



L-Università ta' Malta
Faculty of Medicine & Surgery

FREC FUNCTIONS AND OPERATIONS

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

February 2019

FREC Functions

1. Primary function is to safeguard the rights, safety and well-being of research subjects.
2. Assets investigator qualifications
3. Protocol and any changes or amendments
4. Written informed consent forms and any changes which are required during the research
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6. Written information to be given to the subjects
7. Investigator's brochures
8. Available safety information
9. Patient compensation
10. Other materials that affect patient safety and willingness to participate.

FREC Operations

1. Operations are based on written procedures and rules applicable to the University of Malta and nationally.
2. Provide initial and continuing review if necessary.
3. Review of minor changes to the protocol
4. Written documentation and minutes and records
5. Compliance with GCP (Good Clinical Practice) and other regulatory requirements.
6. Decisions taken with quorum present.