

Study Approved!
What 's next?



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Next Steps

- Review Approval Letter
 - Approval Date: date RSRB approval officially starts
 - Expiration Date: date RSRB approval expires (Max 1yr)
 - PI responsibilities
- Print out watermarked documents
 - Consent, Assent and Permission forms
 - Recruitment forms
- Create a study file
 - Electronic or paper

Approval Letter

University of Rochester Research Subjects Review Board
Letter of Approval

RSRB: RSRB00068892 **Principal Investigator:** Jane Doe

Study Title: A New Study

Initial Approval: 10/13/2010

Study Approval Expires: 10/12/2011

Length of Review: 1 year

Risk Level:

-Minimal Risk - Adults only . Minimal Risk – Children 46.404/50.51

Review Level: Expedited

Expedited Category(ies):

- 7 - individual or group characteristics or behavior

Additional Remarks: Protocol dated: 9/28/2010, Consent to Procedures dated: 9/28/2010, Consent to data: 9/5/2010

Approval Letter

This approval is contingent upon the investigation being conducted in compliance with the approved study protocol including all requirements and/or determinations of the RSRB. Unless a Waiver of Consent is specified above, consent must be obtained and documented in the manner approved by the RSRB. Please note all remarks and/or attachments. **Only consent forms bearing a current 'RSRB Approved' Watermark may be used.** Only the most recently approved version of any consent or recruitment document may be used when obtaining consent. **Consent forms/recruitment letters must be printed on department letterhead.**

As the Principal Investigator, you are responsible for the following activities:

- **Timely submission of continuing review progress reports** apply to RSRB at least 8 weeks before expiration. Federal Regulations require that the RSRB conduct continuing review of research. You will receive an email notification when the expiration date is approaching.
- **Requesting any proposed changes in the above research activity.** All subject recruitment materials must be approved prior to use. Changes may not be initiated without RSRB approval except when necessary to eliminate apparent immediate hazards to the subject(s) and then a report must be submitted along with the amendment request.
- Maintaining all approved study documents in your study file.
- Maintaining signed consent forms for at least three years after the research is completed or for a longer term if required by FDA regulations
- Reporting any unexpected serious problems involving risks to subjects or others (including unexpected deaths, hospitalizations or serious injuries) in accordance with the RSRB Adverse Event guidelines.
- **Submitting a final progress report to the RSRB upon completion of this study**

Amendments

What if changes need to be made to a approved study?

- Submit an amendment for RSRB review and approval. Changes can not be implemented by the study team until investigator receives an amendment approval letter from the RSRB.

What type of changes require RSRB approval?

- Any change to the study protocol, consent documents, recruitment forms, surveys, experiments, interviews, data collection forms or research process.
- Addition of study personnel.

What review level do amendments require?

- If change is a minor change that does not change risk/benefit ratio; does not increase risk above minimal risk the amendment will be given expedited review.

Progress Report Process

- All expedited and convened board studies require renewal, usually annually
- The RSRB cannot extend a study approval period without conducting review of the progress report and related documents.
- A progress report must be submitted to notify the RSRB of the closure or completion of a research study
- Grace periods or administrative extensions are not allowed

Progress Report Process

- PI or designee is responsible to complete the progress report , including any documents specified in the form.
- Progress Report can be completed anytime after the study is approved, but can not be re-approved unless it is less than 30 days from the expiration date.
- RSRB applies the same standards and procedures used for initial approvals to the continuing review process (i.e. convened board, expedited)

Progress Report Form

- Include number of subjects enrolled (persons who provided consent) or subject's records accessed
- Include date first subject was enrolled or first record accessed
- Include subject concerns or withdrawals
- Study Findings (publications, abstracts, presentations)
- Upload scanned copies of the entire last signed consents for "each" of the approved forms used since last review.
- Include documentation of non-UR IRB approvals

Progress Report

- Upon re-approval all recruitment and consent documents will be given an updated approval watermark
- Once study is re-approved, all previously printed documents with RSRB watermarks should be discarded and replaced with currently approved watermarked documents

Resources and Contact Information

- RSRB website: www.rochester.edu/rsrb/
- ROSS (RSRB On-line SubmissionSystem)
www.rsrb01.urmc.rochester.edu/rsrb
- On line submission training—link on RSRB website (ROSS Training) or 275-3050
- Investigator Guidance – link on RSRB website (Investigator Guidance)
- RSRB Phone Contact: 275-2398

