum of 10 working days for processing, review, and final approval of your request for a modification.

To request a modification to a previously approved protocol, send a letter to the IRB containing the information outlined below in section A, and where relevant, attach documents noted in sections B, C, or D.

A. Description of requested modification(s) as outlined below in items 1-3.
   1. Change To Research Protocol - describe what you want to do, how it differs from the original protocol, and the rationale for the change. Be sure to include the IRB protocol number from your approval letter.
   2. Risks - List any changes in possible risks to subjects, including physical, psychological, and economic (loss of employability), pertinent to the requested modification. Also address issues of confidentiality and risks associated with a breach of confidence, if applicable. Any project involving risk of physical injury, civil, financial or criminal liability, risk to a subject's employability, or instances where the research involves sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol, has the potential of involving more than minimal risk.
   3. Benefits - Discuss any changes in benefits to participants. In studies involving risk, discuss the relationship between risks and benefits.

B. Copies of new or revised informed consent or assent documents
C. Copies of new or revised questionnaires, guiding questions, survey instruments, tests, etc.
D. Other pertinent documentation as deemed necessary.

Send your request and accompanying documents to: Research Integrity Services, Service Building, 51 College Road, Durham, NH 03824-3585 or email to julie.simpson@unh.edu. Address questions to Julie Simpson, Director, at julie.simpson@unh.edu or 862-2003. For more information, visit the IRB webpage at http://unh.edu/research/human-subjects.