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Notice to Researchers who receive Department of Health & Human Services (DHHS) Agency funding for studies involving human participants

This is to advise all UBC researchers who receive Department of Health & Human Services Agency funding (List of DHHS funding agencies) for studies involving human participants that, effective January 21, 2019, new US regulations are coming into effect. These new regulations will impact studies that are submitted for Research Ethics Board (REB) approval on or after January 21, 2019.

These new regulations mandate that specific information must be contained in the DHHS funded study informed consent form. They also require that if the study is a clinical trial*, either the study funding agency (e.g. NIH or other agency), or the awardee (e.g. lead principle investigator) must post a copy of the clinical trial informed consent form, within a specified time frame, to ClinicalTrials.gov or to a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

Informed Consent Requirements

Most of the mandated information in informed consents is already required information in informed consents reviewed and approved by UBC's affiliated Research Ethics Boards. There are also some new requirements, the most significant of which is the requirement that informed consent forms must begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.

Detailed information on the mandated informed consent requirements can be found here.

Posting Requirements

Detailed information on the mandated posting requirement can be found here.

For more information, or with questions or concerns, please contact your REB administration, or

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∗ 102 (b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioural health-related outcomes.

October 29, 2018