Just as Children’s Hospital and the Institutional Review Board must comply with federal regulations and honor agreements with the Department of Health and Human Services about how research is to be conducted at Children’s, research investigators have certain responsibilities. Each researcher is obligated to:

1. Protect the rights and welfare of research participants.

2. Notify the IRB of the intent to conduct research involving human subjects by submitting an application for IRB review and approval, and not initiating a study until final IRB approval is received.

3. Defer the decision on whether a research proposal qualifies for exempt review status under the federal regulations to the IRB.

4. Provide copies of the IRB-approved consent and assent forms to each research participant to sign, unless the IRB has specifically waived this requirement for the study. All signed consent and assent forms must be retained for three years after the research is completed.

5. Promptly report proposed changes for studies that have been approved by the IRB. Changes are not to be implemented until the IRB has reviewed and approved them. The only exception is when immediate action is necessary to avoid harm to participants.

6. Report progress for studies underway to the IRB as often as required, and not less than once a year.

7. Promptly report unanticipated injuries or adverse effects involving research participants to the IRB.

8. Obtain verbal approval from the IRB chair or designee for emergency use of an investigational new drug or an investigational device with a single patient when there is not enough time to obtain formal IRB approval. Data collected for a single patient emergency use cannot be considered research data.