

MINISTRY OF HEALTH

Letter No. 51-SEI/2017-CONEP/SECNS/MS

Brasília, September 28th, 2017.

Subject: **Additional clarifications on ICF text.**

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

1. Considering item II.23 of CNS Resolution No. 466 of 2012, which defines the ICF as 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."*

2. Considering the Guidance Manual: Frequent pending issues in clinical research protocols, prepared in 2015 by this Committee, in item 1.1.c, which defines: *"The consent form is a document that must be written as an invitation. It is not appropriate for the ICF body to be written as a statement, as this may reduce the subject's autonomy. Example: "I know that material will be collected" or, "I declare that I will attend the visits", "by signing this document, I authorize the consultation of medical records", etc. Sentences should be written with statements by the investigator directed to the subject. Examples: "a small amount of blood will be collected from the vein in your arm(...)", "we would like to request your permission to check your medical records".*

3. Considering that several ICF include, in the final part, a summary of the points already presented, for confirmation by the subject, besides his/her signature and the signature of the principal investigator, this Commission guides that:

a) Reaffirming what is expressed in CNS Resolution No. 466 of 2012 and in other ethical regulations, regarding the ICF, it is understood that the subject's signature, by itself, is sufficient to consecrate his/her consent to be included in the study;

b) In the case of an ICF that has a synthesis/summary content at the end, it must be written from the investigator's point of view, not as a statement from the subject. Thus, it is acceptable for the final excerpt to have phrases like "You can leave the study at any time without any harm to you," or "we will collect four blood samples during the study period," making it clear that this is a synthesis for the participant who is reading the document, before he/she signs it.

c) If the investigator wants to insert a final statement phrase from the subject, as quoted in the Pending Issue Manual (item 1.c "However, it is acceptable that the final part of the ICF, where the signature fields are and in which the subject manifests his/her will to participate, is written as a statement"), this should have simple wording, such as "I read and agree to participate in the research" or "I state that I agree to participate in the research." It should be emphasized that no new information or information contradictory to the content of the rest of the document is included.

4. Based on this guidance discussed and approved at the CONEP Plenary Meeting, previous contradictory documents become ineffective.

5. In Human and Social Sciences research, CNS Resolution No. 510 of 2016 should be followed, which provides for different registration forms for the informed consent and assent process, in particular Art. 15, 16 and 17.

Kind regards,

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Reference: Process No. 25000.442219/2017-60

SEI No. 0695082