

Section 8:

Federal Guidelines for Research Involving Human Subjects

As a Federally designated comprehensive cancer center, DF/HCC is governed by local policies and procedures, Federal and state regulations and other guidance.

The DFCI IRB is regulated by the Code of Federal Regulations as found at 21 CFR Parts [50](#) and [56](#), as well as the Code of Federal Regulations as found at [45 CFR Part 46](#), Subpart A (*The Common Rule*). Regulations that govern investigational new drugs (INDs) are found in [21 CFR Part 312](#); biologics are found in [21 CFR Part 600](#) and devices are found in [21 CFR Part 812](#). There are other regulations governing devices and other aspects of human subject research that the IRB must adhere to as applicable. DFCI has an assurance on file with the Department of Health and Human Services (DHHS), otherwise known as a Federalwide Assurance (FWA), that sets the standard for ethical review of all research. The OHS and IRB ensure that these standards are met.

The DFCI IRB assurance number is FWA00001121.

The Assurance states that all research involving human subjects that is conducted by DFCI staff or by researchers who fall under the purview of the DF/HCC, or on DFCI premises or under its sponsorship, whether supported by outside funds or not, must be reviewed and approved by the DFCI IRB. Once approved, these trials must be re-reviewed{xe "Human Protection Committee (HPC)"} at least once yearly. This policy also applies to protocols sponsored by DF/HCC staff conducting research at other hospitals, institutions, or community groups, or any other areas outside DF/HCC. Individuals not affiliated with DF/HCC proposing trials using DFCI patients or patient families as trial subjects must have a DF/HCC sponsor investigator and abide by these policies and procedures.

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly aware of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [21 CFR Part 50](#) and [45 CFR Part 46.116](#).

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by [21 CFR Part 50](#) and [45 CFR Part 46.117](#).
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Important Definitions Relating to DF/HCC Human Subject Research

Clinical Investigation (FDA): Any experiment that involves a test article and one or more human subjects. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous.

Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Human Subject (FDA): An individual who is or becomes a participant in research either as a recipient of the test article or on whose specimen a test article is used or as a control. A subject may be a healthy individual or a patient.

Research (DHHS): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Test Article (FDA): Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article for human use.