****

**College of Medical, Veterinary & Life Sciences Ethics Committee for**

**Non-Clinical Research Involving Human Participants**

**APPLICATION FORM FOR ETHICAL APPROVAL FOR INTERVENTIONAL RESEARCH**

**NOTES:**

**THIS APPLICATION FORM SHOULD BE TYPED NOT HAND WRITTEN.**

**ALL QUESTIONS MUST BE ANSWERED. “NOT APPLICABLE” IS A SATISFACTORY ANSWER WHERE APPROPRIATE.**

**The primary remit of this committee is the review of non-clinical research. However, clinical research involving humans, their tissue or data that falls outwith the remit of the NHS Research Ethics Service will also be reviewed by the MVLS committee. If your project involves NHS facilities, or is clinical research, then you must ensure that NHS REC review is not needed before applying to the MVLS REC. The review of the MVLS REC does not obviate the need for NHS review.**

**Please note – it is now a requirement for a Data Protection Impact Assessment (DPIA) to be completed for all research proposals involving the collection, processing and/or storage of data derived from human participants. If you need a DPIA, you must complete it before submission for ethical review. For research involving personal data, you should give participants a Privacy Notice as well as a Participant Information sheet.**

**Information on DPIAs and Privacy Notices**

[**https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/dpia/**](https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/dpia/)

[**https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/privacy%20notices/**](https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/privacy%20notices/)

**Information on the General Data Protection Regulation (GDPR)**

[**https://www.gla.ac.uk/myglasgow/dpfoioffice/**](https://www.gla.ac.uk/myglasgow/dpfoioffice/)

**Information on Research Data Management**

[**https://www.gla.ac.uk/myglasgow/datamanagement/**](https://www.gla.ac.uk/myglasgow/datamanagement/)

**University of Glasgow policy on surveys of students for research purposes**

[**https://www.gla.ac.uk/myglasgow/senateoffice/policies/studentengagement/studentsurveys/policyonstudentsurveys/**](https://www.gla.ac.uk/myglasgow/senateoffice/policies/studentengagement/studentsurveys/policyonstudentsurveys/)

**Project Title:**

**Has this application been previously submitted to this or any other ethics committee? Yes/No**

**If ‘Yes’, please state the title and reference number.**

**Is this project from a commercial source, or funded by a research grant of any kind? Yes/No**

**If ‘Yes’, has it been referred to Research Support Office?**

**Has it been allocated a project Number?**

**Give details and ensure that this is stated on the Informed Consent Form.**

**Insurance Coverage and Restrictions:**

**\*\*Please Note: The Insurance restrictions set out below relate to research of a clinical nature. Non clinical research is not subject to restriction and no additional insurance is required\*\***

**The University insurance cover is restricted under specific circumstances, including, but not limited to the following -**

* **work involving the use of research participants outside Great Britain, Northern Ireland, the Channel Islands or the Isle of Man**
* **the use of hazardous materials**
* **non CE marked medical devices**
* **molecules or compounds developed and manufactured at the University of Glasgow**
* **number of participants in excess of 5000**
* **work involving research participants known to be pregnant at the time of the project**

**All such projects must be referred to Research Support Office and coverage confirmed before ethical approval is sought. Please contact Dr Debra Stuart in the University’s Research Governance Office:** [**debra.stuart@glasgow.ac.uk**](mailto:debra.stuart@glasgow.ac.uk)

|  |
| --- |
|  |

**Please tick here if this project has been referred to the Research Support Office to confirm adequate insurance coverage.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
|  |

**Please tick here if the project includes a technique involving incision, piercing of skin, insertion of a device or object, ingestion of medicines**

**or food substances.**

|  |
| --- |
|  |

**Please tick here if the project involves work on human participants**

**that will be conducted within the Imaging Centre of Excellence (ICE)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of submission:**

**Name of all person(s) submitting research proposal:**

## Position(s) held:

**School/Group/Institute/Centre:**

**Address for correspondence relating to this submission:**

**Email address:**

**Name of Principal Researcher** (if different from above, e.g., Student’s Supervisor):

**Position held:**

**Undergraduate student project:**

**Yes/No** If ‘Yes’, please state degree being undertaken:

**Postgraduate student project:**

**Yes/No** If ‘Yes’, please state degree being undertaken:

For postgraduate student projects, please state whether this a research (PGR) or taught (PGT) degree:

|  |
| --- |
| **1. Describe the purposes of the research proposed. Please include the background and scientific justification for the research. Why is this an area of importance? Please try to describe why the research is novel and experimental.**  *We do not need a comprehensive review of the topic area: a short summary that is sufficient for the reviewers to understand the study is sufficient. Bullet points and references to more detailed texts are both acceptable.* |

|  |
| --- |
| **2. Describe the design of the study and methods to be used. If multiple methods are to be used, please describe them each in turn. Include details of the study sample size and how you decided this. Statistical advice should be obtained if in doubt.** |
| **3. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited? Give details for cases and controls separately, if appropriate**  *You should explain how a person becomes identified as a potential participant and then an enrolled participant. If the initial approach uses a poster, social media or email then the materials should be submitted for review.* |
| **4. Describe the research procedures as they affect the research participants and any other parties involved. It should be clear exactly (i) what will happen to the research participant, (ii) how many times and (iii) in what order. If your research involves administration of a substance, for example saline, topical anaesthetic etc. then please give full details on the substance and manufacturer.  Reference to an existing standardised operating procedure is acceptable.** |

|  |
| --- |
| **5. What are the ethical considerations involved in this proposal? You may wish, for example, to comment on issues to do with consent, confidentiality, risk to participants, etc.** |

**6. Outline the reasons why the possible benefits to be gained from the project justify**

**any risks or discomforts involved.**

**7. Who are the investigators (including assistants) who will conduct the research? What are their qualifications and experience?**

**8. Are arrangements for the provision of clinical facilities to handle emergencies necessary? If so, briefly describe the arrangements made.**

**9. In cases where participants will be identified from information held by another party (e.g., a doctor or hospital), describe how you intend to obtain this information. Include, where appropriate, whether additional Research Ethics Committee approvals will be sought and gained (including overseas committees).**

**10. Specify whether participants will include students or others in a dependent relationship and, where possible, avoid recruiting students who might feel to be, or be construed to be, under obligation to volunteer for a project. This is most likely to be when a student is enrolled on a course where the investigator is a teacher. In these circumstances, the recruitment could be carried out by one of the other investigators or a suitably qualified third party.**

**11. Specify whether the research will include children or participants with mental illness, physical disability or intellectual disability. If so, please explain the necessity of involving these individuals as research participants and include documentation of the suitability of those researchers who will be in contact with children or vulnerable adults (e.g., Disclosure Scotland or membership of the Protection of Vulnerable Groups Scheme).**

**12. Will payment or other incentive, such as a gift or free services, be made to any research participant? If so, please specify, and state the level of payment to be made and/or the source of the funds/gift/free service to be used. Please explain the justification for offering an incentive.**

**13. Please give details of how consent is to be obtained and recorded. A copy of the proposed consent form, along with a separate information sheet, written in simple, non-technical language MUST ACCOMPANY THIS PROPOSAL FORM.**

**14. Comment on any cultural, social or gender-based characteristics of the participants that have affected the design of the project or may affect its conduct.**

**15. Please state (i) who will have access to the data, (ii) how the data will be stored, how will access be restricted, and (iii) what measures will be adopted to maintain the confidentiality of the research participants and to comply with data protection requirements.**

*For studies where participant responses are recorded and transcribed at a later date, give details of storage and transcription. Please give some detail on how long data will be stored for and where. You should clarify how identifiable, anonymised research data and consent forms will be stored.*

**Please tick to confirm that all relevant research data generated during and after the study will be collected and held in compliance with the General Data Protection Regulation (May 2018).**

**Please tick to confirm that you have completed a data protection impact assessment form if required.**

**If this is not required, please specify why not;**

**For guidance in this matter, please refer to the University Data Protection Office webpages:**

[**https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/**](https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/)

**In regard to (ii) above, please clarify (tick one) how the data will be stored:**

**(a) in a fully anonymised form (link to participants broken),**

**(b) in a linked anonymised form (data +/- samples linked to participant**

**identification number but participant not identifiable to researchers), or**

**(c) in a form in which the participant could be identifiable to researcher.**

**If data are stored in linked anonymised form, please state who will have access to the code and personal information about the participant.**

**The data will be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University’s Code of Good Practice in Research. (**[**https://www.gla.ac.uk/research/strategy/ourpolicies/**](https://www.gla.ac.uk/research/strategy/ourpolicies/)**) Please tick and give further details below**

**16. To your knowledge, will the intended group of research participants be involved in other research? If so, please justify.**

**17. Proposed starting date:**

**Expected completion date:**

**18. Please state location(s) where the project will be carried out, including all overseas laboratories, hospitals and other relevant locations.**

**19. Please state briefly any precautions being taken to protect the health and safety of researchers and others associated with the project (as distinct from the research participants), e.g., where blood samples are being taken, home visits.**

**20. Please state all relevant sources of funding or support for this study.**

**21a). Are there any conflicts of interest related to this project for any member of the research team? This includes, but is not restricted to, financial or commercial interests in the findings. If so, please explain these in detail and justify the role of the research team. For each member of the research team please complete a declaration of conflicts of interest below.**

Researcher Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ conflict of interest Yes / No

If yes, please detail below

Researcher Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ conflict of interest Yes / No

If yes, please detail below

Researcher Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ conflict of interest Yes / No

If yes, please detail below

Researcher Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ conflict of interest Yes / No

If yes, please detail below

**21b). If there are any conflicts of interest, please describe these in detail and justify conducting the proposed study.**

**22. How do you intend to disseminate the findings of this research?**

*Please include details of how the study participants will be notified of the study finding. If they are not to be informed, please justify.*

**I confirm that have read the University of Glasgow’s Data Protection Policy.** [**https://www.gla.ac.uk/myglasgow/dpfoioffice/**](https://www.gla.ac.uk/myglasgow/dpfoioffice/)

|  |
| --- |
|  |

Please initial box

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(Proposer of research)**

Please type your name on the line above.

**For student projects:**

**I confirm that I have read and contributed to this submission and believe that the methods proposed and ethical issues discussed are appropriate.**

**I confirm that the student will have the time and resources to complete this project.**

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(Supervisor of student)**

Please type your name on the line above.

**Please upload the completed and signed form, along with other required documents by logging in to the Research Ethics System at -** <https://frontdoor.spa.gla.ac.uk/login/>