

## IRB review process

### What are the IRB forms?

**Final Report of Research Protocol.** Fill this form once your project has concluded. That means that you have gone through the research including data analysis.

**IRB New Application to Use Human Subjects in Research (Expedited or Exempt).** If you are initiating a new project. Make sure you provide concise and brief answers.

**Modification of Protocol.** Modification forms should be filled out when any of the following occur: a change in team members, change in the recruitment, the measurement instruments, the informed consent, or any change in the research procedures. Please make sure to include updated and any additional information related to the modification in the submission.

**Status Reports.** This form should be filled out on an annual basis. The purpose of this form is to inform the IRB that the project is still undergoing. The IRB will check the last approved consent form, the human subject training, and the team members associated with the project. Please make sure to include this information in the application.

**Request for Classroom Research Project Waiver of IRB Application.** Fill this form if you have a classroom project that will be used to teach or demonstrate a research element, but data will not be used for any other purpose.

1. Choose this form if your study does not use minors or vulnerable populations (prisoners, persons lacking capacity to give informed consent) as defined by Title 45 CFR, Part 46;
2. If you do not plan to publish your findings;
3. If you do not plan to videotape the participants; and
4. If the risk is minimal, you can submit this type of project.

**Adverse events** Fill this form when unexpected events occur during the project. A reportable event is one in which a participant(s) is/are exposed to an unanticipated harm or risk. An actual injury to the participant is not required. Any social and psychological risk or harm to the participant(s) should be reported. While social harm may result in well-defined events such as loss of employability, loss of insurability, and criminal or civil litigation, usually it disrupts interpersonal relationships by causing embarrassment, humiliation, discrimination, or stigmatization. Social and psychological risk or harm can be caused by such events as a breach of confidentiality, loss of records, or participant information.

**How do I submit my study?** All forms are submitted electronically through Maestro, a web-based workflow record management system developed by NMSU. MAESTRO is used to automate and streamline the human subject research, IRB protocol submission, and review process. Emails are automatically sent via Maestro to notify users when action is needed from the users.

**I submitted my study to the IRB. Can I start my study now?**

No. You must not do human subjects research until you receive an email notification from Maestro which contains a copy of the approval packet and the IRB approval letter.

**What if I'm unsure whether my activity is human subject research? Can I contact the IRB?**

Absolutely. The IRB wants to continue to be a resource to NMSU research community. Note that human research determinations are not made via phone or in person. If you would like a written determination, please e-mail a synopsis of the proposed activity (approximately 1 page) to the IRB at [ovpr@nmsu.edu](mailto:ovpr@nmsu.edu).

Please include the following in the synopsis:

- Study funding
- Purpose
- Study procedures
- Any draft study measurements (survey, questionnaire, and interview guide).

The IRB will take responsibility for providing guidance and making a determination.

**What if I want to modify my approved study?**

All modifications must be approved by the IRB before implementation of the modification. If you want to change the protocol (conduct of the study) or any other aspect of the study (e.g., research personnel, consent form edits, recruitment changes, or number of subjects), please submit the modification of protocol form request using MAESTRO. Please upload any new documents and any previously approved documents that are affected by the modification, (e.g., initial review application that serves as the protocol; consent form; recruitment materials; survey, questionnaire, interview guide). After the IRB reviews, approves it, and you receive the approval email notification from Maestro, you can implement the change to your research.

**IRB approval for my study expired. What does this mean?**

Once IRB approval expires, you must stop all research activities. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. The Principal Investigator (PI) needs to submit a final report to close out the expired project submission before continuing the research. If the PI wishes to continue with the same research, he/she must then submit a new IRB and wait for the IRB review and approval before continuing the research.

**I need to speak with someone about my IRB application. Is someone available and do I need an appointment?**

You're welcome to call the Office of Research Integrity and Compliance (575-646-7177) or email us at [ovpr@nmsu.edu](mailto:ovpr@nmsu.edu) or stop by the Office of Research Integrity and Compliance at Anderson Hall located on the corner of Espina and Stewart St. An IRB representative is almost always in the office. An appointment is not required to meet with a representative from the Office of Research Integrity and Compliance.