REQUIREMENTS TO CONDUCT CLINICAL TRIALS WITH MEDICINAL PRODUCTS (Royal Decree 1090/2015) IN THE HOSPITAL 12 DE OCTUBRE

If our Ethics Committee for Research with medicinal products (CEIm) acts as an evaluator, our requirements are those described in the Royal Decree (and Instructions Documents for perform Clinical Trials), available in the AEMPS web page. Only, it is necessary to send a mail to **ceicdoc@h12o.es** when the documentation is uploaded at SIC-CEIC. A cover letter explaining the major amendment should be submitted among the files. The clinical trials and the major amendments can be submitted 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 7 days before the date of the meeting.

If a clinical trial (CT) is going to be performed in the *Hospital Universitario 12 de Octubre* and it has been evaluated by other Ethics Committee for Research with medicinal products, the CEIm technical office advises to hospital Management Board about CT viability. Following documents should be submitted to **ceicdoc@h12o.es;** these documents are the same, with some local particularities, that those presented to CEIm during the CT evaluation

1. **Protocol summary** (preferably in Spanish)

2. **Suitability of the investigator** signed by sponsor. A list of sub-investigator participating in the trial at *Hospital Universitario 12 de Octubre* must be included in this document or in an annex (Identified with name and two surnames)

3. **Suitability of the facilities** signed by director or delegated person. All participating departments should be detailed

   In reference to the suitability of the facilities we understand that each centre decides who delegates the signature; this situation may vary by centres and the CEIm does not enter to assess who should or should not sign. However, in cases in which the person delegated coincides with the IP of the trial, it is considered that there could be a conflict of interest and therefore the signature of someone else responsible for the center should be sought. In our hospital, the suitability document of the facilities is completed and the promoter (or CRO) is obtained directly, and the head of the department where the test is to be performed is delegated to the firm. In those cases in which the Principal Investigator agrees with the head of the service, it is the director of the Institute who signs the aforementioned document. In these cases, the PI can send the completed document to the Secretary (fundacion.hdoc@salud.madrid.org, 917792839, Ambulatory Activities Center (CAA), Block D - 6th Floor) for the obtaining the signature.

4. **Economic Memorandum** detailing: scheduled payments to the principal investigator and to other participating (implicated) departments, extraordinary tests.

5. **Insurance policy** including the names of **Hospital**, **Principal Investigator** and Hospital 12 de Octubre **Foundation** for Biomedical Research

6. **Authorization of the CEIm including this Hospital** (*as soon as available*)

7. **Authorization of the Spanish Agency of Medicines and Devices** (AEMPS) (*as soon as available*)

The clinical trial contract will be processed and signed once the Technical Secretariat has issued the approval of the feasibility report of the trial. The Technical Office can request all the necessary documents except for the approval of the CEIm and the AEMPS. To do this, they must contact the Contracts Management Area of the Foundation.

Contact: ensayos.hdoc@salud.madrid.org If you do not have factory models, you can find them at the following link http://imas12.es/documentacion-fundacion/

IN BOTH CASES (CEIm or not):

The Sponsor will notify to CEIm technical office (*stecnicacei@h12o.es) the initial visit date and/or first patient inclusion date. At this time, the authorization of the clinical trial by CEIm and AEMPS should be available at *CEI technical office

A payment for the management of Clinical Trial must be performed.
Contact: **facturacion.hdoc@salud.madrid.org**

DURING THE TRIAL, EVERY CHANGE RELATED TO THE INVESTIGATOR TEAM MUST BE NOTIFIED BY E-MAIL TO TECHNICAL OFFICE OF THE CEI. IF THE AMEND AFFECTS THE CONTRACT, REQUIRED DOCUMENTATION MUST BE SUBMITTED. Available in: http://imas12.es/documentacion-ceic/