REQUIREMENTS TO CONDUCT CLINICAL TRIALS IN THE HOSPITAL DOCE DE OCTUBRE BEING AN IMPLICATED CENTER

Royal Decree (*Real Decreto*) 1090/2015

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 will advise 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*)
8. 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**

DURING THE TRIAL, EVERY CHANGE RELATED TO THE INVESTIGATOR TEAM MUST BE NOTIFIED BY E-MAIL TO TECHNICAL OFFICE OF THE CEI.