
1. A statement that there were no changes from the approved protocol.
2. A description of any adverse events or unanticipated problems involving risks to subjects or others.
3. Any withdrawal of participants from the research or complaints about the research.
4. A copy of the actual informed consent document used in the research.
5. Were the actual risks and benefits as anticipated?
6. Was the IRB informed of any unforeseen problems or accidents that may have occurred?
7. Were the procedures agreed upon at the beginning of the research used?