



# Common Mistakes

PITFALLS TO AVOID TO PREVENT DELAYS IN THE IRB REVIEW PROCESS

## Why It Matters?

It is the responsibility of the researchers to ensure that the conduct of human research is ethical and adheres to the determinations of the IRB. This is achieved through complete, accurate documentation being submitted for IRB review.

Researchers are often concerned with the time for review. Taking steps to avoid common mistakes that delay IRB review can help save on average 8 - 30 days in the review process.

### CITI

Mistake

Researchers submit the wrong CITI Certificate.

We require researchers to:

• affiliate with University of New Mexico, Main Campus, and

Fix

• to complete the Main Campus Researchers course.

Use the CITI Instructions for assistance.

We do not accept UNM HSC CITI certificates.

### Protocols & Consent Forms

#### Protocol

#### **Consent Form**

A document that describes, to the **IRB**, the entire process, purpose, and how you interact with your participants.

A document that describes, to your **participants**, what they will be doing and the risks and benefits of participating in your research.

### Protocols & Consent Forms

#### Mistake

Researchers often do not describe the same processes in the protocol and consent form.

#### Fix

Review both your protocol and your consent to be sure that both describe the same processes.

Have someone not involved in designing the research read the protocol and consent form to help catch any gaps in the explanations and to help gauge understandability.

### Data Collection & Management

#### Mistake

Researchers do not provide enough detail regarding data collection and management for a complete review.

#### Fix

Data collection and management processes need to be written in a detailed manner. How much detail? Like a recipe, the IRB should be able to conduct your research project based on the amount of detail provided.

For detailed information about data management, see the guidance on **UNM Human Research Data Security Standards**.

### Incomplete Submissions

#### Mistake

Researchers do not upload a complete package in IRBNet with the documents in the correct format. The documents most commonly missing are recruitment materials such as fliers, emails, and phone scripts.

#### Fix

Use the **Submission Checklist** (found on our website in the Library) to see what documents are needed and in what format.

Make sure that all documents that require signatures are signed by hand and scanned in **OR** you can use a secure digital signature.

### Amendments

#### Mistake

Researchers do not submit amendments in a way that keeps IRB records consistent with the actions/intentions of the researcher.

#### Fix

Be sure to use **tracked changes** when editing documents. If this is an amendment to documents that already had tracked changes, approve the previous changes before adding new changes. Also, update the **version date**.

Upload edited documents creating **version trails**. This helps keep the IRB record clear and consistent. Instructions can be found in the **IRBNet Submission Instructions**.

### Waivers

**Consent**: a process where participants are told the details of the research so they can make an informed decision about being in the project.

The IRB expects a consent process that includes a form and a physical signature on the form. In some research waivers may apply.

### Waivers

#### Waiver of Consent

Waives the consent process entirely. No communication about what the participant is expected to do. This is the least common waiver granted.

Example: research where researchers observe public behaviors of large groups of people.

#### **Waiver of Consent Documentation**

Waives the requirement of a signature, but there is still a consent process. This is the most common type of waiver granted.

Example: Collecting sensitive information about people where collecting names increases risk to participants.

### Waivers

#### Mistake

Researchers either ask for one waiver when they mean the other or do not request a waiver when they actually want one.

Additionally, researchers may request a waiver, but fail to give the necessary justifications needed by the IRB to grant such a waiver.

#### Fix

Be sure to request and justify a waiver in the protocol. Follow the blue text instructions in the protocol template to frame the justification.

Also, submit consent documents that fit the waiver (e.g. no signature lines if requesting waiver of documentation).

### Researcher Assistance

#### UNM OIRB

<u>irb.unm.edu</u>

(505) 277-2644

irbmaincampus@unm.edu



#### Outreach

- ✓ OIRB is available to come to your next meeting or class
- Presentations can cover all IRB information and can be tailored to meet your needs

#### Training

✓ OIRB provides workshops to explain IRB expectations, policies, and procedures

✓ See the OIRB website for workshop dates

#### **GPSA Walk-in Hours**

✓ Third Thursday of every month from 10:00 am – 12:00 pm in the GPSA office in the SUB

#### Consultations

✓ Get answers to your IRB questions

Complete the Consult Request Form on the OIRB website

#### COMMUNICATION!!!!!!!

✓ Nothing will allow us to serve you better than for you to communicate with us early and regularly! Special issues (short funding deadline, international travel)? Let us know; we will do our best to assist.