Composing a Final Report for the UWF IRB

Federal regulations (45 CFR 46.103) require that investigators promptly inform the IRB of any changes to the research project—including the study completion. As such, principal investigators must submit a final report to the IRB at the conclusion of the approved project period.

The final report must contain the following information:

1. Name of principal investigator.
2. Date of the report.
3. Title of the research project as submitted on the original IRB application.
4. Statement that all data collection is completed
5. Statement of whether or not there were any adverse events or unanticipated problems involving the research participants.
   - If there were adverse events or complaints involving the research participants, include a full written description of the event including the date, time, and nature of the incident.
6. Copy of the informed consent document used in the research.
7. Statement of whether the procedures used were those agreed upon at the beginning of the research.
8. Statement of whether the actual risks and benefits were as anticipated.