

**OPERATIONAL STANDARD No. 01/2012, OF MARCH 7, 2012.**

**Subject:** Processing flow of national multicenter projects: coordinating center

The National Research Ethics Commission (CONEP), considering:

1. The rights and dignity of research subjects, the fundamental reason for Brazilian norms and guidelines that order research involving human beings humans, including CNS Resolution 196/96;
2. Recurrent consultations on responsibility for coordinating studies national multicenters;
3. The definition contained in CNS Resolution 346/2005, on **multicenter project,** as one to be conducted according to a single protocol in several centers research and, therefore, to be carried out in its entirety by a researcher responsible at each center, following the same procedures;
4. The need to standardize all study procedures, so to guarantee the safety of its research subjects;
5. Conducting studies according to a single approved version of the protocol in all participating centers, generating reliable results;
6. The possibility of presenting amendments – any proposed modification to the original project – for analysis and approval by an Ethics Committee in Research (CEP) and CONEP, in the cases provided for in item VIII.4.“c” of CNS Resolution 196/96;
7. The establishment of a single flow for reporting adverse events; reinforcing the safety of the research subject;

Defines the processing flow of national multicenter projects

**obligatorily through a national study coordinating center,** such as \_\_\_\_\_ as is already done in international multicenters, from which the project will be proposed and will also be responsible for aggregating all changes and notifications relating to to the protocol. The CEP of the coordinating center must mediate any and all communication with CONEP, between the CEP participating in the study and between them and the CONEP, if necessary.

All multicenter protocols, both national and international, must start your processing flow in the CEP/CONEP System from the coordinating center of the study.

Yours sincerely,



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