Required Elements of Consent

This document provides for reference the required elements of consent under the Common Rule, including the required elements under the Revised Common Rule (January 19, 2017). Included is a reference to where in the DFCI IRB consent template these elements can be found.

Regulatory Citation*	Regulation/Requirement	Location in DFCI Consent Template
45 CFR 46.116(a)(1)	A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.	Sections A, C, E
45 CFR 46.116(a)(2)	A description of any reasonably foreseeable risks or discomforts to the subject.	Section F
45 CFR 46.116(a)(3)	A description of any benefits to the subject or to others which may reasonably be expected from the research.	Sections A, H
45 CFR 46.116(a)(4)	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	Section D
45 CFR 46.116(a)(5)	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.	Section Q
45 CFR 46.116(a)(6)	For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.	Section J
45 CFR 46.116(a)(7)	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.	Section K

45 CFR 46.116(a)(8)	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	Section A
New Required Element – 45 CFR 46.116(a)(5)(i)	The informed consent must 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 provision further requires that this beginning portion of the informed consent must be organized and presented in a way that facilitates comprehension.	Section A
New Required Element – 45 CFR 46.116(c)(7)	A statement that Biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.	Section H
New Required Element – 45 CFR 46.110(c)(8)	A statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.	Section L
New Required Element – 45 CFR 46.116(c)(9)	A statement about whether the research project might include whole genome sequencing (the sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).	Section S

Additional Elements of Consent Required by the DFCI IRB
(optional under the current regulations)

Regulatory Citation*	Regulation/Requirement	Location in DFCI Consent Template
45 CFR 46.116(b)(1)	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.	Section F
45 CFR 46.116(b)(2)	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	Section G
45 CFR 46.116(b)(3)	Any additional costs to the subject that may result from participation in the research.	Section I
45 CFR 46.116(b)(4)	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	Section E
45 CFR 46.116(b)(5)	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	Section F
45 CFR 46.116(b)(6)	The approximate number of subjects involved in the study.	Section A

* Regulatory citations are subject to change depending on the status of the Revised Common rule.