Request for Information (RFI): NIH and FDA Request for Public Comment on Draft Clinical Trial Protocol Template for Phase 2 and 3 IND/IDE Studies

Thank You - Your Comments Have Been Received. You may want to print this page with your comments for your records.

04/15/2016 at 01:48:28:126 PM

Ease of use of the template

The template is relatively easy to use – we recommend that the toolkit referenced above would be complementary as this offers points to consider for each of the referenced essential elements for ethics that have been identified as well as examples from actual trial protocols and relevant citations and resources.

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Please provide comment on utility, readability and clarity of the protocol template format and instructional and sample text for the purpose of developing and writing a protocol document. You may provide comment to one or all of the topics of interest in the comment boxes below.

Topics of particular interest for comment are:

Areas in which the template enhances protocol development (e.g., trial design, drafting a protocol)

We applaud that the Clinical Trial Protocol Template includes a dedicated section on "Ethics/Protection of Human Subjects." Including an separate ethics section in the protocol has been recommended by a multi-stakeholder team convened by the Multi-Regional Clinical Trials Center at Brigham and Women's Hospital and Harvard that developed the MRCT Ethics Essential Elements and Points to Consider Reference Document (http://mrctcenter.org/wp-content/uploads/2015/11/2014-11-14_toolkit_essentialelementsofethics_108_pg.pdf) and Essential Elements of Ethics online course (https://globalhealthtrainingcentre.tghn.org/essential-elements-ethics). Use of a dedicated ethics section will ensure that the salient ethical issues can be readily located and understood by IRBs and research ethics committees, study investigators, and the study team.

Clarity and utility of **instructional** text (e.g., text adequately explains intended content or suggest additional instructional text that would be useful)

No Response

Clarity and utility of **sample** text (e.g., ability to discern instructional text from sample text)

No Response

Clarity that **sample** text can be modified for a specific study

No Response

General contents for phase 2 and 3 studies

No Response

Ability to find the required information (e.g., per regulations or for scientific or programmatic review) for a submitted study

No Response

Other Comments

We recommend the inclusion of additional ethical issues in the protocol template, as outlined in the MRCT Ethics Essential Elements and Points to Consider Reference Document (http://mrctcenter.org/wp-content/uploads/2015/11/2014-11-14_toolkit_essentialelementsofethics_108_pg.pdf). We have identified certain additional elements to include: Study-related injury, Post-trial access, Return of Aggregate Research Results, Management of Incidental Findings and Individual Results, and Community Engagement. Furthermore, we would suggest enhancing the sections on (1) choice of study population related to specific vulnerable populations, and (2) payment for participation. We understand that these items may also be addressed in other related documents (informed consent form, CTA etc.). Clarifying these concepts in the ethics section would be helpful to investigators, IRB/REC personnel, and others.

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