OHRS Information Sheet
General Requirements for Informed Consent

The Dana-Farber Cancer Institute Institutional Review Boards (IRBs) operate under Federal regulations that set out specific requirements with respect to the informed consent of individuals who participate in research. (45 CFR Part 46; 21 CFR Part 56). Members of institutional review boards and individuals who conduct research approved by any of the DFCI IRBs are expected to know, understand and appropriately implement these requirements.

The Federal regulations unequivocally state:

> **"no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."**

Informed consent is a process and a dialogue, not just a document. Prospective subjects or their representatives must be given sufficient opportunity to consider whether or not to participate in circumstances that minimize the possibility of coercion or undue influence.

Except for broad consent, an informed consent must:

1. Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
2. Present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
3. Provide information to the subject or their representative in language understandable to the subject or representative.
4. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Refer to the following documents for specific information on informed consent:

- DFCI IRB Info Sheet – Required Elements of Consent
- HRP-314 - Worksheet – Criteria for Approval (Contains the Basic and Additional Elements of Informed Consent)
- HRP-410 - Checklist – Waiver or Alteration of Consent Process
- HRP-411 - Checklist – Waiver of Written Documentation of Consent

The informed consent requirements set forth in the Federal Regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.