REQUIREMENTS TO CONDUCT CLINICAL TRIALS WITH MEDICINES (Royal Decree 1090/2015) IN THE HOSPITAL DOCE DE OCTUBRE

If our Investigation Ethic Committee (CEI) acts as CEI evaluator (CEIm), 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 10 days before the date of the meeting.

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

1. **Protocol summary** (Spanish)
2. **Suitability of the investigator** signed by sponsor. A list of sub-investigator participating in the trial at *Hospital Universitario Doce de Octubre* must be included in this document or in an annex
3. **Economic Memorandum** detailing: scheduled payments to the principal investigator and to other participating (implicated) departments, extraordinary tests. Invoice request, contact: **facturación.hdoc@salud.madrid.org**
4. **Insurance policy** including the names of Hospital, Principal Investigator and Hospital Doce de Octubre Foundation for Biomedical Research
5. **Suitability of the facilities** signed by director or delegated person. **All participating departments** should be detailed
6. **Authorization of the CEIm** (*as soon as available*)
7. **Authorization of the Spanish Agency of Medicines and Devices** (AEMPS) (*as soon as available*)

IN BOTH CASES (CEI mor not):

The Sponsor will notify to CEI 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

The agreement among Sponsor, Principal Investigator and Hospital Doce de Octubre Foundation for Biomedical Research can be processed in parallel to the evaluation by CEIm and AEMPs contacting with the "*Área de Gestión de Contratos de la Fundación*"**. Contacto: ensayos.hdoc@salud.madrid.org**

A payment for the management of Clinical Trial must be performed
Invoice can be downloaded and send to: **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.