

## Common Issues Holding Up Protocol Reviews

### Front Sheet.

- Protocol version/date do not correspond with the version/date listed on the protocol document
- Correct IND number is not included. For example, if the PI holds the IND, that number should be reflected on the front sheet rather than the manufacturer's generic IND number.
- Regulatory Sponsor is not correctly identified.
- The ages of the target subject population are not provided and are not consistent with the protocol document and application page.
- The target accrual numbers are not correctly provided:
  - The DF/HCC Target accrual figures are different from the Overall accrual figures for multi-center studies
  - The accrual figure should be one number and not a range of numbers
  - The accrual figures should correspond with the application, protocol document, and endorsement letter, if applicable
  - Target accrual numbers are completely omitted for tissue banking or medical record review studies – these numbers are still required
- The checkbox indicating the percentage of accrual at DF/HCC has not been completed or is incorrect
- The listed DF/HCC participating sites are not consistent with information in the endorsement letter and/or the application form
- All applicable protocol procedures are not checked.
- Title does not match the protocol document title exactly.

### Endorsement Letter.

- Not included or does not provide all requested information. Please refer to the endorsement letter guidance document.
- Not signed by a biostatistics representative

### Application Form.

- The application form is not complete and not consistent with the protocol document (e.g., safety monitoring plan)
- The application indicates that questionnaires, surveys, letters, study diaries, etc. will be used, but these documents were not submitted.
- IND application has not yet been submitted to FDA
- Program leader signature missing for tissue banking and medical record review studies

### Signature pages.

- Signature pages are not complete, i.e., role, conflict of interest disclosure, and training information is missing
- Signatures and/or date are missing
- Signature pages are missing
- Sites are being added after the review process begins

### Protocol Document.

- Draft version instead of final version is submitted
- Protocol plus an amendment are submitted as two separate documents, and the amendment is not incorporated into one document that can be posted to OncPro.

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- Biostatistical section describing the rationale for the sample size is missing.
  - Missed or vomited doses are not discussed. If this information is not included in the protocol and the protocol cannot be revised, please include an Alert Page with your submission.
    - Supporting documentation referenced in the protocol is not included with the submission.  
E.g., Pharmacy Manual, Laboratory Manual, and Dosage and Administration Instruction (DAI).

**Informed Consent Document(s).** The following are important considerations when preparing informed consent documents:

- For cooperative group studies, compare the consent form with the sample consent attached to the protocol and identify any discrepancies with regard to the procedures, alternatives and risks sections. Please note that OHRS Pre-review recommendations should not include deleting such information, but rather clarifications.
- Are the procedures described in the consent form consistent with the protocol document? If not, please summarize the inconsistencies.
- References to “animals” should be rephrased as laboratory experiments or tests. Note: This does not apply to first-in-man studies.
- If applicable, Phase I language explaining that all subjects will not receive the same dose and that they may receive a dose that is not effective should be included.
- In the risk section, are percentages used to categorize risks associated with drugs used in the trial? Please note that for Phase I trials, these percentages may not yet be known.
- Risks associated with all research procedures are included.
- The risks are described in lay language and the technical/medical term, if provided, follows in parentheses.
- Does the cost section specify which drugs and procedures will be provided without cost to the subject and which ones will be charged to the subject or subject’s insurance?
- If children will be participating, have provisions for obtaining documentation for assent been included or is there a separate assent document?
- If it is anticipated that non-English speaking subjects will be participating, has the informed consent document been translated into a language understandable to the subject population?
- Has all non-applicable template language been removed from the consent? For example, if the study intervention does not include chemotherapy, the suggested risk language relating to chemotherapy should not be included.
- The consent form does not include specific doses e.g., 200 mg. As a general policy, the IRB prefers that specific doses not be included in the consent form.
- Symbols are either explained or are written out, e.g. instead of “<”, use “less than”.

**Post Review but Pre Activation Amendments**

- May require review by the full SRC.
- May require review by the full IRB.
- Add sites after the review begins will slow down activation because the added sites have less time to review
  - May affect contracts
  - May affect nursing and pharmacy departments
  - May require RSC review or IBC review

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**Amendments**

- Justification/rationale for the amendment is not provided or is incomplete.
- A description or summary of changes is not provided
- Section "E" – the statement of investigator – is incomplete. Often the box is not checked

**Continuing Reviews**

- Study team information is not current and up to date.
- Study accrual information (part "F") is incomplete. Study-wide accrual is blank or is not broken down site-by-site in item #3
- Numbers provided in part "G" (participant progress information) do not add up to the number provided in part "F" – item #3
- The list of participating sites in part I do not match the sites listed on the front sheet of the protocol

**Deviation Reports**

- Corrective Action Plan is not complete
- Description of the deviation is not detailed enough.