

Cell Line and Dataset Policy

1. Cell Lines

- a. Research using de-identified immortalized cell lines that are obtained from commercial or governmental sources is not considered human subject research, is not governed by 45 CFR 46 or 21 CFR 50&56, and review by the Einstein IRB is not required.
- b. Research using an immortalized cell line that is not commercially or governmentally available must be submitted to the Einstein IRB to determine whether or not it is exempt.
- c. Research to establish a cell line requires Einstein IRB review and approval.
- d. Use of cell lines for potential commercial purposes is permissible in some circumstances with Einstein IRB approval.

2. Datasets

- a. Research using de-identified datasets that are obtained from a commercial or governmental source is not considered human subject research, is not governed by 45 CFR 46 or 21 CFR 50&56, and review by the Einstein IRB is not required.
- b. All other research involving datasets, whether identified or de-identified, requires Einstein IRB review.