

Additional Reviews

Nursing Services

If your protocol calls for nursing resources, please contact the Nursing Director or Vice President of the unit(s)/program(s) where the study will be conducted before this application is submitted to the Committee on Clinical Investigation. If the project is a nursing study, it must be reviewed by the Nursing Research Council **before** submission to the Committee. For more information, contact Jean Connor DNS, RN, CPNP at 58890

Radiation Safety Committee (RSC)

Research protocols that involve administration of radioactive agents or the use of other radiological procedures require approval by the Radiation Safety Committee. The RSC will require an accurate assessment of radiation exposure in order to make a risk/benefit determination. Investigators are encouraged to discuss their protocols with the Radiation Safety Officer, William "Rusty" Lorenzen at 617-355-7516.

Intellectual Property Office (IPO)

If you will be sending biological materials outside the Hospital, please contact the Intellectual Property Office for assistance with a Material Transfer Agreement. If you have thought of a new treatment, new formulation, new use of or improvement upon a known pharmaceutical or device, please contact this office to determine whether you should submit an invention disclosure. Intellectual Property Office, 617-355-7050.

Clinical Trial Agreements

Any research intended to support regulatory approval of a product and/or sponsored by a nongovernmental, for-profit entity requires a clinical trial agreement between Children's Hospital and the sponsor. Sponsorship may be in the form of providing money, drugs, devices, biologics, or software. If a clinical trial agreement is necessary, notification of approval by the Committee will be released only after a clinical trial agreement is signed. Agreements are negotiated by the Manager of Corporate Funding. This individual will negotiate and establish the terms of the agreement and will review the clinical trial. The Director of Clinical Research Compliance is contacted if there are any questions or concerns about human subject protection issues as they relate to the clinical trial agreement. Once the agreement is signed, the IRB will be notified in writing. There is a one time \$2,500 administrative review fee for industry sponsored trials. Final approval notifications and consent documents will not be released by the Clinical Investigation Office administrative staff until they are notified in writing that a clinical trial agreement has been signed.

Committee on Microbiological Safety (COMS)

Any protocol that involves human gene transfer, xenotransplants, xenografts, or therapeutic approaches that involve treating human subjects with infectious agents requires review and approval by COMS prior to the release of final approval by the Committee on Clinical Investigation. Information regarding the COMS' review is provided to the Committee on Clinical Investigation for consideration during review. Final approval will not be released until COMS approval is obtained. A written letter of approval is required for the protocol file before approval is released.

Department of Radiology

Any protocol that involves the use of radiology is forwarded to the Manager of Radiology. Formal approval from Radiology is not required. However, the Department of Radiology is alerted that their services are required and they may contact the investigator regarding questions or concerns.

Dana Farber Cancer Institute - Children's Hospital Agreement

The Children's Hospital (CH) and Dana-Farber Cancer Institute (DFCI) have signed an agreement that permits the review of protocols that involve hematology/oncology patients, by only **one** Institutional Review Board, either DFCI or CH. The agreement specifies which protocols each IRB will review. The criteria may be found at:

<http://www.childrenshospital.org/sites/default/files/2022-03/irb-cipp-051-015-dfci-ch.pdf>.

Please call Susan Kornetsky at Children's Hospital (617-355-7052) or the DFCI Protocol Office (617-632-3029).