

MINISTRY OF HEALTH

Letter No. 17-SEI/2017-CONEP/SECNS/MS

Brasília, July 26th, 2017

Subject: Clarifications on updates to the Informed Consent Form (ICF) occurring during the course of the research.

Dear Coordinator(s) and member(s) of the REC, investigators and further interested parties,

1. The National Research Ethics Committee - Conep, through this letter, provides guidance on updates to the Informed Consent Form (ICF) that occur during the course of the research.
2. As defined in item II.23 of CNS Resolution No. 466 of 2012, the ICF is the "*document in which the free and informed consent of the participant and/or his/her legal representative is made explicit in writing and must contain all the necessary information in clear and objective, easy to understand, language for the most complete clarification about the research proposed for participation.*"
3. In order to ensure protection, autonomy and respect for research subjects, the ICF must consist of a single and complete document, free of addenda and/or other documents that complete it.
4. Given the above, the Commission clarifies that:
 - a) Changes to the ICF made through separate documents (addenda) are not considered acceptable. Therefore, information that needs to be added or removed from the approved version of the ICF during the course of the research requires updating (generation of a new version) of the document, and it should be noted that the new version of the ICF must include information that has not been changed and those that have been replaced and/or changed. Such changes should be duly highlighted.
 - b) Each new version of the ICF must be submitted for ethical analysis by the CEP/CONEP System, through the submission of a protocol amendment, and the altered excerpts and/or words must be duly highlighted.
 - c) New versions of the ICF, once approved by the CEP/Conep System, should be presented to the research subject already enrolled in the study, for purposes of new consent ("reconsent"). It is the responsibility of the investigator, or his/her delegated person and under his/her responsibility, to repeat the process of obtaining the informed consent, with special emphasis on the changes contained in the new versions of the ICF, so that, at the end of the process, the subject manifests whether or not he/she agrees with the continuity of participation in the research.
5. The clarifications presented in this Circular Letter also apply to the Assent Forms.

Kind regards,

Jorge Alves de Almeida Venancio
Coordinator of
National Research Ethics Committee – CONEP



Document electronically signed by **Jorge Venâncio, Administrator**, on 26/Jul/2017, at 1:43 pm, according to official Brasília time, based on Art. 6, paragraph 1, of Decree 8.539, of October 8th, 2015; and Art. 8, of Ordinance No. 900 of March 31st, 2017.



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