DO I NEED PRIOR APPROVAL OF THE ECRmp AT THE BEGINNING OF THE PROJECT?

YES, provided that:

- The research project involves human subjects, personal data or identified biological samples.
- The future possibility of publishing its results is considered.
- The need to obtain the subjects' informed consent is expected.

The ECRmp shall entail a guarantee for the researchers' project, not a bureaucratic overload

WHAT SETS US APART FROM THE HEALTHCARE ETHICS COMMITTEE (HEC) ?

The Healthcare Ethics Committee is a body whose aim is to **DELIBERATE** on ethical conflicts in the health field, which may arise as a result of the healthcare provided, and which serves **HEALTHCARE PROFESSIONALS AND USERS**.

Find out more on our website:

LEGISLATION GOVERNING RESEARCH

The ECRmp must ensure that the studies/projects (including clinical trials with medicines) meet the legal standards. From a legal point of view, they must consider whether the standard is **mandatory** or if its provisions represent **voluntary good practices** (ethical recommendations).

ETHICAL RECOMMENDATIONS

Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences [CIOMS]), Standards of Good Clinical Practices...

LEGAL STANDARD

- General legislation governing research: General Data Protection Regulation (GDPR).
- Projects with biological data and samples: Spanish Law 14/2007 governing Biomedical Research.
- Research with medicines: Spanish Royal Decree 1090/2015 (for clinical trials) and Order SAS/3470/2009 (for observational designs).
- Research involving medical devices: RD 1591/2009 and RD 1090/2015.

Ethic Committee for Research with medicinal products (ECRmp)

Hospital Universitario 12 de Octubre

Aimed at healthcare professionals that wish to make use of the services of the ECR

Hospital Universitario 12 de Octubre

Instituto de Investigación Hospital 12 de Octubre

Fundación Investigación Biomédica Hospital Universitario 12 Octubre

Version: may 2018

WHAT IS A ETHIC COMMITTEE FOR RESEARCH WITH MEDICINAL PRODUCTS—ECRmp?

INDEPENDENT and multidisciplinary body whose main purpose is to ensure the protection of the rights, safety and wellbeing of the subjects participating in a biomedical research study/project, and offer public guarantee in this respect by issuing an opinion on the document related to the research study/project.

The ERCs evaluate the research **BEFORE** its start, and approve and monitor it during its execution.

WHAT MUST THE ECRs EVALUATE ?

- Standard practice versus experimental intent.
- Risks/benefits.
- Clinical repercussion of the use of a placebo.
- Health data protection guarantee.
- Expertise of the Principal Investigator.
- Suitability of the facilities.
- Patient information sheet and informed consent form (PIS/ICF) specific to the research project. Adequate and understandable.

THE ECRmp HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

WHO COMPRISE IT?

⇒ Healthcare professionals.

⇒ A law graduate.

⇒ Workers from outside the healthcare field.

⇒ Patient representatives.

HOW TO REACH US?

Technical Secretariat

6th floor - Block D. Centro de Actividades Ambulatorias (Hospital Universitario 12 de Octubre).

Call center: 4614 / 4615 / 4616

E-mail: stecnicacei@h12o.es

BASIC DOCUMENTS THAT MUST BE SUBMITTED TO THE ECR FOR THE-EVALUATION OF A STUDY

1. Research Protocol.
2. Signed Commitment from the Principal Investigator (PI) and his/her CV.
3. List of members of the research team.
4. Patient information sheet and informed consent form.

* ***Consult the need for additional documentation.***

All request must be sent via e-mail to:

ceicdoc@h12o.es

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

Summary of the essential elements that must be included:

- Project title
- Which is the study's purpose?
- Why have I been chosen to participate?
- What will happen to me if I consent (or if I don't) to participate?
- What will I have to do?
- May I withdraw my consent during the study? What will happen if I withdraw my consent?
- Which treatment/procedure will be tested? Which are the diagnostic/treatment alternatives available?
- What are the side effects of taking part?
- What are the possible benefits of taking part?
- What happens if something goes wrong?
- Will my participation in this study be kept confidential?
- Who organizes and finances the research?
- Who approved this study?
- Contact information, including the names and telephone numbers, for added information
- **If biological samples are taken, describe how the samples were used upon completion of the project**