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 o EPA-OD) by Spanish Agency of Medicines and Devices (AEMPS)

C. Study protocol, identified with date and version number

D. Informed Consent, including the Information Document for participant (in Spanish), identified with date and version number

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

F. Signed commitment by principal investigator and sub-investigators

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

H. Compliance of Department Responsible.

I. If it is a multicenter EPA, a listing of all participating centers should be included.

J. In case of other center under CEIm influence, acceptance by the center´s responsible and suitability of facilities

*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) any day during the month, and they will be evaluated in the following CEIm meeting (two per month), always the application is received at least 10 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 again evaluated. The CEI technical office assess the local viability and a report will be done

The agreement among 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, after approval and previously to start the study the sponsor must notify to CEI, the AEMPs or Madrid Autonomous Community authorization (depending the EPA classification) and the expected date to start.

As soon as the study ends, within maximum fifteen days after their discontinuation or ending, the sponsor must notified to CEI, and provides an end report copy (within six month after their discontinuation or ending)