REQUIREMENTS TO CONDUCT POST-AUTHORIZATION OBSERVATIONAL STUDIES (EPA) IN THE HOSPITAL DOCE DE OCTUBRE

To conduct a post-authorization observational study in the Hospital Universitario Doce de Octubre, it is necessary to have an authorization of an accredited Ethic Committee of Investigation with medicine (CEIm) in Spain.

Two procedures are possible depending on the study is approved or not by other CEIm.

1) ASESSMENT NEW EPAs (Without previous approval by other CEIm)

If the CEIm of Hospital Universitario Doce de Octubre acts as CEIm evaluating an EPA, according the provisions stablished in the regulation **ORDEN SAS/3470/2009, de 16th December**, the following documents will be assessed:

A. Letter of application evaluation

B. Classification of EPA type (EPA-LA, EPA-AS, EPA-SP, EPA-OD or NO-EPA) by Spanish Agency of Medicines and Devices (AEMPS)

C. Full protocol (accepted in English, **dated and versioned**) and protocol summary (in Spanish)

D. Informed Consent Form (in Spanish), **dated and versioned**

E. Economic Budget detailing: scheduled payments to the principal investigator and to participants (if it is applicable)

   This document must include the amounts and the manner in which the researchers and subjects may be, if applicable, remunerated or compensated for their participation in the study, as well as the relevant elements of any contract envisaged between the promoter and the centre.

F. Signed commitment by principal investigator and sub-investigators.

G. Description of the qualification of the investigators (principal and sub-investigators) in an updated curriculum vitae.

H. Chief (or Responsible) Department acceptance.

I. If it is a multicentre EPA, a listing of all participating centres should be included.

J. In case of other centre under this CEIm influence, acceptance by the centre's responsible and suitability of facilities.

K. For EPA-SP, the resolution of the CCAA must be presented; for EPA-AS and EPA-LA, the resolution of the AEMPS must be presented (once they are available).

   *If a **major amendment is submitted to assess**, besides modified documents (with **tracked changes**), a cover letter summarising and justifying the changes should be submitted

The documents will be submitted by mail (ceic@h12o.es) at any moment, and they will be evaluated in the following CEIm meeting (calendar can be consulted in: http://imas12.es/documentacion-ceic/), if the application has been received at least 7 days before the date of the meeting.

2) NOTIFICATION OF EPAs AUTHORIZED BY OTHER ETHIC COMMITTE

The documentation related in the previous section, except the Informed Consent, the Information Document for participant and a copy of the CEIm authorization should be submitted by mail (stecnicacei@h12o.es) any day during the month. A summary of the protocol can be submitted instead complete protocol

In these cases, the CEIm recognizes the approval and the study will not be evaluated again. The CEI technical office assesses the local viability and a report will be sent.

The contract between Sponsor, Principal Investigator and Hospital Doce de Octubre Foundation for Biomedical Research can be processed in parallel to the evaluation by CEI contacting with the "Área de Gestión de Contratos de la Fundación". Contact: ensayos.hdoc@salud.madrid.org

3) SPONSOR´S OBLIGATIONS

According to regulation **ORDEN SAS/3470/2009, de 16th December**, the expected start date should be notified. As soon as the study ends, and within maximum fifteen days after their discontinuation or ending, the sponsor must notify it to the CEIm, and provide a final report copy (within six month after their discontinuation or ending).

***Information to take into account: if the CEIm requests clarifications or additional documentation, the promoter has 3 months to respond. After that time, the application is considered dismissed and must be resubmitted.**