Guidance On Conversion Process For Previously Approved Paper Studies

Background:
In February 2012, the New Brunswick Health Sciences IRB went live with eIRB system. Since then, we have been accepting conversions of previously approved paper studies into eIRB on a department or PI special request.

Recently, we sent notification that effective December 31, 2017 we would no longer be accepting paper submissions for continuing reviews. All full board and expedited studies originally submitted and approved in paper that are still actively enrolling, or collecting data, records, surveys, or specimens must be converted into e-IRB by December 31, 2017.

Process Overview:
The IRB recommends that you begin the conversion process 90 days prior to the paper study’s expiration date to allow time for this conversion to be reviewed and approved prior to expiration.

Please note that any paper study previously approved as Exempt, Non-Human Subject, or that remains open for data analysis only WILL NOT NEED to be converted into e-IRB.

As of December 31, 2017, no continuing review applications of paper studies that are still actively enrolling, or still collecting data, records, surveys, or specimens will be approved via the paper continuing review process.

Please contact our office at 732-235-9806 should you have any questions or to discuss the conversion process.

WHAT NEW OR UPDATED STUDY DOCUMENTS DO I NEED TO SUBMIT?:

- New eIRB application
- Include the following language in the study summary section 7.1 Q 3.0 of the application: ‘This study once approved will replace the previously approved paper study IRB# __________’,
- A new protocol utilizing our current template (with current version date) that details all research activities currently being conducted.
- For Non-Rutgers initiated protocols –
  - Currently approved non-Rutgers protocol.
  - Local context supplement utilizing our current template (with current version date) that details all research activities currently being conducted at the Rutgers site(s).
- For studies still enrolling –
  - Consent document(s) utilizing our current template(s) with current version date(s).
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- Non-English document(s) utilizing our current template with current version date(s). Please note you will need new translation attestation certificate(s) that correspond to the new version date(s).
- Recruitment material(s) currently being used with current version date(s).
- Surveys, questionnaires, study tools with current version date(s).

WHAT PREVIOUSLY APPROVED DOCUMENTS SHOULD BE SUBMITTED?

- Most recent continuing review approval letter (to be uploaded in section 15).
- Most recently approved stamped documents (to be uploaded in section 15).
- Any previous ancillary approvals (i.e. SRB, IBC, NICU ROC, Radiation Safety, RUG, UBHC, ESCRO, OCRA (University Hospital)) should be uploaded in appropriate sections.
- Current IRB approval(s) or previous IRB Authorization Agreement(s) for all non-Rutgers site(s) still engaged in the research (to be uploaded in non-Rutgers site section).
- For sites previously engaged in the research but not currently engaged, please upload previous IRB approval or previous IRB Authorization Agreement(s) for these sites in non-Rutgers site section.
- For non-Rutgers sites providing access to subjects or data, but not engaged in research, upload the original permission letter/letter of cooperation.
- Funding – List all funding source(s) and upload any grants and/or awards.

HOW DO I START THE CONVERSION PROCESS?

- Log into eIRB and create a NEW STUDY.
- Complete the application questions as they relate to the current research activities (do not include past research activities).
- Include only current study personnel and current Rutgers and Non-Rutgers sites.
- Please submit current eCOI for all investigators and study personnel under the new Pro# in eCOI (do not upload prior disclosures).
- Upload all required documents as detailed above (please refer to the following two sections: ‘What new or updated study documents do I need to submit?’ and ‘What previously approved documents should be submitted?’)
- Once the application is completed and all the documents are uploaded, the PI will need to submit the study to IRB.
- Once submitted and approved by department chair(s), the study will be directed to the IRB office to begin the review process.
- The study will be reviewed based upon the submission type and once the IRB has issued an approval letter through eIRB, the IRB office will administratively close the paper study and no further action will be necessary. (The IRB will maintain the paper file records for reference.)