L-Università ta' Malta
Faculty of Medicine & Surgery

GOOD CLINICAL PRACTICE (GCP)

Faculty Research Ethics Committee (FREC)
Faculty of Medicine and Surgery

February 2019

In order to expedite the application process, researchers are recommended to:

- Read the Guidelines for the Research Ethics Review,
- Read FREC Functions and Operations,
- Read distinction between Audit and Research,
- Read the FAQs
- Read this document (GCP) and
- Read the UREC Ethics Review Procedures.

Good Clinical Principles (EU Directive 2001/20/EC on Good Clinical Practice)

1. Clinical trials should be conducted in accordance with ethical principles enlisted in the Declaration of Helsinki.
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual and society.
3. Rights, safety and well-being of trial subjects must prevail over the interests of science.
4. Available non-clinical and clinical information on an investigational product should be adequate to support the proposed research.
5. Research should be scientifically sound and described in a clear and detailed protocol.
6. Research should be conducted in accordance with any protocols that have received institutional REC approval.
7. Medical care and decisions should always be made on behalf of subjects by a qualified physician.
8. Researchers should be qualified by education, training and experience.
9. Freely given informed consent should be obtained before the research.
10. All research information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.
11. Confidentiality and privacy should be respected in accordance with Data Protection directives.
12. Systems and procedures that ensure the quality of every aspect of research should be implemented.