REQUIREMENTS FOR THE CONDUCT OF CLINICAL INVESTIGATIONS WITH MEDICINAL PRODUCTS IN THE HOSPITAL 12 OF OCTOBER

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, **dated and versioned**)
- Documents regarding informed consent, including the information sheet for the subject of the investigation (**dated and versioned**)
- Documents on the suitability of the principal investigator in this centre and his CV. Good Clinical Practices should be referenced. (Identified with name and two surnames)
- The commitment of sub-investigators of our center that are expected to participate in the research (identified with name and two surnames).
- Documents on the suitability of the facilities.

  In reference to the suitability of the facilities we understand that each center decides who delegates the signature; this situation may vary by centers 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 (Dr. Arenas) who signs the aforementioned document. In these cases, the PI can send the completed document to the Secretary of Dr. Arenas (Ms. Yolanda Bastante fundacion.hdoc@salud.madrid.org, 917792839, Ambulatory Activities Center (CAA), Block D - 6th Floor) for the obtaining the signature.
- 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.
- 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 (ceicdoc@h12o.es):

- Protocol summary. (Preferably in 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 12 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

In cases in which the study requires the signing of a contract, it will be processed and signed once the technical secretariat has issued the approval or feasibility report of the trial. The contract can only be signed once the Technical Secretariat has at its disposal all the required documents, except for the approval of the CEIm and the resolution of the AEMPs. To do so, they must contact the Contracts Management Area of the Foundation. Contact: ensayos.hdoc@salud.madrid.org If you do not have the necessary contract models, you can find them at the following link http://imas12.es/documentacion-fundacion/

Payment will be made for Clinical Trial processing. Contact: facturacion.hdoc@salud.madrid.org

ANY CHANGE OF THE INVESTIGATING TEAM DURING THE RUNNING OF THE TEST MUST BE NOTIFIED BY MAIL TO THE CEIm TECHNICAL SECRETARIAT. IF THIS CHANGE REQUIRES MODIFICATION OF THE CONTRACT, THE REQUIRED DOCUMENTS MUST BE PROVIDED IN A RELEVANT MODIFICATION AVAILABLE AT: http://imas12.es/documentacion-ceic/