Research Ethics

Policy, procedure and guidance

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1. INTRODUCTION

Research is generally understood as a scientific enterprise invested with mutual respect and trust between researchers[1] and society. According to the OECD,[2] research and experimental development comprise creative work and systematic work undertaken in order to increase the stock of knowledge of – including knowledge of humankind, culture and society – and to devise new applications of available knowledge.

In the context of UK higher education,[3] research is work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

Research is classified by the OECD[4] as follows.

- Basic Research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- Applied Research is original investigation undertaken in order to acquire new knowledge and is primarily directed towards a specific practical aim or objective.
- Experimental Development is systematic work that draws on existing knowledge gained from research and/or practical experience and is directed towards producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already in place.

All research should be conducted with integrity; research ethics is one aspect of research integrity.

The European Code of Conduct for Research Integrity defines the fundamental principles of research integrity. These principles are:[5]

- *Reliability* in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
- *Honesty* in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.

[1] Researchers = all students and staff of the University of Gibraltar who are undertaking research, and encompasses anyone involved in conducting research with the University of Gibraltar, whether on or off the premises or in collaboration with University staff or students

[2] http://www.oecd.org/publications/frascati-manual-2015-9789264239012-en.htm

[3] http://www.ref.ac.uk

[4] http://www.oecd-ilibrary.org/science-and-technology/frascati-manual 2002_9789264199040-en

[5] https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf

- *Respect* for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
- *Accountability* for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

2. POLICY

The University of Gibraltar (the University), requires that the ethics of all research be considered and respected by its researchers.

Compliance with this requirement is the responsibility of University's Academic Board; it delegates this responsibility to its Research and Research Degrees Committee (RRDC).

The RRDC is required to establish ethical standards of practice in University research in order to:

- ensure that research is conducted in accordance with established legal frameworks and international conventions on research ethics;
- protect participants, sites and researchers from harm;
- protect the rights of participants;
- take account of the legitimate interests of other individuals, bodies and communities associated with the research and provide reassurance to the public and outside bodies that this is being done;
- promote, not hinder, valuable research;
- ensure research is conducted with integrity.

The RRDC will fulfil these obligations by undertaking a Research Ethics Review (RER) following the request for review of the Principal Investigator of a research project prior to commencement of the project.

RER will address the range of ethical issues that need to be taken into consideration during the planning for, conduct of, supervision of and utilisation of research. It includes the need to work within professional codes of conduct and legal statutes.

RER will not hinder scientific progress, knowledge production or the academic freedom of researchers. Rather the over-arching ethical principle that guides all research at the University is that ethics consideration should be to ensure the maximum benefit of the research whilst minimising the risk of actual or potential harm.[6]

RER will apply to all research involving animals, people and data pertaining to people carried out by University staff, students, associate researchers and/or other affiliated persons (e.g., honorary fellows, professors and or visiting academics) on the University premises and/or in the name of the University; and to all types and stages of research.

[6] http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015

RER is intended to be a constructive and collaborative enterprise that promotes valuable research in the interest of the common good.

The RRDC will maintain a database of RERs and prepare and submit an annual report thereon to the Academic Board.

3. SCOPE of RESEARCH ETHICS REVIEW (RER)

The scope of the University's RER follows that of European Commission.[7]

The primary responsibility for the conduct of ethical research lies with the Principal Investigator (PI) of the research, activity. Every research project needs to have a PI. PIs are required to have a PhD or other relevant degree for the independent conduction of research. In some cases, it is acceptable for a project to have a PI without a PhD, provided that the project has a co-PI with PhD.

In all research matters, researchers are expected to manage themselves and their enquiries in accordance with the relevant professional and disciplinary codes of conduct and ethics. Further, there is an expectation that researchers adopt and maintain a personal commitment to act ethically, to encourage ethical behaviour in those with whom they collaborate and consult appropriately where ethical concerns or issues arise. In projects where there are multiple researchers, while primary responsible rests with the PI each researcher shall have overall responsibility for the ethical conduct of the project and staff compliance with codes of conduct and ethical expectations.

3.1. Basic principles

- Beneficence. The research makes a meaningful contribution to knowledge and the benefits of the research outweigh any risks; consequently, it must be conducted through a defensible methodology to insure the best results or findings are secured.
- Non-Maleficence. Any possible harm must be avoided or at least mitigated by robust precautions; any risks must be clearly communicated to the people or community involved.
- Integrity. The researcher is open and transparent about any actual or potential conflicts of interest and adheres to the expectations of research integrity in conducting the research.
- Respect the principle of proportionality. Do not impose more than is necessary on research subjects or go beyond stated research objectives (mission creep).
- Justice. Treat societal concerns seriously, listen to the public and engage fairly with them in constructive dialogue, transparently, honestly and with integrity.
- Try to prevent being openly available for misuse or malignant dual use by terrorists or military organisations.
- Common good. Build on the understanding that any benefits are for the common good of society; widely shared expressions of concern about threats from research must be

[7] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

considered (with the acknowledgement that perhaps certain research practices might have to be abandoned).

3.2. Principles specific to people and data pertaining to people (medical and social science)

- Autonomy. Participants are made aware that they participate voluntarily without coercion or fear of penalty; and that they are free to withdraw at any time without reason and without threat of adverse consequences. This is elaborated in *Appendix 1,* which also includes a template Participant Information Sheet to be used to ensure participant autonomy.
- Informed Consent. People asked to participate in research are made as aware as they possibly can be of the purpose, methods, the nature of their participation, any risks and benefits that participation might entail, and the intended uses of the research; on the basis of the information, people proceeding to participate give their informed consent. This is elaborated in *Appendix 2*, which also includes a template form to be used for securing consent.
- Any research that falls within the remit of the Gibraltar health care system or the health care system of the country where the research is being undertaken falls under medical ethics and is therefore subject to the review and approval mechanisms of those health care systems. See *Appendix 4*.
- Participation of children (under the age of 16) relies upon the informed consent of parents or guardians. Additionally, children who are able to give assent are required to do so; and withholding/declining assent takes priority over consent. See *Appendix 5*.
- Confidentiality and anonymity. Personal data must remain unknown to all but the research team unless the participating people agree otherwise, or wish to be identified, or where there is legal or professional obligation to breach confidentiality in order to prevent harm. If agreeing to public disclosure, people do so formally through a recorded form of informed consent. The move to Open Access Research and Data does not override the principle of confidentiality.[8] See *Appendix 6.*
- Data protection. All personal data of participants is subject to the provisions of the General Data Protection Regulation (GDPR) and underlying legislation. See *Appendix 7*.
- Respect and justice. Respect human rights, such as those to privacy, data protection and use of data for other-than-disclosed perceived benefits, property and cultural artefacts. Collect scientific data as least intrusively as possible in order to: maintain the material and locational integrity of artefacts, property and people; minimise the environmental impact of research activity (e.g., the safe disposal of chemicals); have open and responsible communication with the local population; store and preserve data samples and/or artefacts with due respect to individuals, families and communities and with due regard to the future interests of the scientific field.

[8] Some funders now require, in the interests of scientific advancement, transparency and public accountability, that research papers and underlying data are made freely and widely accessible. However, there are no mandatory requirements to release research data (see Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf) particularly where there are sensitivities concerning human participants (see RCUK Policy on Open Access and Supporting Guidance: http://www.rcuk.ac.uk/documents/documents/rcukopenaccesspolicy-pdf/)

3.3. Principles specific to animals and their environment

- Respect and Conservation. The natural environment is treated with appropriate respect; the collection of scientific data is least intrusive as possible in order to protect individual organisms, species, ecosystems and landscapes; the environmental impact of research activity is minimised (e.g., the safe disposal of chemicals); there is open and responsible communication with the local population; samples are stored and preserved with due respect and with due regard to the future interests of the scientific field.
- Treat animals with respect and under humane conditions before, during and after the research.
- Design animal research in accordance with the principles of Replacement, Reduction, and Refinement. See *Appendix 7*
- Recognise the wholeness of an individual and ensure that any modification (genetic or technological) does not interfere with this principle.
- Respect biodiversity and not impose irreversible change that threatens the environment or ecological balance

3.4. Principles specific to the research ethics reviews

- Research activities all require ethical review, unless the research is ONLY desk-based or library-based research which:
  - includes the further analysis and synthesis of existing data and information already in the public domain and/or other publications;
  - does not require access to or use of medical data;
  - does not require direct or indirect contact with people or animals; and
  - has no direct impact on the environment.

3.5. 3rd party Research Ethics Review

In the below listed specific cases Research Ethics needs to be requested in lieu of the University of Gibraltar RER:

- For medical research and research on a clinical population and conducted within the Gibraltar health care system, an ethics review from the Gibraltar Medical Ethics Committee needs to be requested in lieu of the University of Gibraltar RER
- For medical research and research on a clinical population and conducted within health care system of another country, research ethics process must follow the laws and regulations of the country where the research is conducted. If a medical research ethics review is provided by the relevant medical research ethics committee of the given country RER does not need to be requested from the University of Gibraltar.
- In case of an international collaborative research project, involving data-collection in multiple countries, where the PI (or co-PI) is affiliated with another university and a research ethics certificate has been issued by the academic research ethics board of co-PI covering data collection in all involved countries, no additional research ethics process is required for conducting the research in Gibraltar.

It is always the responsibility of the PI to ensure that no research project is started without an appropriate research ethics approval. In any case where the PI is not in a clear position to decide whether a research ethics review from the University of Gibraltar is required, they will follow the guidance of the DARP.

4. PROCEDURE

When a proposed research project requires ethical review from the University of Gibraltar, the principal investigator must request a Research Ethic Review of their proposed research using the appropriate form (see Appendix 10). The request for ethical review must take place before researchers engage with potential participants or other forms of fieldwork and data assembly begins. This does not preclude researchers from getting underway with aspects of their study that are not bound by ethical considerations, such as their literature review. The completed form should be signed by the principal investigator. The completed form should be submitted to the Director of Academic Programmes and Research (DAPR), who will invite one or in the cases of more complex research projects, two appropriately competent experts to review the proposal. When two reviewers are included and there is divided opinion among the reviewers the Director of Academic Programmes and Research (DAPR) will adjudicate.

In requesting ethics review, the researcher undertakes:

- not to begin the proposed research until it has been granted ethics approval; and
- to adhere to the project design and principles as approved.
- and only make substantial amendments to the investigation that affect the application of principles identified in s/s 3.2 or 3.3 (as appropriate) with the further approval of the REP.

The DAPR requests the reviewer(s) to review the proposals within 20 working days of receipt of the request. The DAPR will revise the review and inform the researcher of the outcome. If, however, further external expertise and/or adjudication are required, the decision may take longer and the researcher will be advised accordingly.

4.1. Types of Research Ethics Review (RER)

There are three categories of research ethics review and the researcher should determine in which category (possibly categories) ethics review is required. Guidance and ethics review request forms are provided in the sections indicated.

- Research in a clinical population (*Section 5.2*)
- Social Science Research (*Section 5.3*)
- Animal Research (*Section 5.4*)

On the basis of ethics review, the DARP may:

- approve the proposed research on the ground that its ethics are satisfactory;
- withhold approval pending amendments and enhancements to address shortcomings;
- withhold approval because the ethical demands exceed the remit of the DARP.

Where approval is withheld, the researcher has the option to address the concerns and resubmit.

Approval concludes RER and the research can begin. However, if the ethical dimensions of research change, the researcher will need to submit a request for ongoing approval to the DAPR before continuing with the research. Should the DAPR deem that the changes are significant and that the research is no longer compliant, the DAPR will request a modification of the ethical review.

5. GUIDANCE and PROFORMA for RESEARCH ETHICS REVIEW

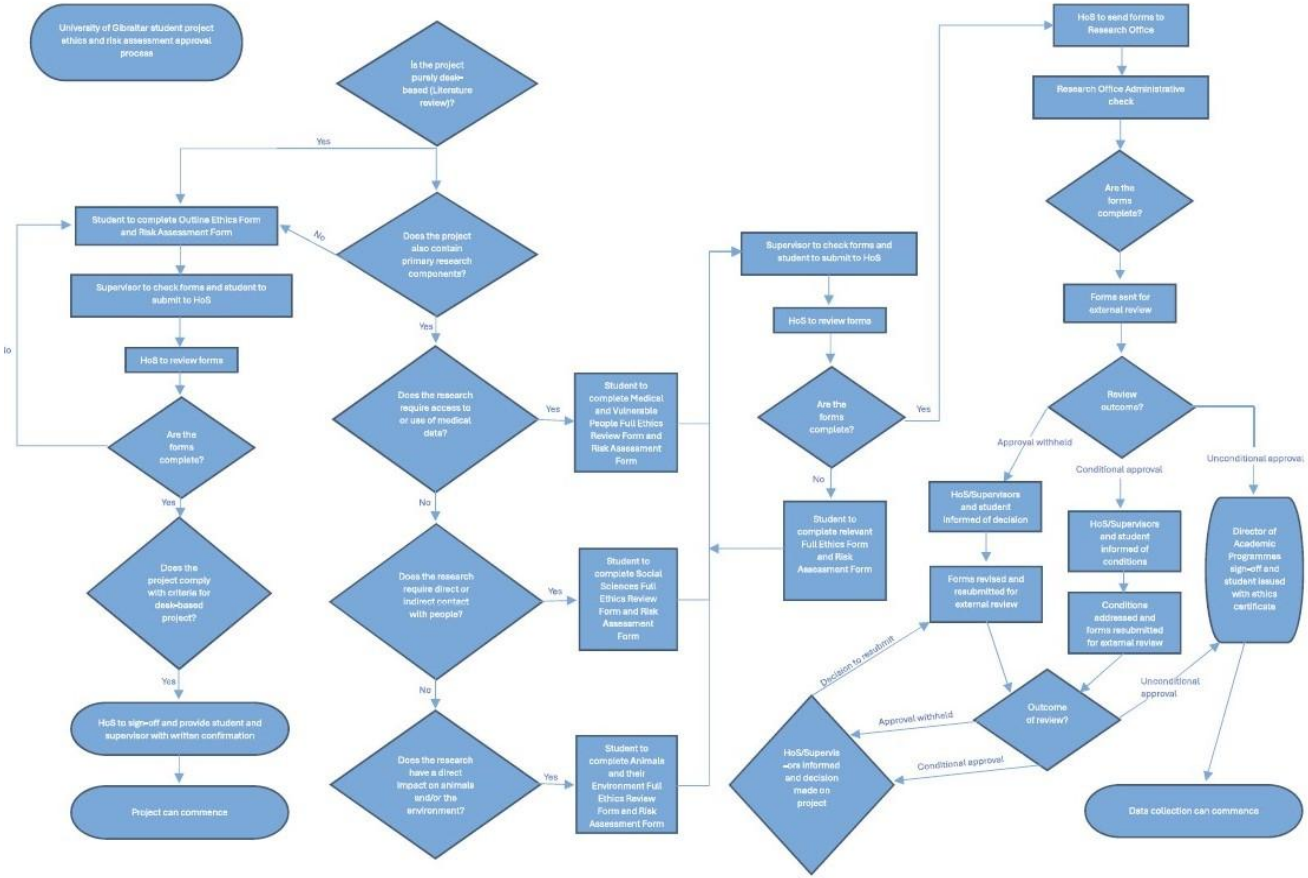

Figure 1: Research Ethics Review Procedure Flowchart

5.1. Research Ethics Review of **Research in a clinical population / setting**

The DARP routinely refers requests in this category to the Gibraltar Medical Ethics Committee (GMEC) of the Gibraltar Health Authority (GHA), whose finding the DARP accepts.

This category covers not only research that is strictly medical (in the sense of clinical or involving patients) but also research conducted within the Gibraltar health care system:

- Recruitment of patients through the GHA/ERS patient data or samples.
- Collection of tissue samples (including blood, saliva, urine, etc.) or other biological samples from participants, or the use of existing samples.
- Clinical investigation of a non-CE Marked medical device, or a medical device that has been modified or is being used outside its CE Mark intended purpose, conducted by or with the support of the manufacturer or another commercial company to provide data for CE marking purposes.
- Clinical trial of an investigational medicinal product or a medical device.
- Administering drugs, placebos or other substances (e.g., vitamins) to the study participants or involving invasive, intrusive or potentially harmful procedures of any kind

If the proposed research does NOT involve any of the above, it probably does NOT fall in the category of research in a clinical population / setting.

If the proposed research DOES involve any of the above, it probably DOES fall in the category of research in a clinical population / setting and the request for ethics review should be channelled through the GMEC using the form RER for research in a clinical population / setting (see Appendix 9). The form is in two parts: Part 1 is a preliminary checklist covering the bullet points above; Part 2 may be required depending on the answers to questions in Part 1.

5.2. Research Ethics Review Social Science Research

Social science research, which, for the purpose of ethics review, is research that: (a) requires direct or indirect contact with adults able to give informed consent, data pertaining to people, and studies of societal artefacts; and (b) is not medical-related. Such research typically involves any of the following participants:

- Adults at least 16 years of age able to give informed consent.
- Children under the age of 16 where informed consent is given by parents or caregivers, and assesnt is required by the child

Whenever participants are accessed via a gatekeeper (education, social care system, residential or nursing care home, prison, club etc.) a conformation of support from the relevant gatekeeper or its supervising agency needs to be attached with the research ethics application in related to the planned research.

In case of doubt, refer to Section 5.1 to check whether the proposed research falls research in a clinical population / setting .

Requests for ethics review in the category social science research are made by completing and submitting the appropriate Ethics Review Form (see Appendix 9) form to the DAPR.

5.3. Research Ethics Review Animal Research

Research on animals in Gibraltar and Gibraltar waters is regulated by HM Government of Gibraltar Animal Experiments (Scientific Procedures) Act 1999[9]. Within the terms of this Act, research that involves observations and measurements of animals and their environment which are likely to cause no or no more than minor, limited and temporary distress to the animals and/or no or no more than minor, limited and temporary disturbance of their environment are permitted. The role of the REC is to ensure that proposed research falls within these ethical boundaries.

Proposed research that falls outside these boundaries is likely to fall under the regulatory legislation and third party approval takes the form of government or government agency licencing and/or certification. It is the responsibility of the researcher to secure the licence and/or certificate. The application and licence and/or certificate should be submitted to the REC as an attachment to the appropriate form (see Appendix 9).

Where research on animals is to be conducted outside Gibraltar or Gibraltar waters, but in the name of the University, there is likely corresponding/similar overseas legislation. The researcher should refer to this, if necessary, secure appropriate licences and/or certification, and submit a copy of the legislation and, if needed, the licence and/or certification, and submit these to the REC as an attachment to the form.

6. MONITORING and REVIEW of POLICY and PROCEDURE

The DAPR presents, to the first RRDC meeting after the end of each academic year, an annual report summarising RERs and continuing compliance during the preceding academic year

This report also comments upon the implementation of this policy and procedure and may recommend improvements. Where the RRDC supports improvements, it may make minor amendments to this policy and procedure.

The RRDC will review this policy and procedure biennially and commend it, amended as necessary, to the Academic Board.

[9] Its scope covers procedures and experiments likely to cause pain, suffering, distress or lasting harm to any living vertebrate other than man.

APPENDIX 1 AUTONOMY

In order to exercise their autonomy, potential participants need as much information as possible about the study and it is the responsibility of the researcher to provide them with this information. The information provided should be as full as is reasonable, comprehensible and accessible and usually in written form. For various groups of research participants (e.g., children, people with learning disabilities or memory impairment) it might be appropriate to provide a short audio and/or video recording detailing the project. The information should include:

- the title of the research
- who is undertaking it;
- a brief summary of the research and its purpose;
- why the individual has been asked to participate and an explanation of how they will be involved in the study;
- duration of the study;
- the potential benefits and risks of the research;
- advice on the permissions for the research;
- funding details and dissemination of results;
- the participant's right to withdraw;
- the parameters of confidentiality and anonymity.

Unless otherwise agreed, all researchers are required to follow the template and its guidance. Where particular items are irrelevant to the study, they can be deleted/omitted.

The Information Sheet must clearly identify the project as run by The University of Gibraltar, using the University logo at the head of the page(s) if possible.

You need to consider the best way of informing research participants about your research study and also take into account inclusivity for participants who may require the information in alternative formats (e.g.: audio, visual, braille). You should also think about any cultural differences that might need to be accounted for in the presentation of your research.

You are advised to show your participant information sheet to someone outside of your field to see if they are able to understand it. It is important to remember to use only clear and accessible language and only the most necessary technical terms. Try to avoid the use of abbreviations, but if you do use them make sure you write the term in full in the first instance.

You also need to adapt your participant information sheet for different participants, for example children of varying age groups.

You may want to insert a passport-style photograph of yourself (next to your name and contact details), this can be helpful to potential participants.

Participants should be given a copy of the participant information sheet and consent form to keep. Consent must be viewed as a process, during which you discuss the research with the participant. Participants should usually be given as long as they need to decide whether to take part in the research, within the time frame of recruitment for your study. If there is any doubt that a participant can give fully informed, voluntary consent, you must not proceed with the research.

If you are going to use the data collected in this project for future projects that are similar but different to the specific study you should seek extended consent from the participants to ensure you have their permission to use their data for purposes other than the project described in the information sheet. Inclusion of a data set in an Open Access repository or any other mechanism allowing secondary use of that data may only occur where participant consent has been granted.

Where it is necessary to seek renewed consent, participants should be given a revised version of the information sheet and should sign a Renewed Consent Form.

Consent for the involvement of children and young people (i.e. those under 16 years of age) is initially attained through parents and/or guardians, however assent of the child or young person is also required; even where parental/guardian consent is forthcoming, a child or young person is entitled to withhold their consent or assent and not participate in a research project.

All information sheets should include a version control number.

All consent and withdrawal forms should be clearly dated.

Participants should have access to a copy of the Information Sheet.

PARTICIPANT INFORMATION SHEET

(Amend this form as needed for your research project)

Section A: The Research Project

1. **Title of Project**

2. **Brief Summary of Research.**
   Give the participant a *brief summary* of your research in order to help them decide whether they are interested in taking part in the study (you will provide more details about the research later on).

3. **Purpose of the study**
   Tell the participant *why* you are doing the research.
   Tell the participant whether the research is part of your PhD at the University of Gibraltar/a funded, national or international study at The University of Gibraltar.
   Where appropriate you need to state if the study is managed through an Institute or Associate Campus (e.g., the Museum, the Garrison Library) of the University.

4. **Name of the Principal Investigator**

5. **Why have I been asked to participate?**
   Tell the participant why you have approached them: are they a member of a particular group or organisation, or do they have a certain condition or illness, are they representative of something or possibly a unique case?

6. **How many people will be asked to participate?**
   Tell the participant how many other people will be included in the study.

7. **What are the likely benefits of taking part?**
   It is unlikely that there will be any direct or immediate benefits to participants and this must be made clear.
   The study may yield some useful information, but be careful not to make claims that the research is very important or may lead to changes in the field, unless this is the case.

8. **Can I refuse to take part?**
   Make clear to participants that they can refuse to take part without giving a reason.
   Under no circumstances should participants feel coerced into taking part.

9. **Does the study have ethical approval?**
   Tell the participant that the study has ethical approval from the ethics committee at The University of Gibraltar.
   If you also have permission from an organisational ethics committee, this also needs to be noted.

10. **Has the organisation where you are carrying out the research given permission?**
    Where you are carrying out research in an organisation, you must make it clear that they have given permission for the research.

You need to make it clear, however, that this constituted general permission to approach participants and it is the decision of each person whether they would like to take part in your research. They are not obliged to participate.

11. **Legal Requirements**
If your research falls under specific legislation, you need to state that your research complies with it (e.g., legislation governing the collection of biological samples from human beings).

12. **Source of funding for the research, if applicable.**
If the research is funded you must name the organisation/funding body.

13. **What will happen to the results of the study?**
Tell the participant where your research will be disseminated (e.g., written up for your degree/thesis/published in journals/presented at conferences).
Tell the participants whether it is likely that their data will be used in other similar but different projects.

14. **Confidentiality**
Unless otherwise agreed by the ethics committee, participants need to know that the personal information they share will remain confidential and will not be disclosed in any identifiable manner to others.

15. **Complaints**
Tell participants where they can lodge a complaint about the conduct of the research.

16. **Contact for further information**
Do not disclose your own personal contact information to participants.
Only a University of Gibraltar or professional-organisational email address must be given and only mobile numbers (not personal landline numbers) should be given out for contact purposes.

PARTICIPANT INFORMATION SHEET

Section B: Your Participation in the Research Project

1. **What will I be asked to do?**
   Tell participants what they will be asked to do, e.g., be interviewed/observed/take part in a focus group/complete tests or procedures/keep diaries/complete questionnaires.

   Describe this participation in detail, e.g.: how many times a participant will be interviewed/observed/attend a focus group/tested, for how long on each occasion and over what period of time (e.g.: a day, a week, three monthly, twice in a year, etc.).

2. **Will my participation in the study be kept confidential?**
   Tell the participant who will have access to their data and that it will be in an anonymised format (unless otherwise agreed by the ethics committee).

   Tell the participant that personal or sensitive data will be anonymised in dissemination.

   Tell the participant if you are going to use any recording equipment, explain how recordings will be kept secure and who will have access to the recordings.

   Tell the participant if you are going to take and use photographs; this will require the consent of all individuals that they may be identified.

   Tell participants if you are planning to use direct quotes in the dissemination of the study as this will increase the likelihood of being identified.

   Tell the participants that the outcomes of the study will be written and disseminated in an anonymised format.

3. **Are there any limitations to confidentiality?**
   Make clear that although every attempt will be made to ensure anonymity it cannot be guaranteed absolutely. Other than in clinical/medical trials and some other experimental health-related studies, it is possible that participants may be identified by their colleagues and/or peers if not by the general public.

   Advise participants about the types of information you might need to disclose to someone else (e.g., if you feel the individual or others are at risk, if the individual reveals anything of an illegal nature, or if unprofessional practices become evident where you are you are researching in an organisation) for advice and possibly further action.

4. **Will I be reimbursed for my participation/time/travel?**
   Tell participants if there are any incentives for taking part in the research; ensure that any such incentives are appropriate to the type of research and the participant group, and that it does not invalidate freely given consent.

   Tell participants if they will be reimbursed in any way for their time; if they are to be reimbursed explain the terms and the process.

Tell participants whether or not travel expenses will be reimbursed. If not, they need to know this; if travel expenses are available explain the terms and process.

5. **Are there any possible disadvantages or risks in taking part?**
Make clear any potential disadvantages/risks, these might include: the potential to become distressed, any risks to confidentiality (e.g., disclosure of illegalities, abuse), fatigue and/or boredom, physical harm.

Explain what measures are in place to ensure participant's well-being and safety (e.g., rest breaks, safe cessation of an intervention, termination of an interview, access to support services), and to minimise harm.

6. **Can I withdraw at any time?**
Tell participants that they can withdraw from the study at any time and at any stage without giving a reason. There should be no coercion in their continuing participation. Tell participants how they can withdraw from the study, as participants may not be comfortable telling you directly that they wish to withdraw and may need other options (e.g., by email, return of a withdrawal form).

Tell participants that on withdrawal they have a choice as to whether data collected from them up to that point can still be used or removed from the study. Participants must be advised of the last date by which they can ask to have their data removed from the study (this cannot be after a thesis has been written and/or research findings published).

7. **What will happen to any information/data/samples *(delete as applicable*) collected from you?**
Tell participants how their information/data/samples will be stored securely, how long the materials will be stored for and when they will be destroyed.

Tell participants whether their data will be used in future similar but different projects.

Inform participants about the University's Personal Data Protection provisions and direct them to the Privacy Notices section of the University's website and, if helpful, provide participants with a copy.

Tell participants in qualitative studies if they will be shown a copy of interview/focus group transcripts for member checking; describe how this will happen and any amendments/reversions managed within the data set.

Tell participants if you intend to send them a summary of research findings.

8. **Contact details for complaints.**
Advise participants that if they have any complaints about the study, they should be encouraged to speak to you or your Supervisor (for students) in the first instance. They should also, however, be given access to details about the University's complaints procedure and/or the complaints procedures at Associate Campuses.
Email address: ResearchOffice@unigib.edu.gi
Postal address: The University of Gibraltar
Europa Point Campus
Gibraltar GX11 1AA

APPENDIX 2 INFORMED CONSENT

In social science projects, it is expected that participants be invited to make informed and voluntary decisions about whether or not they participate in a study and/or whether they continue their participation in a study.

Participants should not be subject to coercion at any stage of the investigation and should not be subject to covert or deceptive practices other than in exceptional circumstances. Where covert or deceptive approaches and methods of investigation are proposed, it should be because these are the only means to obtain the required data, and a strong case for such approaches would need to be made to the Ethics Committee.

In studies where there are inherent power inequalities (e.g., those involving children or colleagues), consent must be appropriately and freely given, and the actual conduct of the research must be carefully considered to ensure that participants do not feel coerced. Equally, where the study involves elite participants (e.g., people in high office, business contacts) attention has also to be paid to attaining appropriate consent and to the actual conduct of the study to ensure the validity of the research.

Where research involves a lengthy data-gathering period or repeat data gathering cycles this should be made clear to prospective participants so that their consent covers the life of the project. This normal or specific consent should also encompass the dissemination of the project over time. In preparing a participant information sheet and consent form researchers should be clear about dissemination strategies that will embrace a number of formats including publication in the popular and broadcast media.

In some projects, it may be advisable to seek *'extended consent'*. This allows for the data collected in one study to be used at a later future date in another project that might not be quite the same but related. A related project, for example, might arise out of a pilot study or the conclusions of the current study. Seeking extended consent from the outset is intended to insure that the use of valuable data and the contribution of participants is maximised.

In exceptional circumstances – where the fieldwork of a project runs for longer than expected - it may be necessary to seek *'renewed consent'*. This is managed in two ways.

i) A revised, re-signed and dated participant consent form. The participant consent form (appendix 6) is designed to accommodate initial consent and renewed consent. In order to give informed consent participants will need to be provided with a revised version of the participant information sheet, as indicated on the consent form.

ii) Through an extension request for ethical approval. If the fieldwork period of the study is anticipated to extend beyond the original approval period application for an extension must be submitted to the Research Ethics Committee.

Even where access to a research site is gained through a gatekeeper, researchers should also obtain the informed consent of prospective research participants. Even where gatekeepers have granted permission, individuals are not obliged to participate in the research, and participation or otherwise should remain confidential and not be divulged to the gatekeeper. It is important to remember that

the relationship between research participants and the gatekeeper may continue long after the research has been undertaken, completed and disseminated.

It is recognised that in some studies, such as those that investigate crowd behaviour or behaviour and interaction in public spaces (e.g., shopping malls, bars, and casinos), individual and group consent cannot be easily attained. Nonetheless, there is an expectation that the researcher will think through the ethical implications of their research.

Thought must always be given to the capacity of a participant to consent, i.e., their capacity to understand the risks and benefits of deciding to take part in research. Particular attention needs to be given to the consent process where those involved are under the age of 18 and/or where individuals have a cognitive impairment such as a learning disability, dementia or mental health difficulties. These are only examples of where specific attention to the capacity of a prospective participant(s) need to be considered. Where researchers have reservations about the parameters of consent and capacity issues in their study, they should seek further advice from the REC.

Whatever form of consent they sign, participants always have the right to withdraw from studies at any point they wish, without consequence. To accommodate the possible eventuality of participant withdrawal it is good practice to seek consent for the continued use of already collected data at the outset of the project.

The following form should be amended and used to secure informed consent from each participant in a research project.

PARTICIPANT CONSENT FORM

- **and participant renewed consent form**

Not all statements here may be applicable to your research and you may need to make amendments and/or additions, please amend and delete text accordingly.

Title of the research project:

Principal investigator and contact details:

Members of the research team:

NAME OF PARTICIPANT:

1. I agree to take part in the above research. I have read the Participant Information Sheet (add version control number of Participant Information Sheet) for the study.
2. I understand what my role will be in this research, and all my questions have been answered to my satisfaction.
3. I understand that I am free to withdraw from the research at any time, without giving a reason.
4. I understand that I am free to ask any questions at any time before and during the study.
5. I understand that quotes from me will be used in the dissemination of the research (delete as applicable).
6. I understand that the interview will be recorded (delete as applicable).
7. I understand what will happen to the data collected from me for the research.
8. I have been provided with a copy of this form and the Participant Information Sheet.

Data Protection: I agree to the University[10] processing personal data that I have supplied. I agree to the processing of such data for any purposes connected with the Research Project as outlined to me. I am aware of and understand the University's Personal Data Protection provisions (*Appendix 6*).

Signed…….. Date……

PARTICIPANT WITHDRAWAL
If you wish to withdraw from the research, please speak to the researcher or email them at (add email address) stating the title of the research.

You do not have to give a reason for why you would like to withdraw.

Please let the researcher know whether you consent to the use, or not, of information and/or data collected from you up to the date of your withdrawal.

[10] "The University" includes the University of Gibraltar and its Associate Campuses.

APPENDIX 3 VULNERABLE PERSONS

Vulnerability in research is usually linked to research participants' ability to provide voluntary and informed consent. It is therefore usually linked to limitations that they may have in their decision-making capacity or to their situation and circumstances, and it may also be because they are at heighted risk of exploitation. Vulnerability is, consequently, linked to a potential research participant's freedom to act in regard to their participation or otherwise in the project; this includes their right to withdraw.

Aside from children and young people, the University does not prescribe a list of those considered to be vulnerable in research terms. In considering whether there are participants whose decision making ability may be constrained, or who may be vulnerable to exploitation or other forms of harm in any project, researchers should take careful account of the interaction of the research questions, the research design and methodology, and the recruitment criteria and procedures. In particular, researchers should consider the power relations within a research project, including those linked to any gatekeepers who might be involved in access to, identification, or recruitment of participants.

This issue of vulnerability is closely linked to questions related to consent. Accordingly, participants should also be considered vulnerable if there are issues related to:

1) Their capacity to consent;
2) Their ability to comprehend and understand the consent process,
3) Their ability to retain information;
4) Ensuring the voluntariness of any consent;
5) Their ability to communicate their consent.

There are, however, groups that are more likely to be vulnerable, often on the basis of historic mistreatment of disadvantaged or institutionalised populations, including but not only prisoners, military personnel, and various categories of disabled people. Researchers should therefore pay particular attention to historic treatment and current circumstances influencing the potential for participants to be considered vulnerable because they fall into one or more of the following categories:

1) Institutionalised groups;
2) Groups where the capacity to consent might be an issue;
3) Traditionally marginalized, stigmatized, or otherwise disadvantaged groups;
4) People living in dangerous or impoverished structural environments;
5) People engaging in risky behaviours;
6) Populations that have been over-researched.

In some cases, participants might be made vulnerable as a result of the sensitivity of the research topic. Sensitive topics include but are not limited to:

1) Those that are not part of everyday discourses, are taboo, or are otherwise stigmatized;
2) Those that relate to criminal or illegal activities;
3) Those that are likely to cause distress to participants.

In considering these issues researchers should carefully consider socio-cultural contexts in identifying sensitivity, and be aware that sensitivity may vary considerably between socio-cultural groups within the same social setting or environment.

From a data protection perspective, all vulnerable persons (child and adult) require special protection.

APPENDIX 4 ADULTS WITHOUT LEGAL ABILITY TO GIVE CONSENT

It should be assumed that prospective adult participants have the mental capacity and legal ability to consent to participate, unless there is evidence to the contrary. Documentation advising participants should be accessible and comprehensible to enable individuals to make their own decisions, and ongoing consent should be confirmed.

Potential participants should not be excluded and discriminated against because of a deemed lack of capacity.

Where there is a legal inability or deemed to be a lack capacity to give consent the researcher should identify the legally authorised representative of the participant and ask for their consent. Any such decision needs to be made in the best interests of the participant and the interests of the individual must always outweigh those of science and society. However, even where consent from the legally authorised representative has been secured the prospective participant retains the right not to participate. In these circumstances, assent could be sought for.

As in all other studies ongoing participation should be reviewed and participants should have the right not to participate/withdraw at any stage of the study.

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APPENDIX 5 INFORMED CONSENT/ASSENT for CHILDREN and YOUNG PEOPLE[11]

For young people under the age of 16 consent should be sought from parents/guardians. Whilst parents/guardians may be asked to consent on behalf of a child or young person, the child or young person's refusal of assent or consent should always overrule the adult's consent. Where a child or young person has a learning difficulty further thought needs to be given to the merits and general value of the research. In those rare occasions where the requirement for parental or guardian consent poses a risk of harm to the research participant, in the absence of a responsible adult acting in loco parentis the research project may be approved on the basis of consent or assent by the child or young person as participant; in such a case this approval must be by both the DAPR and Chair of REC. This approval may not be delegated.

Table 1 provides an overview of the key considerations concerning the consent for and assent of children and young people.

Any research with schoolchildren should be conducted in accordance with the legal framework and protocols pertinent to the country in which the research is being undertaken. It should not contravene any of the ethical practice guidelines published in this guidance document.

Footnotes to Table 1

***Informed consent** is the voluntary agreement of an individual who has the legal capacity to give consent, and who exercises free power of choice, without undue inducement or any other form of constraint or coercion to participate in research. The individual must have sufficient knowledge and understanding of the nature of the proposed research, the anticipated risks and potential benefits, and the requirements of the research to be able to make an informed decision. (Levine, R.J. "Ethics and Regulations of Clinical Research." New Haven: Yale University Press, 1988.)

****Assent** is defined as the child or young person's permission or affirmative agreement to participate in research (Broome and Richards 1998). The seeking of assent may vary from situation to situation. It may approximate the consent process in an older child; with a younger child or a child or young person with significant learning difficulties assent may be established through ensuring that the child or young person is not troubled or disturbed by the research. An approach relying on assent should only be adopted when it is clear that fully informed consent is not able to be secured.

[11] The guidance offered here is taken from a 2015 briefing paper published by Nicholas Drey, Chair of the National Society for the Prevention of Cruelty to Children (UK).

Table 1: Framework for Consent with Children and Young People

Age		**Capacity to give informed consent*?** (Lack of capacity may be due to age, cognition or other factor)	**Consent process** (A child or young person's refusal of assent or consent should *always* over-rule parent or guardian's consent to take part in research)
Under 16		No	Parental consent, plus child's **assent****
16 or 17		Capacity	Young person's consent (We would encourage parental consent as well, if appropriate, for young people age 16-17)
		No capacity	Consent of legally authorised representative and assent of participant
18+		Capacity	Adult's consent
		No capacity	Consent of legally authorised representative and assent of participant.

APPENDIX 6 CONFIDENTIALITY and ANONYMITY

Confidentiality is about information and data shared with a researcher in confidence. The expectation is that the information/data will only be used for the purposes described in the participant information sheet and that personal information will not be divulged to others. All participants will be concerned to know that their personal information and data remains confidential and this may be particularly so in work-based and community studies, where the content of the study is concerned with sensitive issues, and/or where participants occupy significant roles in organisations and/or communities.

If there is a need or likelihood of data being shared with or divulged to others – for example, in anticipation of open access publication, or because of the need to include other researchers – this should be made clear from the outset and the potential uses of the data discussed with participants. Agreement for the sharing of personal information should be clearly signed-off in the participant consent form.

Where a participant or a group of participants wish to be identified the consent form should clearly reflect this and be signed off accordingly. Individual participants and/or a group retain the right to renegotiate the confidential nature of their information and data. Any change in status should be recorded, signed and dated on an updated consent form.

Confidential information and data should be stored securely (e.g., password protection on computers) and anonymised. Participants should be assigned a code number or pseudonym (depending on the accepted practices of the discipline) and identifying information – including consent forms – separated from the data at the earliest opportunity. Recorded materials should be stored in a locked space. Access should be limited to those identified in the participant information sheet.

Participants (and researchers) should be aware that confidentiality is compromised where data is stored in a 3rd party document storage facility (e.g., GoogleDocs, DropBox, OneDrive). Although you retain ownership of your documents and materials the digital storage company are constantly running back-ups and various analysis on usage, some of these services are contracted out to other software companies. This means that the security of the data cannot be guaranteed. It may be more advisable to store data on a personal hard-drive.

In addition, participants should be made aware how long personal information and data will be kept, when and how it will be destroyed or - if it is to be kept for an indefinite period – how it is to be stored and curated.

Usually and if preferred by the participant, all data and information should be anonymised for the purposes of storage, analysis, publication and dissemination. Once extracted from the original data collection tools, quantitative data are usually anonymous. In qualitative studies, data may have to be excluded or obscured to protect the confidentiality of participants.

One of the purposes of research is to disseminate research findings, e.g., by publication, and whilst this does not normally breach confidentiality or anonymity, participants should be made aware of the increasing practice of open access to the data underlying research. Some research funders

require, in the interests of scientific advancement, transparency and public accountability, such that anonymised data underlying published research are made freely and widely accessible. There is an expectation that all research publications include a statement as to how underlying research materials, such as data, samples or models, can be accessed. In principle it should not affect the right to confidentiality and anonymity as it does not require the release of individual or corporate identities, nor does it over-ride the good practice of anonymising data (it does, however, draw attention to the need to be meticulous in data management and protection). Open access is not mandatory if, for example, there are compelling reasons for the protection of data, such as commercial confidentiality or legitimate sensitivities around data derived from potentially identifiable human participants[12].

When seeking and negotiating consent researchers should make it clear the limits to confidentiality that might arise in the conduct of the study. The need to breach confidentiality would usually arise where individuals, groups or communities are at risk of some kind of danger, or where illegalities become known. Where the researcher is alerted to danger and/or criminal/illegal activity they are obliged to take action in response to the disclosure. Participants need to know that if the researcher becomes aware of significant risk to the well-being of individuals and/or groups this information will need to be disclosed. Equally, where projects involve collecting data on criminal behaviour it may be necessary to explain that confidentiality will be preserved as far as the law permits. Any disclosure of confidential information should be fully justified in the public interest, for example in the need to avert significant harm. Disclosures should only be made to parties who can act on the information. Researchers should think about the potential risks to confidentiality in any given study and establish procedures to help manage in the event of disclosure.

[12] Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020 : http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf) particularly where there are sensitivities concerning human participants (see RCUK Policy on Open Access and Supporting Guidance : http://www.rcuk.ac.uk/documents/documents/rcukopenaccesspolicy-pdf/) RCUK Policy on Open

APPENDIX 7 PERSONAL DATA PROTECTION

Overview

Personal data obtained as a result of participation in University of Gibraltar research is processed in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2004 (amendments and Regulations 2018). The current University of Gibraltar 'Privacy and Data Protection Policy' is published on the University's website along with its suite of Privacy Notices. For further information the University Data Protection Officer may be contacted by email at: DPO@unigib.edu.gi

APPENDIX 8 REPLACEMENT, REDUCTION and REFINEMENT in ANIMAL RESEARCH[13]

Replacement
Replacement refers to technologies or approaches which directly replace or avoid the use of animals in experiments where they would otherwise have been used.

For many years, research animals have been used to answer important scientific questions including those related to human health. Animal models are often costly, time-consuming and, depending on the research question, present scientific limitations, such as poor relevance to human biology. Alternative models can address some of these concerns. In the last decade or so, advances in science and technology have meant that there are now realistic opportunities to replace the use of animals.

Full replacement avoids the use of any research animals. It includes the use of human volunteers, tissues and cells, mathematical and computer models, and established cell lines.

Partial replacement includes the use of some animals that, based on current scientific thinking, are not considered capable of experiencing suffering. This includes invertebrates such as *Drosophila*, nematode worms and social amoebae, and immature forms of vertebrates[2]. Partial replacement also includes the use of primary cells (and tissues) taken from animals killed solely for this purpose (i.e. not having been used in a scientific procedure that causes suffering).

Reduction
Reduction refers to methods that minimise the number of animals used per experiment or study consistent with the scientific aims. It is essential for reduction that studies with animals are appropriately designed and analysed to ensure robust and reproducible findings.

Reduction also includes methods that allow the information gathered per animal in an experiment to be maximised in order to reduce the use of additional animals. Examples of this include the use of some imaging modalities which allow longitudinal measurements in the same animal to be taken (rather than for example culling cohorts of animals at specific time points), or microsampling of blood, where small volumes enable repeat sampling in the same animal. In these scenarios, it is important to ensure that reducing the number of animals used is balanced against any additional suffering that might be caused by their repeated use.

Sharing data and resources (e.g., animals, tissues and equipment) between research groups and organisations can also contribute to reduction.

Refinement
Refinement refers to methods that minimise the pain, suffering, distress or lasting harm that may be experienced by research animals, and which improve their welfare. Refinement applies to all aspects of animal use, from their housing and husbandry to the scientific procedures performed on them. Examples of refinement include ensuring the animals are provided with housing that allows the expression of species-specific behaviours, using appropriate anaesthesia and analgesia to minimise pain, and training animals to cooperate with procedures to minimise any distress.

[13] From www.nc3rs.org.uk

Evidence suggests that pain and suffering can alter an animal's behaviour, physiology and immunology. Such changes can lead to variation in experimental results that impairs both the reliability and repeatability of studies.

APPENDIX 9 CERTIFICATE OF RESEARCH ETHICS TEMPLATE

Ethics ID: xxxx [YEAR] / xxx [3-digit sequential] /UniGib

Certificate of Research Ethics Review

This is to certify that the University of Gibraltar has reviewed and approved the below study.

Study Title:	
Name of Principal Investigator:	
Email of Principal Investigator:	
Name of student investigator (if applicable)	
Co-Investigators:	
Department:	
Planned timeframe of the study:	
Date of submission:	

Note for projects with external ethical approval: Approved by Research Ethics Committee on date [xxxx], confirmed by UoG Research Office on date [yyyy].

Date: [Month Day, Year]

Dr Darren Fa

Director of Academic Programmes and Research

University of Gibraltar

APPENDIX 10 ETHICS FORMS

RESEARCH ETHICS REVIEW - SOCIAL SCIENCES RESEARCH

Section A : Researcher Details			
1. Principal Investigator Details *(all applicants to complete these details please)*			
Forename			
Family Name			
Department/Hub/Associate Campus			
Email			
Professional Address			
Contact Number			
Employing Organisation, Address and Contact Number			
Project Title			
Prospective Data Collection Start Date			
Expected Project Completion Date			
Is the project externally funded?			
License number (if applicable), or funder details			
2. Student Investigator details If the research project is part of the thesis / course work of a student, please complete the following section.			
Student name			
Student Identification Number			
Course Title			
Supervisor(s)			
Project/Thesis Title			
3. Co-Investigators. Please expand to accommodate names and contact details of any collaborating organisations and/or project co-researchers			
1.			
2.			
3.			
4. Confirmation Statements		**Yes**	**No**
All researchers involved have completed relevant training in research ethics			
The research complies with the Gibraltar Data Protection Act 2004 and/or the data protection laws of the country/countries in which the research is being conducted			
Section B : Ethics Checklist			
Does your research: -		**Yes**	**No**
➢ Involve the administration of drugs, placebos or other substances (e.g., food/drink, vitamins) to human participants?			

➢ Cause or potentially cause pain, physical and/or psychological harm or negative consequences beyond the risks encountered in normal life?		
➢ Involve prolonged or repetitive testing?		
➢ Involve any deliberate deception and/or covert data collection without informed consent of participants/those observed?		
➢ Potentially involve researchers and/or participants in the disclosure of illegalities?		
➢ Relate to military sites, personnel, equipment and/or the defence industry?		
➢ Risk damage or disturbance to culturally, spiritually or historically significant artefacts or places and/or human remains?		
➢ Cause any negative impact on the environment over and above that of normal daily activity, e.g., use of environmentally toxic chemicals, ionising radiation?		
➢ Involve any risk to the researcher, e.g., lone working, international fieldwork?		
➢ Contain elements that you or members of the research team are not trained to conduct?		
➢ Does the research involve members of the public as participant researchers?		
➢ Require the cooperation of a gatekeeper for initial access to documents, data sets, a research site or research participants, e.g., employees, school children, members of self-help groups, prisoners, charities, museums, government departments, international agencies?		
➢ Involve administrative or secure data that requires permissions from the appropriate authorities before use?		
➢ Involve internet participants or other visual/vocal methods whereby participants may be identified?		
➢ Take place outside of Gibraltar, in full or part?		
➢ Involve participants (whose engagement may be influenced by the power relationships between yourself and them, e.g., colleagues, students, business contacts, persons in high office?		
➢ Present a risk of breach of confidentiality/anonymity to either individuals and/or participating organisations?		
➢ Offer financial inducements (other than reasonable expenses and compensation for time) to participants?		
Section C : Ethical Review		
1. Please provide a brief description of the project including the rationale, aims and anticipated value of the study *(this description should be written for a lay audience, i.e., readers who may not be an expert in the research area)*		
2. Please describe the overall design of the study/project and the methods of data collection and analysis *(e.g.: quantitative, qualitative, mixed methods, action research, creative*		

methods, experimental, laboratory based, observational, ethnographic, interviews, focus groups, excavatory, documentary, trial and/or intervention, etc.)
3. For social science projects involving direct contact with people (whether in person or via internet media) please attach all questionnaires, interview schedules, observational proformas that will be used in the study
4. Detail any laboratory techniques/experimental interventions that will be undertaken (to include the safe use and disposal of chemicals in the laboratory and the field; and/or to insure the least intrusive interventions in the human, social and natural environment)
5. Describe the research participants including the age range, gender and any particular characteristics pertinent to the project (*e.g., ethnicity, culture, ability/disability, experience*) and provide a rationale for the inclusion/exclusion of individuals/groups. **Experimental studies *must state* the inclusion and exclusion criteria pertaining to the project**
6. How will participants be selected and recruited, how many participants will be involved in the study and how was the sample size determined *(please attach any recruitment literature or provide a link to web-based recruitment material)*
7. How will power relationships between yourself and the participants be managed (most particularly where the study involves, colleagues, students, business contacts, and/or persons in high office)?

8. Where access to documents, data sets, research sites and/or participants is through a gatekeeper how will you manage this *(please attach proposed request and information letters to gatekeepers)*?
9. How will you brief and debrief participants *(please attach participant information sheets)*?
10. Will the participants be asked for their informed consent, and will they be able to withdraw from the study at any stage without prejudice *(please attach consent forms)*? • **If participants are not to be asked for their consent please explain why and the procedures in place to insure the ethical conduct of the study** • **If participants are not to be afforded the right to withdraw without penalty please explain why and the procedures in place to insure the ethical conduct of the study**
11. Will direct payments or payments in kind be made to the participants? If so, please describe, including detail of funding source.
12. How do you intend to maintain the confidentiality and anonymity of individuals, groups and/or organisations?
13. Should it arise, how do you intend to manage the disclosure of sensitive information *(e.g., criminal or illegal activity)*?
14. Are there any potential risks in the study to participants, how do you intend to manage these potential risks?

15. Are there any potential risks in the study to the researcher(s)? How do you intend to manage these potential risks *(e.g., physical/emotional risk; conflicts of interest concerning funding sources and research findings; conflicts of interest concerning research findings and organisational and/or community interests; research that accesses, collects and stores security-sensitive material)*
16. Are there any potential risks in the interests of organisations and/or the local community; how do you intend to manage these potential risks *(e.g.: conflicts of interest concerning funding sources and research findings; conflicts of interest concerning research findings and organisational and/or community interests; research that accesses, collects and stores security-sensitive material)*
17. How will you insure the safe storage of data during the course of the project *(ie: documents, transcripts, tissues, biological materials)*?
18. How will data be stored or destroyed on completion of the project?
19. If this is an externally funded project, has the funder been informed of and agreed to the University's ethics procedures and guidelines? If not please explain.
20. If this is an externally funded project, are there any restrictions on: (i) the conduct of the research; (ii) publication of results; (iii) copyright; (iv) open access to data?
21. Declaration & Signature(s)
▪ **Principal Investigator**

I confirm that to the best of my knowledge the information included in this application is a full description and account of the ethical considerations of this project.
In submitting this application, I confirm I will only commence the project once ethical approval has been obtained, that I will undertake the project in accordance with the terms of the approval, and I understand that I may not substantially amend the project without further approval.

Signature: …….. Date: ……

- **Student Investigator (where appropriate)**

Signature: …….. Date: ……

Section D : Application Checklist

	Applicant Check			Administrative Check		
	Yes	**No**	**N/A**	**Yes**	**No**	**N/A**
Are all the questions answered?						
Are the CVs of co-researchers attached?						
Are all the questionnaires, interview schedules, and/or observational proformas that will be used in the study attached?						
If required is a conformation from the gate keeper attached?						
Is the participant recruitment literature or link to web-based recruitment attached?						
Are participant information sheets attached?						
Are participant consent forms attached?						
Reference list is attached as necessary.						
Applicants have signed the form.						

Section E : Research Office Approval

The Research Ethics Committee is

☐satisfied with this ethical review and grants ethical approval for the proposed research;
☐satisfied with this ethical review and grants ethical approval for the proposed research subject to the conditions detailed below;
☐is not satisfied with this ethical review and withholds its approval for the reasons given below.

Name…… Signature: …….. **Date:** …… *Director of Academic Programmes and Research, or nominee*
Conditions pertaining to this approval or reasons why approval not granted

RESEARCH ETHICS REVIEW FOR RESEARCH IN A CLINICAL POPULATION / SETTING

PART 1, GMEC preliminary checklist

I: Project details			
Project title:			
Planned start date:		Planned end date:	
Funder:			

II: Applicant details			
Principal Investigator's name:			
Department:	University of Gibraltar		
Email:		Telephone number:	
Contact address:			
Student Investigator's name (if the project is part of a student's thesis or course work)			
Email:		Telephone number:	
Contact address:			
Undergraduate ☐	Taught Postgraduate ☐	Research Postgraduate ☐	Staff ☐

III: Declaration and signatures			
Please note that it is your responsibility to follow, and to ensure that, all researchers involved with your project follow accepted ethical practice and appropriate professional ethical guidelines in the conduct of your study. You must take all reasonable steps to protect the dignity, rights, safety and well-being of participants. This includes providing participants with appropriate information sheets, ensuring informed consent and ensuring confidentiality in the storage and use of data.			
Principal Investigor's signature		**Date**	
Student Investigator's signature (if applicable)		**Date**	
University of Gibraltar signature (Director of Research and Partnerships)		**Date**	

Section IV Research that may need full review by the GMEC **Tick either "yes" or "no" for every question** **For "yes", please give brief details as an annex**	**YES**	**NO**
Will the study involve recruitment of patients through the GHA/ERS patient data or samples?	☐	☐

Will the study involve the collection of tissue samples (including blood, saliva, urine, etc.) or other biological samples from participants, or the use of existing samples?	☐	☐
Will the study involve participants, or their data, from adult social care, including home care, or residents from a residential or nursing care home?	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
Is the research a clinical investigation of a non-CE Marked medical device, or a medical device which has been modified or is being used outside its CE Mark intended purpose, conducted by or with the support of the manufacturer or another commercial company to provide data for CE marking purposes? (a CE mark signifies compliance with European safety standards)	☐	☐
Is the research a clinical trial of an investigational medicinal product or a medical device?	☐	☐
Are drugs, placebos or other substances (e.g., vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?		

If one or more answers in IV(A) is YES, complete Part 2.

	YES	NO
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
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	☐	☐
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	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

PART 2, GMEC full ethics review

Overview
Name of Principal Investigator(s)

Contact Details (Please include your address, email and telephone number)
Title of Project
Lay Summary (Please provide a brief summary of the study)
Name of Student Investigators (If applicable)

Risks and ethical issues
Please list the principal inclusion and exclusion criteria
How long will each research participant be in the study in total, from when they give informed consent until their last contact with the research team?
What are the potential risks and burdens for research participants and how will you minimise them? (Describe any risks and burdens that could occur as a result of participation in the research, such as pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Describe what steps would be taken to minimise risks and burdens as far as possible)
Please describe what measures you have in place in the event of any unexpected outcomes or adverse effects to participants arising from involvement in the project
Will interviews/questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?
If yes, please describe the procedures in place to deal with these issues
What is the potential benefit to research participants?
What are the potential risks to the researchers themselves?
Will there be any risks to the GHA? (Consider issues such as reputational risk; research that may give rise to contentious or controversial findings; could the funder be considered controversial or have the potential to cause reputational risk to the GHA?)

Will any intervention or procedure, which would normally be considered a part of routine care, be withheld from the research participants? (If yes, give details and justification). For example, the disturbance of a schoolchild's day or access to their normal educational entitlement and curriculum.

Recruitment and informed consent
How and by whom will potential participants, records or samples be identified?
Will this involve reviewing or screening identifiable personal information of potential participants or any other person? (If 'yes', give details)
Has prior consent been obtained or will it be obtained for access to identifiable personal information?
Will you obtain informed consent from or on behalf of research participants? (If 'yes' please give details. If you are not planning to gain consent, please explain why not).
Will you record informed consent in writing? (If 'no', how will it be recorded?)
How long will you allow potential participants to decide whether or not to take part?
What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or have special communication needs? (e.g., translation, use of interpreters?)
If no arrangements will be made, explain the reasons (e.g., resource constraints)

Confidentiality
In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.
If you will be undertaking any of the following activities at any stage (including in the identification of potential participants) please give details and explain the safeguarding measures you will employ • Electronic transfer by magnetic or optical media, email or computer networks • Sharing of personal data outside the European Economic Area • Use of personal addresses, postcodes, faxes, emails or telephone numbers • Publication of direct quotations from respondents • Publication of data that might allow identification of individuals, either directly or indirectly • Use of audio/visual recording devices

• Storage of personal data on any of the following: – Manual files – Hospital or University computers – Home or other personal computers – Private company computers – Laptop computers
How will you ensure the confidentiality of personal data? (e.g., anonymisation or pseudonymisation of data)
Who will have access to participants' personal data during the study?
How long will personal data be stored or accessed after the study has ended? (If longer than 12 months, please justify and comply fully with data protection legislation)
Please note: as best practice, and as a requirement of many funders, where practical, researchers must develop a data management and sharing plan to enable the data to be made available for re-use, e.g., for secondary research, and so sufficient metadata must be conserved to enable this while maintaining confidentiality commitments and legal requirements concerning security and storage of data.

Incentives and payments
Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research? (If 'yes', please give details)
Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research? (If 'yes', please give details)
Does the Researcher or any other investigator/collaborator have any direct personal involvement (e.g. financial, shareholding, personal relationship, etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest? (If 'yes', please give details)

Publication and dissemination
How do you intend to report and disseminate the results of the study? If you do not plan to report or disseminate the results please give your justification
Will you inform participants of the results? (Please give details of how you will inform participants or justify if not doing so)

Management of the research		
Other key investigators/collaborators. (Please include all grant co-applicants, protocol authors and other key members of the Chief Investigator's team, including non-doctoral student researchers)		
Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country? (If yes, please give details of rejected application and explain in the summary of main issues how the reasons for the unfavourable opinion have been addressed in this application)		
How long do you expect the study to last?		
• Planned start date:	• Planned end date:	• Total duration:
Where will the research take place?		

Insurance/indemnity
Does GHA's insurer need to be notified about your project before insurance cover can be provided? *The majority of research carried out at GHA is covered automatically by existing policies, however, if your project entails more than usual risk or involves an overseas country in the developing world or where there is or has recently been conflict, please check with the Insurance Office that cover can be provided. Please give details below.*

Children
Do you plan to include any participants in the clinical research who are children under 16? (If no, go to next section: if yes, you may need safeguarding training)
Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research with this age group
Please describe the arrangements for seeking informed consent from the legally authorised representative
If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding

Adults unable to consent for themselves
Do you plan to include any participants in the clinical research who are adults unable to consent for themselves through legal, physical or mental incapacity? (If yes, the research must be reviewed externally and you may need safeguarding training)
Is the research related to the 'impairing condition' that causes the lack of capacity, or to the treatment of those with that condition?

☐ Yes	If 'yes' proceed to next question
☐ No	If 'no' the study should proceed without involving those who do not have the capacity to consent to participation
Could the research be undertaken as effectively with people who do have the capacity to consent to participate?	
☐ Yes	If 'yes' then the study should exclude those without the capacity to consent to participation
☐ No	If 'no' then the inclusion of people without capacity in the study can be justified
Is it possible that the capacity of participants could fluctuate during the research? (If yes, the research must be reviewed externally)	
Who inside or outside the research team will decide whether the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?	
What will be the criteria for withdrawal of participants?	

Declaration

I, the researcher, agree

- to comply, and will ensure that all researchers involved with the study comply with all relevant legislation, accepted ethical practice, GHA policies and appropriate professional ethical guidelines during the conduct of this research project;
- to notify the GMEC of any significant changes to the design of the research and understand that further review may be required before I can proceed to implement the change(s);
- to notify the GMEC of any unexpected adverse events that may occur during my research;
- to notify the GMEC of any complaints I receive in connection with this research project.

Signed: Name:	Date:

What to do next

Send your completed form, along with all supporting documentation, to the GMEC 5th Floor SBH: Roy.piri@gha.gi together with required supporting documentation.

Checklist	
Please ensure you have included the following with your application (*where relevant):	
• Full research proposal (current project)	☐
• Participant information sheet (see *Appendix 2*)	☐
• Consent form (see *Appendix 3*)	☐
• *Covering letter	☐
• *Any questionnaires/interview schedules/topic guides to be used	☐
• *Any approved instruments/measures to be used	☐

• *Any advertising material to be used to recruit participants • *Confirmation that project is covered by GHA insurance policies (if necessary)	☐ ☐

FULL ETHICS REVIEW ANIMALS and their ENVIRONMENT

Section A : Researcher Details	
1. Principal Investigator Researcher Details *(all applicants to complete these details please)*	
Given name	
Family Name	
Department/Hub/Associate Campus	
Email	
Professional Address	
Contact Number	
Employing Organisation, Address and Contact Number	
Project/Thesis Title	
Prospective Data Collection Start Date	
Expected Project Completion Date	
Is the project externally funded?	
License number (if applicable), or funder details	

2. Student Investigator details If the research project is part of the thesis / course work of a student, please complete the following section.	
Student name	
Student Identification Number	
Course Title	
Supervisor(s)	
Project/Thesis Title	
3. Co-Investigators. Please expand to accommodate names and contact details of any collaborating organisations and/or project co-researchers	
1.	
2.	
3.	

4. Confirmation Statements	Yes	No
All researchers involved have completed relevant training in research ethics		
The research complies with HM Government of Gibraltar Animal Experiments (Scientific Procedures) Act 1999 and/or the corresponding laws of the country/countries in which the research is being conducted		
Section B : Ethics Checklist		
Please state how your research fit the following criteria.	**Yes**	**No**
➢ Does it involve observations, measurements or experiments with animals?		
➢ Are these observations, measurements or experiments conducted in the natural environment of the animals?		
➢ Are these observations, measurements or experiments likely to cause more than minor, limited and temporary distress to the animals and/or more than limited and temporary disturbance of their natural environment? ➢ If yes, please provide details and evidence to justify.		
➢ Do any experiments involve the use of environmentally toxic chemicals, ionising radiation, or other techniques that may harm animals and/or pollute the environment in the vicinity of your observations, measurements or experiments? ➢ If yes, please provide details of mitigation and risk reduction steps you intend to take.		
➢ If distress or disturbance is considered to exceed these limitations, do you understand that a separate licence may need to be provided, and your review (re-)submitted?		
➢ Does the research involve any risk to the researcher, e.g., lone working, working underwater?		
➢ Does the research involve elements that you or members of the research team are not trained to conduct? ➢ If yes, please explain how appropriate training is to be accessed.		
➢ Is your research conducted, in full or in part, outside the territory of Gibraltar, its territorial waters or its airspace?		
➢ Are all those associated with the research *(e.g., partners, funding organisations, cooperating organisations)* properly informed of		

the University's ethics procedures, guidelines and the importance of complying?		

Section C : Ethical Review

Please describe the overall design of the study/project and the methods of data collection and analysis *(e.g., quantitative, qualitative, mixed methods, action research, creative methods, experimental, laboratory based, observational, trial and/or intervention, etc.)*

Please detail in full the laboratory techniques/experimental interventions that will be undertaken *(to include the biomedical procedures to obtain biological samples, the safe use and disposal of chemicals in the laboratory and the field; and/or to ensure the least intrusive interventions in the natural environment)*

Are there any potential risks in the research related to conflicts of interest concerning funding sources and research findings? If yes, how do you intend to manage these potential risks?

Are there any potential risks in the research related to conflicts of interest concerning research findings and organisational and/or community interests? If yes, how do you intend to manage these potential risks?

What safeguards are necessary in relation to collecting and storing research data and, in particular, personal and sensitive material? Will digital data be stored in the University's digital data repository or elsewhere? Are there data in non-digital formats and, if so, how will these be stored securely? If data will be destroyed during or at the end of the research, how will this be done safely and securely?

Are there any potential risks to collecting and storing research materials *(e.g., animals, tissues, biological materials)*? If these will be destroyed during or at the end of the research, how will this be done safely and securely?

Declaration & Signature(s)

- **Principal Investigator**

I confirm that to the best of my knowledge the information included in this application is a full description and account of the ethical considerations of this project.
In submitting this application, I confirm I will only commence the project once ethical approval has been obtained, that I will undertake the project in accordance with the terms of the approval, and I understand that I may not substantially amend the project without further approval.

Signature: …….. Date: ……

- **Student Investigator (where appropriate)**

Signature: …….. Date: ……

Section D : Application Checklist

Are all the questions answered?	Yes	No

	Yes	No	N/A
	☐	☐	☐

Are all experimental and observational protocols attached?	☐	☐	☐
Is any necessary written permission(s) or licence(s) of persons, organisations and/or authorities attached?	☐	☐	☐
Is a reference list attached?	☐	☐	☐
Has the PI and, where appropriate, student(s) signed this form?	☐	☐	☐

Section E : Research Ethics Committee approval

The Research Ethics Committee is:

☐satisfied with this ethical review and grants ethical approval for the proposed research;

☐satisfied with this ethical review and grants ethical approval for the proposed research subject to the conditions detailed below;

☐is not satisfied with this ethical review and withholds its approval for the reasons given below.

Name……

Signature: …….. **Date:** ……

Director of Academic Programmes and Research, or nominee

Conditions pertaining to this approval or reasons why approval not granted