Common Issue that Unnecessarily Delay IRB Review/Approval

IRB approval is often delayed because of missing, incomplete or contradictory documentation, errors, or omissions in the informed consent form (ICF) or in the application. Please review the following and ensure they are proactively addressed to help facilitate and ensure timely review:

ICF:

- **Reading Level** - The most common issue is the ICF reading level is too high. The CHA IRB requires the reading level to be at or below a 7th grade reading level. Avoid scientific terms or jargon. Investigators are strongly urged to check the reading level by using the readability test statistic in Microsoft Word or another readability statistic program. The IRB office routinely uses the Microsoft Word feature to determine the reading level of an ICF. If the statistic does not display or is inactive in Microsoft Word, please click here for instructions on how to activate it. The Stanford University IRB has an extensive lay language glossary to help investigators simplify terminology. ICF simplification checklists may also be helpful.
- **Missing Information** – Procedures, risk information, etc., which is present in the protocol/application is not included in the ICF. The protocol/application and ICF should accurately reflect each other.
- **Costs** - What is, and what is not, paid for by the study sponsor, insurance, etc., is either unclear or not stated in the ICF.
- **Grammar and spelling errors**.
- **Therapeutic misconception –** Persons enrolled in a research study are "subjects" or "participants" and should not be referred to in the ICF or protocol as "patients."
- **Misleading terminology/words** – "Treatment" or "therapy" should not be used to refer to a research intervention; "medication" or "medicine" should not be used to refer to an investigational drug.
- **Readability** - The use of tables, charts, a calendar of events, and outlines to explain the procedures and study design is recommended.

Applications:

- **Incomplete sections in the application** - Please answer all questions on the submitted IRB forms. If something does not apply do not leave it blank, insert "N/A" or something similar.
- **Inconsistencies** - The IRB often finds inconsistencies in the submission. It is imperative that the information in the protocol, the application, the executive summary, the ICF, the clinical trail agreement with the sponsor, etc., all agree. Common inconsistencies researchers should safeguard against are:
    - Disagreement about the number of subjects to be enrolled.
    - The number of subject visits in a study.
    - The amount participants will be paid and the payment schedule should be in the protocol and the ICF.
    - All procedures listed in the protocol/application are not stated in the ICF.
    - Payment for research-related injury must agree among the documents.
- **Recruitment/ Informed Consent Process** – Recruitment methodology details and/or the informed consent process are not included or are not adequately detailed. Note: A PI cannot directly recruit his/her clinic patients.
- **Cut/Copy and Paste Errors**: Documents from a prior study are used as templates for a new study, but information from the prior study remains.
- **Subject Confidentiality** - Please do not ignore the importance of explaining how subject confidentiality will be maintained in the study.
- **Research Education** - All research team members (see definition), including those performing data entry and data analysis, must be listed in the application. Only those listed, and those who have completed human subject research education training, may participate in the project. (See reminder below.)

Version dated 12/01/12

- **Signatures** - Required signatures are not present.

Missing Documents:

- A completed conflict of interest form for each member of the research team.
- If the study is funded by a federal grant, a copy of the grant must be submitted. IRBs are required to review federal grants to ensure that the proposed protocol is within the scope of the grant.
- Requisite supporting drug or device documentation – Investigator's Brochure for an investigational drug, device user's manual, drug package insert, etc.
- Recruitment materials, surveys, questionnaires, scales, assessments, telephone scripts, etc. Note: Even if a scale, assessment tool, etc., was submitted with a previous study it must be submitted again with each new study.

Other:

- When a study is to be amended submit a tracked and untracked tracked copy of each revised document to the IRB office for review and approval before the change is implemented. Please click here if you require help using the track changes feature in Microsoft Word.
- When a document is updated or amended, be certain to include an updated version date or number to assist with document version control.

REMINDER: Per the updated 2012 CHA Research Education Requirements, each individual is to keep a copy of his/her documentation of education completion. Principal Investigators are to retain a copy of education certificates for all research team members; these documents are subject to audit. A copy no longer needs to be submitted to the IRB office.