REQUIREMENTS FOR THE CONDUCT OF CLINICAL INVESTIGATIONS WITH MEDICINAL PRODUCTS IN THE HOSPITAL DOCE OF OCTOBER

Promoters who wish to carry out an Investigation with medicinal products at the University Hospital 12 de Octubre must have the authorization of an accredited CEIm in Spain.

The two procedures described below are established according to whether or not this prior opinion is given.

1) EVALUATION OF CLINICAL INVESTIGATIONS WITH SANITARY PRODUCTS WITHOUT OPINION OF ANOTHER CEIm

The Royal Decree 1090/2015 of clinical trials with medicines which also regulates clinical research with medicinal products, in its second additional provision indicates that in the cases of carrying out a study with a medical device in several centers, the opinion will be issued by a CEIm, which will be unique and binding.

At the moment, no instructions have been developed regarding the documentation necessary to evaluate an investigation with medicinal products in cases of multicenter studies. Therefore, the required documents are the same as those described in circular 07-2004. The necessary documents for the evaluation as CEIm should be sent to the following email ceicdoc@h12o.es:

- Application letter
- The clinical research plan (protocol in English or Spanish and summary in Spanish)
- The researcher's manual.
- Documents regarding informed consent, including the information sheet for the subject of the investigation (versioned and dated)
- Documents on the suitability of the principal investigator and his CV. Good Clinical Practices should be referenced.
- Documents on the suitability of the facilities.
- Financial report (detailing payments to the principal investigator, services involved, extraordinary evidence)
- A copy of the insurance policy or proof of the financial guarantee of the clinical investigation or a certificate of the same which includes the name of the Hospital, the Principal Investigator and the Biomedical Research Foundation Hospital 12 de Octubre, when appropriate.
- The procedures and material used for the recruitment of the subjects of the investigation.
- The commitment of the researchers that are expected to participate in the research.
- Letter from the promoter committing to supply the device under study in the Center, if applicable.
- CE marking certificate, if applicable.
- In cases where the product in question does not have CE marking, it must be notified to the AEMPS and this notification must be attached.

* Regarding the suitability documents of facilities and researchers, the model published in the Instructions for carrying out clinical trials with medicines can be used, available on the AEMPS website, and must be presented for each of the participating centers.

In the case of r**elevant amendments**, in addition to the modified documents (with change control), the letter summarizing and justifying the proposed changes must be submitted.

2) NOTIFICATION OF CLINICAL INVESTIGATIONS THAT HAVE ALREADY BEEN DICTATED BY ANOTHER CEIm

In these cases the Committee DOES NOT EVALUATE, only an assessment of the local feasibility is made by the Technical Secretariat of the CEI. The following documentation will be sent by mail (stecnicacei@h12o.es):

- Protocol summary. (Spanish)
- Suitability document of the principal investigator and CV. In this document or in an annex the collaborating researchers must be indicated in the Hospital Doce de Octubre
- Document of suitability of the facilities, signed by the director of the center or delegated person being able to be the person in charge or head of service, where all the services implied in the Hospital are detailed.
- Financial report: This document will detail the breakdown of payments to the principal investigator, services involved, extraordinary evidence.
- Model of insurance certificate including the name of the Hospital, the Principal Investigator and the Biomedical Research Foundation Hospital 12 de Octubre
- Letter from the promoter committing to supply the device under study in the Center, if applicable.
- The opinion of the CEIm evaluator and the resolution of the AEMPs will be sent as soon as they are available for archiving in the study file

The promoters may initiate the procedures of the contract in parallel to the request for evaluation / notification by the CEI, for this they must contact the Contracts Management Area of the Foundation of the Hospital 12 de Octubre. Contact: ensayos.hdoc@salud.madrid.org. In those cases of economic memory 0 a cost 0 contract will be formalized.