

GBS HE Malta

Research Ethics Policy

Contents

1. *Purpose and Scope*
2. *Ethical Principles in Research with Human Participants*
3. *Ethical Review Process*
4. *Data Protection and Privacy*
5. *Ongoing Monitoring and Reporting*
6. *Training and Support*
7. *Breach of Policy*
8. *Policy Review*
9. *Related GBS HE Malta Documents*

1. Purpose and Scope

1.1 This policy sets out the ethical standards and procedures that govern all research involving human participants conducted under the auspices of GBS HE Malta. It ensures that such research respects the dignity, rights, safety, and well-being of participants and complies with applicable laws, regulations, and ethical guidelines.

1.2 This policy applies to:

- All staff, students, and affiliates undertaking research involving human participants or their data.
- Research conducted on or off campus, domestically or internationally.
- Collaborative research involving external institutions or funding bodies.

2. Ethical Principles in Research with Human Participants

2.1 The following seven ethical principles govern research involving human participants of human data. These are informed by the Declaration of Helsinki (<https://www.wma.net/policies-post/wma-declaration-of-helsinki/>), The Belmont Report (<https://pubmed.ncbi.nlm.nih.gov/25951677/>) and national research ethical guidelines. The principles are as follows:

- (a) *Respect for Persons (Autonomy)*. Recognise the dignity, rights and autonomy of all individuals. Participants must give *informed, voluntary consent* to take part in the research. Special protections are required for those with diminished responsibility, for example, children, cognitively impaired individuals.
- (b) *Informed Consent*. Participants should be fully informed about the purpose, methods, risks, benefits and their right to withdraw at any time. Consent should be given freely, without coercion or undue influence. Information must be presented in *clear, understandable language*.

- (c) *Beneficence and Non-Maleficence*. Researchers must aim to maximise benefits and minimise harm to participants. Physical, psychological, social, legal and economic risks must be identified and mitigated. Studies should be scientifically sound to justify exposing participants to risk.
- (d) *Justice*. The selection of participants must be fair and equitable. Vulnerable populations should not be exploited, and benefits of research should be distributed fairly. No group should bear an unfair share of risks.
- (e) *Privacy and Confidentiality*. Participant data must be handled securely and used only for the purposes of the stated consent. Anonymisation should be used wherever possible. Data protection laws, for example, GDPR, must be followed.
- (f) *Scientific Integrity*. Research must be methodologically sound, with transparent and honest reporting of results. Plagiarism, fabrication and falsification are unethical and prohibited. Ethics approval must be obtained before the research begins.
- (g) *Ongoing Responsibility*. Ethical obligations continue beyond the conclusion of data collection. Researchers should monitor for unanticipated risks and report adverse events. Participants should be debriefed where possible and appropriate.

3. Ethical Review Process

3.1 All research must be reviewed and approved by the GBS HE Malta Research Ethics Committee. Applications using provided templates must include:

- Research protocol
- Consent documents
- Risk assessment
- Data protection plan

3.2 Ethics approvals are valid for a specified period and must be renewed for continuing research.

4. Data Protection and Privacy

4.1 The following data protection and privacy applies to research conducted by staff and students of GBS HE Malta:

- Research must comply with relevant data protection laws, for example GDPR.
- Secure storage, access control, and responsible data sharing must be enforced.
- Participants have the right to access, rectify, or withdraw their data, where feasible.

4.2 Where the research takes recordings of interviews with participants the researcher must keep these confidential to themselves. The supervisor of the research project may also have access to these recordings. The researcher should retain these recordings in a secure place and not delete them until after the GBS Malta Assessment Board has met and approved the grade awarded for the project write up.

4.3 Where possible and practicable GBS Malta should archive these recordings in a secure place and retain them for at least one calendar year. Thereafter they should be deleted.

5. Ongoing Monitoring and Reporting

5.1 Researchers must report:

- Adverse events or unexpected risks
- Changes to approved protocols
- Final outcomes of the study

5.2 The GBS HE Malta Research Ethics Committee may audit projects to ensure compliance.

6. Training and Support

6.1 Staff and students preparing to undertake a research project involving human participation and/or access to employees at organisations must be provided with research ethics training prior to beginning their study and preferably at the stage in which research proposals are being prepared.

7. Breach of Policy

7.1 Failure to comply with this policy may result in:

- Withdrawal of ethical approval
- Disciplinary action under university policies
- Notification to funding agencies or regulatory bodies, where appropriate.

8. Policy Review

8.1 This policy will be reviewed on an annual basis in its first three years of implantation, then every two years thereafter.

9. Related GBS HE Malta Documents

9.1 The following policies and other documents should be considered in relation to the GBS HE Malta Research Ethics Policy:

- GBS HE Malta Research Ethics Committee Terms of Reference and Constitution
- Interview Participant Consent Form
- Interview Organisation Consent Form
- Ethics Review Checklist for Undergraduate and Taught Postgraduate Research
- GBS HE Malta Data Protection Policy and associated documents
- GBS HE Malta Equal Opportunities Policy
- GBS HE Malta Health and Safety and Risk Assessment Policy