

Guidance on Conversion Process of Previously IRB-Approved ArtSci Paper Studies

Background

In October 2017, the **Arts & Sciences IRB** went live with eIRB system. Since then, we have been accepting conversions of previously IRB-approved paper studies into eIRB per a department or PI special request.

Recently, we sent notification that effective **January 22nd, 2020** we would no longer be accepting paper submissions for continuing reviews. **This means that 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 January 22nd, 2020.**

Process Overview

Please be advised in order to avoid a lapse in approval, please ensure that conversion of your paper-based study has been submitted in eIRB (along with all relevant materials) to the IRB at least 90 days PRIOR to the study's expiration date.

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

As of January 22nd, 2020, 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. *If at any point study activities change from data analysis to open enrollment/additional data collection, then the conversion process must be done before the study will be allowed to collect additional data.

Please contact our office at 732-235-2866 should you have any questions or to discuss the conversion process.

What New Or Updated Study Documents Do I Need To Submit?

1. Begin a new eIRB application online: <https://eirb.rutgers.edu/>
2. Include the following language in the eIRB study overview summary section 7.1 in Question #1 of the application: ***'This study once approved will replace the previously approved paper study IRB# _____.'***



3. A new protocol utilizing our current template (with current version date) that details all research activities **currently** being conducted: <https://orra.rutgers.edu/formsandtemplatesirb>
4. **For Non-Rutgers Initiated Protocols – Using Administrative Review Procedures**
 - o Upload the currently approved non-Rutgers protocol.
 - o Upload the **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 –

- Upload the Consent document(s) utilizing our current template(s) with current version date(s).
- Upload, where appropriate, any Non-English translated 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).
- Upload all Recruitment material(s) currently being used with current version date(s).
- Upload all current versions of any Surveys, questionnaires, interview guides, and study tools with current version date.

What Previously Approved Documents Should Be Submitted?

- Most recent paper continuing review approval letter (to be uploaded in section 15).
- Most recently paper approved stamped documents (to be uploaded in section 15).
- Any previous ancillary approvals (i.e. Site Authorizations, non-Rutgers IRB approvals, Biosafety, RUG, etc.) 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?

1. Log into [eIRB \(https://eirb.rutgers.edu/\)](https://eirb.rutgers.edu/) and create a NEW STUDY.
2. Complete the online application questions as they relate to the current research activities (do not include past research activities).
3. Include only current study personnel and current Rutgers and Non-Rutgers sites.
4. Please submit current Conflict of Interest disclosure (eCOI) for all investigators and study personnel under the new Pro# in eCOI (do not upload prior disclosures).
5. Upload any personnel's CITI certifications (in Section 15) if their certificates do not appear under the "CITI Training Records" tab.
6. 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?')
7. Once the application is completed and all the documents are uploaded, the PI will need to submit the study to IRB.
8. Once submitted and approved by department chair(s), the study will be directed to the IRB office to begin the review process.
9. 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.)