Engagement in Research and Reliance Agreements

Policy

Investigators at Children's Hospital often participate in research projects that may involve human subjects at other institutions or locations. In some instances Children's Hospital is the coordinating center and all activities are coordinated by Children's Hospital. In other instances the Children's Hospital investigator is one collaborator of a study that is being coordinated elsewhere. There are also circumstances when research conducted under the auspices of Children's Hospital involves populations and/or sites that are not under the jurisdiction of another IRB.

- The CCI will ensure that all collaborating institutions and investigators engaged in federally supported human subject research operate under an appropriate OHRP or other federally approved Assurance for the protection of human subjects if federally funded . Assurances, reliance agreements and other appropriate mechanisms to assure appropriate IRB oversight may be used for non federally funded research. An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research Purposes; or (ii) obtain individually identifiable private information for research Purposes [45 CFR 46.102(d),(f)]. For further assistance in determining whether a non-CH performance site is "engaged," reference the OHRP guidance document (http://www.hhs.gov/ohrp/policy/index.html#engagement)
- In the conduct of cooperative research projects, the CCI acknowledges that , when applicable, each institution is responsible for safeguarding the rights and welfare of human subjects .If a reliance agreement is signed, the CCI may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. When doing so, the CCI will ensure that:
  - The review arrangement is approved by the appropriate officials of the institutions involved, and
  - The particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by the CCI or (ii) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other HSC members.
  - Appropriate state or national laws are considered in the locations where the research is conducted . (i.e informed consent, definition of emancipated or mature minors)
- When research covered by this policy takes place in a foreign country, the CCI will ensure that procedures prescribed by the international institution afford protections that are at least equivalent to those provided in this Policy

- The CCI will also ensure that engagement in human research activities of independent investigators who are not employees or agents of Children's Hospital will be in accordance with a formal, written agreement of commitment to relevant human subject protection policies and CCI oversight. **(see policy on Clinical Research Credentialing)**
- When research covered by this policy takes place at other institutions, , the Director of Clinical Research or the Protocol Administrators are responsible for assuring that appropriate approval has been obtained form other institutions before any research may begin at other sites. This may involve assuring that a reliance agreement has been signed and/or receiving a copy of another site's IRB approval Final approval will not be granted for the site until such documentation is obtained. Any questions regarding clarification on roles of investigators, IRBs and required oversight should be referred to the Director Of Clinical Research Compliance

Related Content

Policy 3.1 Jurisdiction of the Committee on Clinical Investigation

Policy 4.1 Clinical research Credentialing

Document Attributes

Title	Engagement in Research and reliance Agreements		
Author	**Susan Kornetsky**	**Dates Reviewed/ Revised**	04/01/05 06/20/05 04/28/2010 05/14/2010
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Children's Hospital Boston, 2012	**Last Modified**	05/28/2010
Approved	Susan Kornetsky Director of Clinical Research Compliance Carleen Brunelli, MBA, PhD Vice President for Research Administration		