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BULLETIN OF THE TUFTS SBER IRB MEDFORD CAMPUS INFO ON THE CODE OF FEDERAL REGULATIONS

1. Did you know that a copy of the IRB approved consent form must be given to all participants in your study?

REF: 45 CFR 46.117 (a): Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

2. Did you know that you are required to retain your data for a minimum of 3 years after the research project is completed?

REF: 45 CFR 46.115 (b): The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

3. Did you know that all protocols are subject to continuing review by the IRB at least once a year?

REF: 45 CFR 46.109 (e): An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

4. Did you know that there are seven categories of research that may be reviewed by the IRB through an expedited review process?

REF: 45 CFR 46.110 (b): An IRB may use the expedited review procedure to review either or both of the following: (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, or (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

These research categories can be found at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>