

REQUIREMENTS TO CONDUCT POST-AUTHORIZATION OBSERVATIONAL STUDIES (EPA) IN THE HOSPITAL 12 DE OCTUBRE

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

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

If the CEIm of Hospital Universitario 12 de Octubre acts as CEIm 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, EPA-OD or NO-EPA) by Spanish Agency of Medicines and Devices (AEMPS)
- C. Full protocol and protocol summary (In Spanish or English, **dated and versioned**)
- 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 in this Hospital (Identified with name and two surnames).
- G. Description of the qualification of the investigators in this Hospital (principal and sub-investigators) in updated curriculum vitae.
- H. Chief (or Responsible) Department acceptance in this Hospital.
- 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 COMMITTEE

The documentation related in the previous section, should be submitted, except the Informed Consent or the Information Document for participant. In addition a copy of the CEIm authorization should be submitted. This documentation can be sent by mail (ceicdoc@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 CEIm technical office assesses the local viability and a report will be sent. Nevertheless, the contract cannot be signed without the viability report, which will only be sent once the technical office has all the required documents at its disposal.

The contract between Sponsor, Principal Investigator and Hospital 12 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. Templates and additional documentation can be found in <http://imas12.es/documentacion-fundacion/>

3) SPONSOR'S OBLIGATIONS

According to regulation **ORDEN SAS/3470/2009, 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.