

FAQs and Common Mistakes: IRB Non-Compliance

The research procedures and materials approved by the IRB are what you are expected to do when conducting your research. Any unapproved departure from your approved IRB protocol results in non-compliance. Non-compliance has many different consequences, but can result in your being prevented from using data that were collected outside of IRB approval, or require reporting to the federal government. Most importantly, any departure from your approved IRB protocol that **INCREASES RISK TO PARTICIPANTS**, without IRB approval, results in serious non-compliance that must be immediately addressed and reported to the federal government.

Common Examples

- Working on your study without up to date IRB approval. See your IRB approval letter for information on when your IRB approval expires.
 - Working on a study includes participant recruitment, data collection, data analysis, and writing.
 - Commonly, a study's approval will expire without being renewed. When a study's approval expires, all work on that study must stop. Should any work take place during the period of time where approval has lapsed, then you would be non-compliant.
 - Failing to submit for study approval renewal when you are working with an identifiable data set.
- If you diverge from your approved protocol, you will likely be in non-compliance. What does this mean? It means that you should do exactly what your IRB submission said you were going to do. The following are examples of changes that many people don't think about when enacting them:
 - Increase or decrease of participants when that percentage exceeds 10%
 - Adding, removing, or editing questions from surveys/interviews/focus groups
 - Editing any materials that participants would be exposed to
 - Collecting identifying information about your participants when you state in your protocol that no identifying information would be collected.
 - REMOVING study activities – an important part of IRB approval involves an assessment of benefits from participation and the removal of procedures may impact that assessment.
- Implementing study procedures that the participant did not agree to when they agreed to participate in other activities in your research. For example: the participant may have agreed to be a part of the study but elected not to be video-taped. If a participant has declined participation, in any aspect of your study, you must take care to NOT involve them in those activities, incidentally or otherwise.
- Failing to record, store, strip, manage identifying information, and destroy data as noted in your approved IRB submission.
- "Approval with Modifications" is not official IRB approval. So, If you receive a notice of "Approval with Modifications" and begin your research without official IRB approval (denoted by a formal letter received after submitting the requested modifications) then you would be non-compliant
- Using data from a minor who did not have parental consent (minor of any age). For example: this can happen with undergraduates who choose to participate in a study but are not actually eligible.
- Changing or adding a location where the research would be taking place
- Using consent forms that were not approved by the IRB. This includes using old drafts and creating new forms.
- Implementing study procedures that were not in line with your protocol or in line with what your consent forms communicate.
- Pre-testing and piloting research without IRB approval.

Tips

- If you find yourself editing materials while in the middle of researching, before you enact them, you must get them approved.
- If you need a change made immediately, contact the IRB and let us know so that we can help you. Also indicate a timeframe that you need to get the changes made.
- Train your graduate students and make sure everyone on your research team knows what to do, what's expected of them, and more importantly pitfalls to avoid when it comes to non-compliance. Advisors are held responsible for non-compliance in research that they oversee and are expected to guide students through the IRB process.
- When in doubt, ASK! The IRB office is here to help you.