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Common Rule Consent Form Guidance

Effective January 21, 2019, the following must be implemented to informed consent forms for (new) studies falling under the U.S. Department of Health & Human Services (HHS) Regulations (i.e. United States federally sponsored research projects). These are studies conducted/supported by HHS (e.g., NIH), or conducted at an institution that assumes responsibility for the research and complies with 45 CFR 46.

When the above criteria are met, the following details must be presented in the consent form:

1. A concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study must be included at the beginning of the consent. The key information must be presented at the beginning of the consent form and include the following five key factors:
    a. Identification of the project as a research study and that participation is voluntary
    b. Purpose of the research, duration of participation, and a description of research procedures
    c. Foreseeable risks or discomforts, if any
    d. Expected benefits to subjects or others, if any
    e. Alternative procedures or treatments that might benefit the subject (this applies primarily to clinical research)

    Note: if the consent form is already brief, the whole consent can be considered key information.

2. If the study collects identifiable information (i.e., health information or biological samples), there must be a statement about future data use (whether this information will be used or shared, and whether it will be identifiable or de-identified).

3. If biological specimens are being collected as part of the research study, the potential for commercial profit must be noted in the consent form, as well as an indication whether or not the participant will share in that profit. This is only required if commercial profit is a possibility.

4. If the study contains whole genome sequencing, it must be disclosed in the consent.

Additionally, the Common Rule now requires that clinical trials consent forms be posted *on a publicly available Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject*.

There are currently two federal websites: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). More information about the revised Common Rule is available on the on the OHRP website (https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html).

Please direct questions related to the Common Rule to reoffice@ualberta.ca