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.