

# CHICKEN SOUP FOR THE BUSY COORDINATOR

April 2025

## 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?**

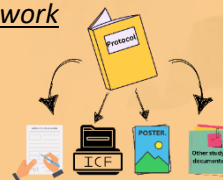
### Checks Before Submission to IRB

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](#)*

2. Confirm that the naming conventions used in the **IRB ethics application form, informed consent forms (ICFs), protocol, posters and other study documents** are consistent. Ensure that the **study protocol title** is reflected on the study documents.



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



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



5. Check that the **enrollment target numbers** listed in the IRB ethics 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](#).

[MOH | Decision Tool on the Human Biomedical Research Framework](#)

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*\*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*