

OHRs Information Sheetⁱ
DFCI IRB Two-Year Continuing Review for
Qualifying Non-Federally Funded Minimal Risk Studies

The DFCI applies the Federal Regulations for the Protection of Human Subjects (45 CFR Part 46) to all research regardless of funding, even though this has not been extended in the Federal-wide Assurance, *except* for the following limited exception regarding continuing reviews. A small number of studies that would previously have been reviewed on an annual basis may be eligible for a two year continuing review approval period. For the vast majority of studies reviewed by the DFCI IRB, this policy will have no impact.

The types of studies that would qualify for this extended review period are research protocols where all of the following apply:

1. The DFCI IRB has determined that the research is minimal risk under 45 CFR 46.110(b)(1), categories 5, 8(c) and 9; and the research involves:
 - no Federal funding of any type; and
 - no FDA-regulated components in the research; and
 - no sponsor or other contractual limitations are in place; and, no subjects are prisoners; and,
 - no NIH Certificate of Confidentiality has been issued.

A new study that meets all of the above criteria would still be reviewed after one year of the initial approval. Only after the first continuing review would a study be considered for a two-year approval period. Non-federally funded studies that have been permanently closed to enrollment and the remaining research is limited to data analysis 45 CFR 46.110(b)(1), category 8(c), but did originally involve interventions determined to be greater than minimal risk, may also qualify for a two-year continuing review approval period.

Please note that the determination of a two-year review period is not guaranteed and will be made after review by an IRB member or IRB committee review.

ⁱ This Information Sheet is only applicable for minimal risk studies approved prior to January 21, 2019 that were granted a 2-year continuing review period.