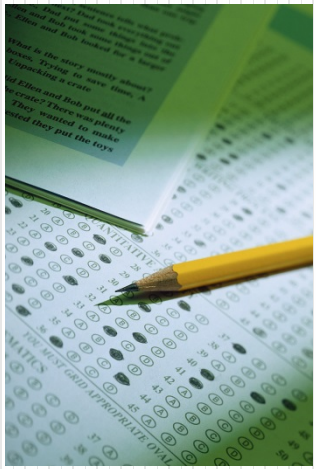
IRB: I'm Approved! … Now What?

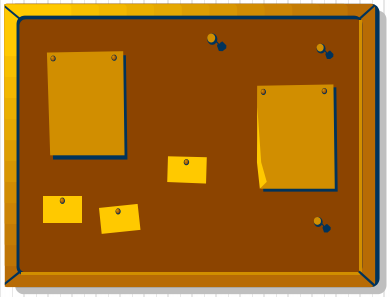
Hila Berger, MPH, CIP
Research Compliance Administrator

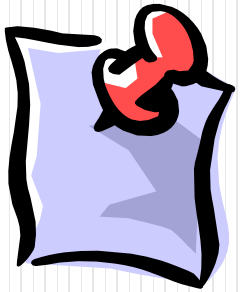
Amy Krenzer, CIP
IRB Coordinator

MONTCLAIR STATE
UNIVERSITY

Using Approved Documents







Approved Documents

- At the time of approval the IRB will stamp the following
  - Consent documents
  - Recruitment material
  - Data collection material

- Use stamped versions only!
  - Exclusion: online surveys

Compensation/Incentives

- To purchase your compensation with grant funding:
  - Submit IRB approval letter and consent document
- Compensation should be consistent with the amount described in application and consent
  - Changes to compensation/incentives requires approval through the submission of an amendment

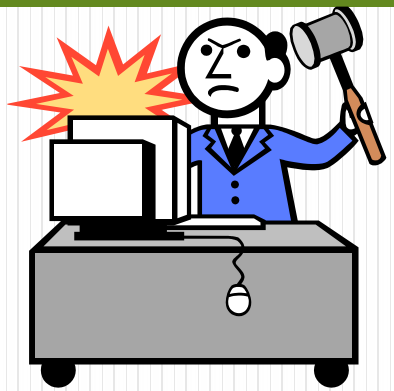
Amendments

- Amending Protocol
- Adding Research Team Members
- Adding a Research Site

Amendments

- Apply for an amendment if you plan to change your research protocol
  - Minor amendments will take 1-2 weeks for approval
  - Significant amendments may take 2-4 weeks for approval
- Add research team members using the IRB Amendment Form to Add/Remove/Change Personnel
  - Make sure research team members have CITI certification
- Add a research site using the IRB Amendment Form to Add/Remove Research Sites
  - Include site approval letter

Adverse Events or Unanticipated Problems

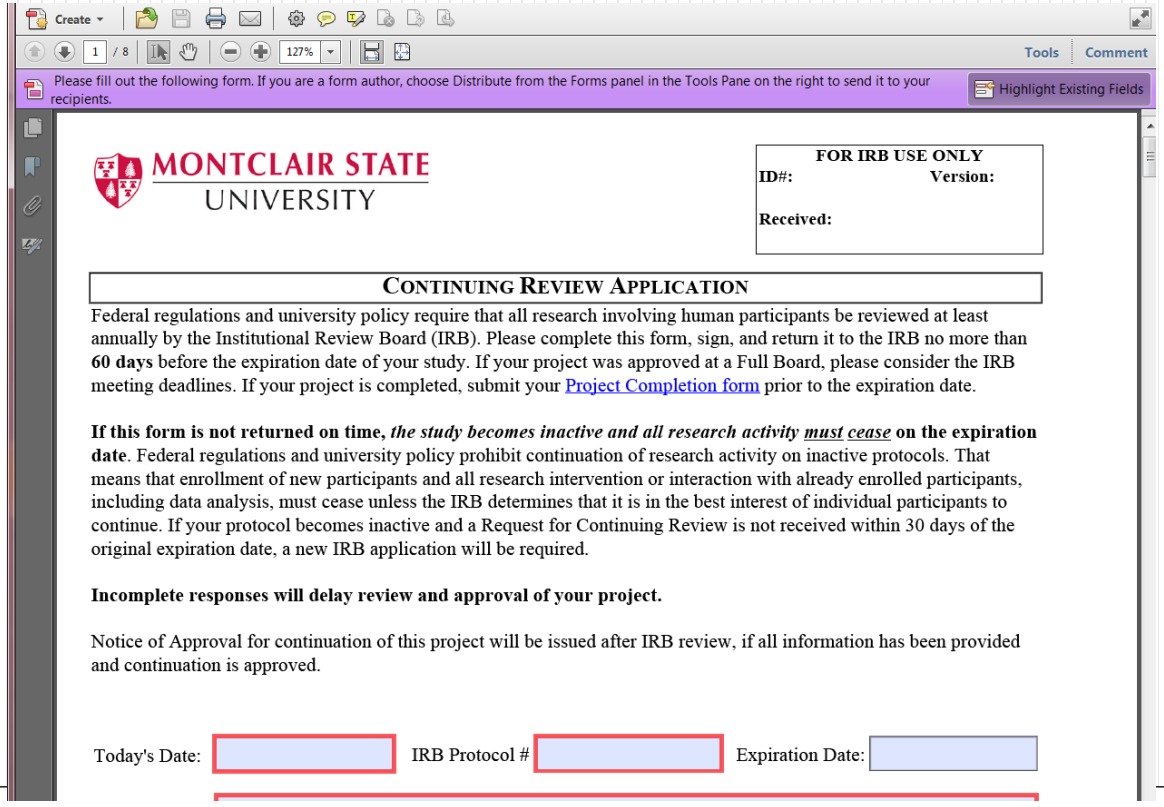


Adverse Events and Unanticipated Problems

- Report any adverse events to the IRB within 72 hours
  - Form for reporting available online
  - Students should also report to faculty sponsor
- Adverse Events include
  - any injury, problem, or unfavorable occurrence experienced by human participants or others during conduct of research activities
- Adverse events may or may not be caused by the research protocol
- If the IRB office learns of an adverse event, they will inform and request an AE form be submitted
- Complaints should also be reported to IRB

Continuing Review and Expiration

Don't Let Your Approval Expire!



Create | 1 / 8 | 127% | Tools | Comment

Please fill out the following form. If you are a form author, choose Distribute from the Forms panel in the Tools Pane on the right to send it to your recipients. Highlight Existing Fields

MONTCLAIR STATE UNIVERSITY

FOR IRB USE ONLY
ID#: **Version:**
Received:

CONTINUING REVIEW APPLICATION

Federal regulations and university policy require that all research involving human participants be reviewed at least annually by the Institutional Review Board (IRB). Please complete this form, sign, and return it to the IRB no more than **60 days** before the expiration date of your study. If your project was approved at a Full Board, please consider the IRB meeting deadlines. If your project is completed, submit your Project Completion form prior to the expiration date.

If this form is not returned on time, *the study becomes inactive and all research activity must cease* on the expiration date. Federal regulations and university policy prohibit continuation of research activity on inactive protocols. That means that enrollment of new participants and all research intervention or interaction with already enrolled participants, including data analysis, must cease unless the IRB determines that it is in the best interest of individual participants to continue. If your protocol becomes inactive and a Request for Continuing Review is not received within 30 days of the original expiration date, a new IRB application will be required.

Incomplete responses will delay review and approval of your project.

Notice of Approval for continuation of this project will be issued after IRB review, if all information has been provided and continuation is approved.

Today's Date: IRB Protocol # Expiration Date:

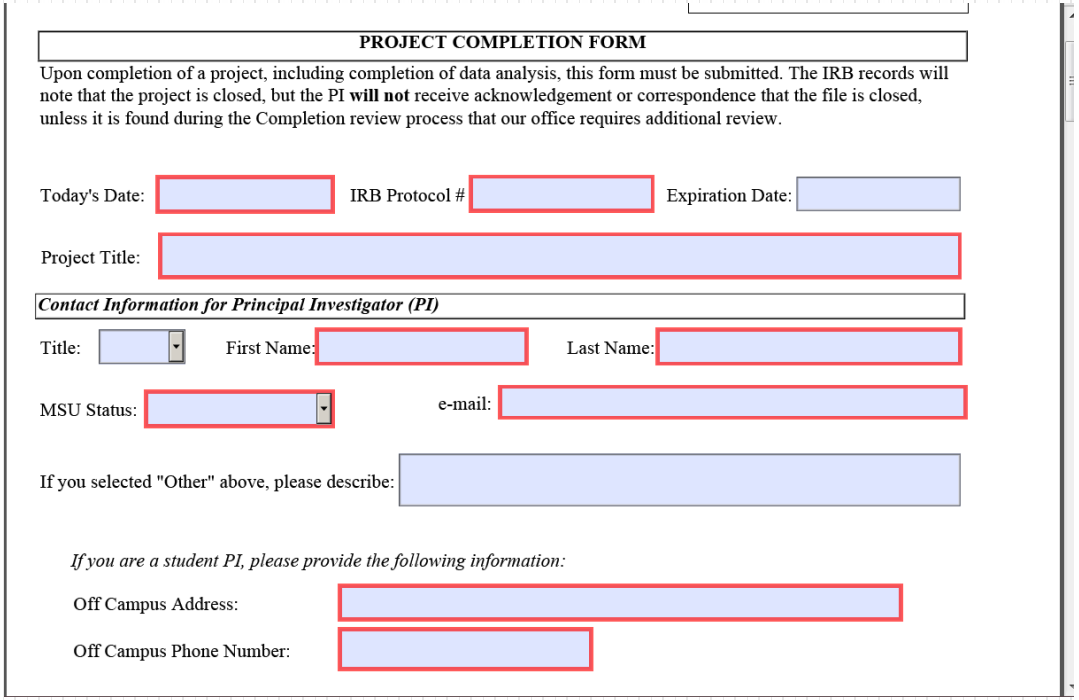
Continuing Review

- Check your approval letter for expiration
  - Tip: put a reminder on your work calendar at the time of approval
  - If your email address (home address for students) changes please notify IRB asap
- Reminders are sent to PIs about 60 days prior to expiration
  - Letter and Email
- If your approval expires all research activities must stop! This includes recruitment, data collection, AND data analysis.

Continuing Review Application

- Available online
- Information required
  - Any new funding?
  - Research Status (enrolling, closed to enrollment, data analysis etc.)
  - Number of participants that have participated
  - Number of participants expecting to participate in next 12 months
  - Research findings (preliminary and/or final)
- Amendments can be requested at time of CR
- Submission timeline
  - Full Board be mindful of deadlines for full committee review; available online
  - Expedited submit ~25-30 days before expiration

Project Closure



PROJECT COMPLETION FORM

Upon completion of a project, including completion of data analysis, this form must be submitted. The IRB records will note that the project is closed, but the PI **will not** receive acknowledgement or correspondence that the file is closed, unless it is found during the Completion review process that our office requires additional review.

Today's Date: IRB Protocol # Expiration Date:

Project Title:

Contact Information for Principal Investigator (PI)

Title: First Name: Last Name:

MSU Status: e-mail:

If you selected "Other" above, please describe:

If you are a student PI, please provide the following information:

Off Campus Address:

Off Campus Phone Number:

Project Closure

- Once your study is complete and you are done with data analysis submit a project completion form
  - If research is for a thesis/dissertation, do not submit project completion till you have finished your thesis/dissertation presentation
  - If you are attempting to publish, there is a possibility your editor may ask you to go back to your data for additional analysis, in this case you may want to keep your project current and not close it.
- Form information
  - Participant info (number, withdrawals etc.)
  - Summary and research findings
  - Unexpected or adverse events
  - If applicable – Faculty Sponsor signature

Data Retention after project closure

- Four years of data retention after project closure
  - Consent documents
  - Data collection instruments
  - Data/Results
- Destruction of data before that time is only permitted if explicit in approved protocol

Self-Audit Process

- Each semester IRB makes 4 - 6 self-audit requests
- chosen studies will primarily focus on Faculty submissions reviewed at either expedited or full level, from researchers who have either long-running studies or multiple active studies
- Investigators have 4 weeks to complete and submit the form for self-audit
- If self-audit meets 45 CFR 46 requirements (Code of Federal Regulations), the PI will be notified by email
- Any problems noted, the IRB Coordinator or Research Compliance will address

IRB/Compliance contact information

- IRB Coordinator: Amy Krenzer
  - reviewboard@mail.montclair.edu
  - Ext. 7583
- IRB Program Assistant: Mylka Biascochea
  - biascocheam@mail.montclair.edu
  - Ext. 3021
- Research Compliance Administrator: Hila Berger
  - bergerh@mail.montclair.edu
  - Ext. 7781
- IRB Chair: Dr. Katrina Bulkley
  - Ext. 5189
- IRB Office: College Hall 248