

POST-AUTHORIZATION OBSERVATIONAL STUDIES (EPA)

To conduct a post-authorization observational study in the Hospital Universitario Doce de Octubre or in their influence area (Area 11 of Madrid), it is necessary to obtain an authorization by the Ethic Committee of Investigation (CEI) **submitting by mail** (ceicdoc@h12o.es) the documentation detailed below.

The time period is established from 1th to 5th of every month (labour days); it is possible to submit until 15th if the study has an approval from other CEI

1) ASESSMENT NEW EPAs

If the CEI of Hospital Universitario Doce de Octubre acts as CEI evaluating an EPA, according the provisions established 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. Case report form.
- F. Economic Memorandum detailing: scheduled payments to the principal investigator and to participants (if it is applicable)
- G. Signed commitment by principal investigator and sub-investigators
- H. Description of the qualification of the investigators (principal and sub-investigators) in current curriculum vitae. A
- I. Compliance of Department Responsible.
- J. If it is a multicenter EPA, a listing of all participating centers should be included.
- K. In case of other center under CEI influence, acceptance by the center's responsible and suitability of facilities

2) ASSESSMENT OF EPAs WHICH HAS AN AUTHORIZATION BY OTHER ETHIC COMMITTEE

Besides on previous documentation, a copy of the CEI authorization should be submitted

Any documentation requiring acknowledgment of receipt by paper must be sent with a postage envelope. Acknowledgment of receipt will not be sent by other route, including fax

The CEI postal address is following:

AREA DE GESTION DE PROYECTOS – UNIDAD ADMINISTRATIVA CEIC
INSTITUTO DE INVESTIGACIÓN HOSPITAL 12 DE OCTUBRE (I+12)
CENTRO DE ACTIVIDADES AMBULATORIAS — Bloque D – Planta 6
Avda de Córdoba s/n / 28041 - Madrid

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 DURING THE STUDY

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)

THE CEI WILL NOT PROVIDE INFORMATION ABOUT THE ASSESSMENTS. THE CALLS PHONE DELAY THE DEVELOPING AND COMUNICATION OF THE CEI’S ASSESMENT REPORT. THE CEI WILL RESPOND BY PHONE ONLY IF A NOTIFICATION HAS NOT BEEN RECEIVED