IRB Updates

Effective Monday, April 29, 2013, the ERICA system has been updated. Please find a summary of the changes below.

Application Changes

- **New Study Application, Study Location and Sponsors page, question 4:** You can now indicate any of the following sites specifically if they are participating in the study: Intermountain Healthcare Hospitals, Utah Department of Health, Utah State University, and Brigham Young University. You are still able to enter the names of any other sites that may be participating, as per the normal process.

- **New Study Application, HIPAA and the Covered Entity page, question 2c:** You will now get a warning message if you mark question 2c as "Yes", this is an investigator-initiated drug or device trial, but also indicate earlier (questions 2a and 2b) that this study does not involve the use of an investigational drug or device.

- **Request for Waiver of Authorization page:** You will now be able to easily request a Waiver of Authorization for Recruitment Only. This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. With this option, you are not required to provide any justification for the request, so long as you accept and adhere to the terms of the waiver that will display when you select this option. The PI will be required to confirm acceptance of the terms when submitting the study in ERICA. The terms of the Waiver of Authorization for Recruitment Only can be viewed on the IRB website at: http://irb.utah.edu/_pdf/Terms%20for%20the%20Waiver%20of%20Authorization%20for%20Recruitment%20Only%20Apr%2029%202013.pdf

  All other waiver of authorization requests can be made as per the normal process.

- **New Study Application, CCTS-CSC application:** Users who request approval for services in the CCTS Clinical Services Core will be required to submit an application via the ERICA system. Users will be prompted to complete the CCTS Clinical Services Core application when they indicate that the study intends to involve these services on the HIPAA page of the IRB application, question 2g. Please see the previous notice sent via the IRB listserv for additional information regarding this change.

Other Changes

- Faculty sponsors are always required to submit their approval on student projects before a study will be reviewed by the IRB. This applies to new study, amendment, continuing review, and report form submissions. As of this update, faculty sponsors will now receive a weekly reminder from the ERICA system if a submission is pending their review and approval.

- The PI and study team inbox in ERICA has now been updated to display the current expiration date for each approved, active study. This change was made to improve the study team's ability to monitor study expiration and the need for continuing review. You will continue to receive continuing review reminder notices, as well as study expiration notices from the ERICA system,

as per the normal process.

- On the e-Protocol Summary, the title page heading for “Sub-Investigators” has been changed to “Internal Staff and Sub-Investigators”.

- Invoices for language translation services through the University Hospital Research Translator will now be sent through the ERICA system. Payment of these invoices will not affect the IRB review process. Translation of consent forms and other materials will not begin until payment is received. For more information about these translation services, please send an email to research.translation@hsc.utah.edu.

This message was sent via the IRB listserv. Please do not reply to this message. If you have questions or concerns, please respond to irb@hsc.utah.edu or 801-581-3655.

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