




wcg IRB

Parameters for IRB Review and Approval of Electronic Consent Documents

David Forster, JD, MA, CIP - CHIEF COMPLIANCE OFFICER, WCG

REGULATORY AND GUIDANCE BACKGROUND

The IRB must review consent documents to ensure that the elements of consent in 45 CFR 46.116 and 21 CFR 20.25 are included as appropriate, and to ensure that there is appropriate documentation of consent. IRBs have the authority to approve a consent form as written, to give conditional approval of a consent form, or to defer or disapprove the consent form if extensive changes are necessary. The requirements for conditional approval are provided in the OHRP [“Guidance on IRB Approval of Research with Conditions.”](#) FDA agrees with the provisions in this OHRP guidance. The guidance explains that an IRB can approve research with conditions in situations where it requires investigators to:

- “(a) make specified changes to the research protocol or informed consent document(s),
- (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or
- (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46.”

The guidance also provides specific examples of research that can be approved with conditions. The most relevant to the approval of electronic consent documents

is section D.11, which provides the following as an example of an appropriate situation for a conditional approval: “Requiring simplification of the description of the study risks in the informed consent document to be at an 8th grade comprehension level, and designating the IRB chairperson to review the revised informed consent document and ensure that risks are accurately described and understandable at an 8th grade comprehension level.”

When an IRB conditionally approves a consent form, the IRB can assign a single individual to confirm that the condition(s) has been satisfied and issue final approval. However, if the IRB defers or disapproves the consent form, the form must return to the convened meeting for final approval. In the FDA guidance [“Recruiting Study Subjects,”](#) FDA has clarified that it expects IRBs to review the final version of audio and video advertisements:

“When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude retaping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures. The IRB may wish to caution the clinical investigators to obtain IRB approval of message text prior to taping, in order to avoid re-taping because of inappropriate wording.”

APPLICATION TO WCG APPROVAL OF ELECTRONIC CONSENT

Electronic consent can be simply the content of a paper copy in an electronic format, or it can have additional features such as video descriptions of randomization and graphic presentations of disease processes and physical risks.

The WCG process of review for electronic consent documents requires that the IRB review the final product to ensure that it meets the regulatory requirements for the elements and documentation of consent. However, sponsors and investigators may wish to obtain IRB approval of the consent text prior to developing the electronic consent, in order to avoid revising the electronic consent because of inappropriate wording. Therefore, sponsors are advised to submit a paper version of the consent to the IRB in advance of creating an electronic version in order to get IRB approval of the general document and avoid extra expense. In this initial review phase, the IRB can either provide a conditional approval if content is largely written down, or must defer the consent document if substantial sections of the consent document or process have not been written down.

The IRB's decision as to conditional approval versus deferral will depend on the extent to which the draft version reflects the content of the final electronic version. If the bulk of the electronic process has been provided in draft text or in story boards, then the IRB

can conditionally approve the consent form. However, if there is still substantial content to be developed, then the IRB must defer the consent form for future full board review.

Sponsors must determine how much time and resources they want to commit to developing an electronic consent before seeking an IRB decision. The most optimal process is for the sponsor to provide in writing to the IRB a complete description of the electronic consent process, with story boards for videos if applicable. Then the IRB will likely be able to provide conditional approval and have a single individual review the final product.



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