



**NATIONAL HEALTH COUNCIL
NATIONAL RESEARCH ETHICS COMMISSION**

Circular Letter nº 040/2015/CONEP/CNS/MS

Brasília, March 27, 2015.

Subject: **Processing of the Investigator's Brochure on Plataforma Brasil (PB).**

Dear Coordinators of the Research Ethics Committees,

1. The National Research Ethics Commission – CONEP hereby inform them of the plenary deliberation regarding the processing of new versions of the brochure of the investigator (BI) on Plataforma Brasil (PB) after approval of the research protocol search.
2. New versions of this document are frequently limited to updates regarding the efficacy and safety data of the investigational product and the instructions addressed to the team of researchers, without altering the research already approved and, possibly, ongoing. Therefore, they must be processed as a notification in PB.
3. It is worth noting that, if changes to the BI impact changes to the Project Detailed and/or in the Free and Informed Consent Form (TCLE) it is necessary to presentation of an Amendment to the protocol. In this case, the BI will be analyzed together to other documents pertinent to the Amendment and, if necessary, the necessary adjustments and/or clarifications will be requested.
4. CONEP is available for further clarification.

Yours sincerely,



JORGE ALVES DE ALMEIDA VENANCIO
COORDENADOR DA CONEP/CNS/MS

Attachment to Of. Circ. 046/2015.