CHICKEN SOUP FOR THE BUSY COORDINATOR

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Preventing Information Discrepancies between IRB Application Form & Study Documents

Scenario:

Professor Y, a Principal Investigator (PI) of a study submitted an IRB application form on ECOS. During the IRB review process, Professor Y received several queries as there were discrepancies between the information indicated in the study documents (e.g. Protocol and Informed Consent Form) and the IRB application form. This resulted in a longer review process due to clarifications required from the inconsistent information.

What should Professor Y / PIs of studies do to ensure that the information is consistent in both IRB Application Form(s) and Study Documents?

Checks Before Submission to IRB

1. Ensure that the correct **study classification** is selected.

   Classifications: Clinical Trial, Human Biomedical Research (HBR) or Restricted HBR, Others

   Tip: Use the MOH Decision Tool on the Human Biomedical Research Framework here

2. Confirm that the document naming conventions used in the **IRB application form, informed consent forms (ICFs), protocol, posters and other study documents** are consistent across all documents. *For example, not using different document naming e.g. "Informed Consent Form (Intervention Arm).docx" and "Informed Consent Form (XY Program).docx" to refer to the same ICF document in the various platforms.*

3. Ensure that the **study protocol title** is reflected on the study documents.

4. Verify that the **risk and benefits** listed in the IRB application form are **consistent** with the information indicated in the ICF.

5. If there are study documents mentioned in the IRB application form, ensure that they are also attached to the form for review. For example, **Data Collection Forms, Case Report Forms**.

6. Check that the **enrollment target numbers** listed in the IRB application form tally with the numbers indicated in the other study documents.

Actions After IRB Approval

1. If there are proposed changes to the protocol or study documents, ensure that the **changes are submitted to the IRB for approval before implementing any changes**. Changes can be submitted via an amendment on ECOS. Make sure that the version number and version date of the new documents are updated.

References:

For more details, please refer to the IRB Guidebook: Application Form here.

7. Regulation of human biomedical research | Ministry of Health

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