REQUIREMENTS TO CONDUCT CLINICAL RESEARCH PROJECTS IN THE UNIVERSITY HOSPITAL 12 DE OCTUBRE

Two procedures are possible depending on the study is approved or not by other CEIm.

1) NEW PROJECTS EVALUATION (WITHOUT CEIm APPROVAL)

The submission should be by mail (ceic@h12o.es), the following documentation is required

A. Full protocol and Protocol summary (Spanish or English, **dated and versioned**)

B. Informed Consent Form (in Spanish), **dated and versioned.** ***If it is not presented, justify the cause***

C. Principal Investigator´s in our center commitment signed and curriculum vitae (Identified with name and two surnames)

D. Sub-investigator´s in our center commitment signed and curriculum vitae (if applicable). Identified with name and two surnames)

E. Chief (or Responsible) Department acceptance

F. Economic Budget detailing: scheduled payments to the principal investigator and to participants (if it is applicable)

This document must include the amounts and the manner in which the researchers and subjects may be, if applicable, remunerated or compensated for their participation in the study, as well as the relevant elements of any contract envisaged between the promoter and the center.

G. Insurance policy including the names of Hospital, Principal Investigator and Hospital 12 de Octubre Foundation for Biomedical Research (if needed)

*If a **major amendment is submitted to assess**, besides on modified documents (with **tracked changes**), a cover letter summarising and justifying the changes should be submitted

In the cases of:

1) Projects submitted to calls for public or private funding through Hospital 12 de Octubre,

2) Academic work

Prior to submission to the CEIm, the Hospital Research Commission's Evaluation Report is required, which should be requested through: National and International Projects Processing / Project Management Area. Research Management (email: fvalero.imas12@h12o.es). Once assessed by this Committee, if CEIm evaluation is required, they will be forwarded by this Management Area to the CEIm

2) NOTIFICATION OF PROJECTS AUTHORIZED BY OTHER ETHIC COMMITTE

In these cases, the CEIm recognizes the approval and the study will not be again evaluated. The CEIm technical office assesses the local viability and a report will be done. The documentation indicated in point 1 will be sent by mail (stecnicacei@h12o.es), except for the Informed Consent Form; and a copy of the **Favorable Report issued by the CEIm that evaluated the study** should be submitted. The protocol can be replaced by the Summary of the same. In addition, it should be indicated in a separate document, which is the implication of the researchers of our center (obtaining biological samples with prospective character or that are stored in the biobank of the center, analysis of samples...)

***Information to take into account**: **if the CEIm requests clarifications or additional documentation, the promoter has 3 months to respond. After that time, the application is considered dismissed and must be resubmitted.**

These requirements among others can be found on our website: www.imas12.Es/documentacion-ceic/