Special Considerations

What should I do if I find out that my study will be audited by a federal agency?

If you receive word that you will be audited by a federal agency (FDA, OHRP, NIH, etc.), please notify Duke University Office of Audit, Risk & Compliance (OARC) and the IRB immediately and we will assist you.

What research-related activities are permissible in the interim between IRB approval and Institutional approval?

The policy called ?Permissible Interim Activities? provides clarification regarding research-related activities that are allowed in the interim between IRB approval and Institutional approval.  Click here for the full policy detailing the list of permissible activities.

I am developing a case report; do I need to submit my proposal to the IRB?

Development of a single case report for publishing or presentation at a meeting generally would not require submission of a proposal to the IRB. However, development of multiple case reports (a case series) to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, may meet the federal definition of 'research involving human subjects' and requires review by the IRB. Click here for the Case Report Policy if you are developing a case report.