Faculty of Engineering and Physical Sciences
Full Ethics Application – Question Specific Guidance

1.	Outline briefly the aims and rationale of your study. Include the main research questions(s)
You should provide a clear description of the aims and rationale for your study in lay language. This should include the main research question(s).	

2.	Outline briefly the methods and analysis you intend to use.
You should explain your proposed research methods and plans for analysis of project data. Your outline should state how these will be used to address the main research question(s).	

Potential Ethical Issues

1.	Does the study require participants to disclose information of a sensitive or personal nature? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐
You should consider carefully whether you will be asking participants in the study to provide information which may be considered sensitive or personal. You should justify the need for requesting such information and outline what measures will be put in place to mitigate any distress or other adverse effects, e.g. debriefing protocol, protocol for managing participant distress. Any such protocols should be described and submitted for review.			

2.	Does the research have the potential to cause adverse environmental impact? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐
You should indicate whether the research procedures have the potential to cause adverse environmental impact. 'Adverse environmental impacts' refer to any harmful effects on the environment – for example, degradation of soil, water or air, changes that reduce flora or fauna habitat or make the local environment socially unacceptable. If this is possible, you should explain why this is necessary and outline the measures which will be put in place to minimise any adverse effects. Any such protocols should be described and submitted for review.			

3.	Does the study involve any significant deception or withholding information? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐

In some studies, it may be necessary to withhold information from participants or to engage in the deception of participants, e.g. to prevent participants changing their behaviour because they are aware they are being studied.

It is generally considered ethically unacceptable to use deception in research, particularly if it may cause anger or distress to participants. You should explain why it is not possible to answer the research question without the use of deception or the withholding of information. It is important to carefully consider whether this is appropriate and justify this to the REC. You should also outline what measures will be put in place to debrief participants and manage any distress.

Alternatives to the use of deception should be considered and demonstrated to be ineffective. The use of deception to induce severe physical pain or emotional distress is not justified. Researchers should inform participants regarding their deception as soon as possible after their participation in the study, and usually not later than at the conclusion of the data collection.

Participants should, in most circumstances, be given the opportunity to withdraw their data.

4.	Does the study involve invasive procedures, e.g. the administration of drugs or other substances (e.g. food, supplements), vigorous physical exercise, or techniques such as hypnotherapy that would not usually be encountered in everyday life? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐

If participants will be asked to undergo any invasive procedures as a result of taking part in the study this should be justified to the REC. You should outline any potential risks associated with these and if there may be potential benefits, these should also be described. This will allow the REC to make a judgement on the risk/benefit ratio of the study.

If participants are to be asked to give any samples, e.g. blood, urine, sputum, saliva, or other relevant material as defined to the Human Tissue Act (2004), then you should clearly document what samples are being obtained, at which time points, how these will be collected, stored, analysed and disposed of. The Information Sheet and Consent Form should include this detail and explicit consent should be obtained. If there is an intention to retain the samples for use in future research, this should be outlined below and participants should be informed of this and provide consent.

5.	Does the study involve any visual/vocal methods where participants or other individuals may be identifiable in the images used or generated, where consent for the use of the images in research has not been obtained? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐

If your study will involve use of identifiable images obtained without consent for use in research, the need for this should be fully justified, as it is not generally considered ethically acceptable. You should describe what measures will be put in place to minimise any adverse effects.

6.	Does the study involve the covert observation of individuals in non-public places without their consent? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐
If your study will involve covert observation of individuals in non-public places without consent, the need for this should be clearly justified, as this is not generally considered ethically acceptable. You should outline what measures will be put in place to minimise any adverse effects. Observational studies are sometimes conducted in naturalistic settings in which the 'participants' are unaware that an investigation is taking place. Unobtrusive observation raises significant ethical questions regarding informed consent and invasion of privacy. Before conducting unobtrusive observational studies it is essential to undertake an assessment of the extent to which human dignity may be jeopardized, and that threat must be weighed against the value of the study. Such research is only acceptable in situations where those being observed would expect to be observed by strangers. Particular account must also be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.			

7.	Does the study involve any psychological risk (e.g. stress, anxiety or humiliation) that would not usually be encountered in everyday life? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐
If participants will be exposed to any psychological risk as a result of taking part in the study this should be justified to the REC. You should fully outline any potential risks and if there may be potential benefits, these should also be described. This will allow the REC to make a judgement on the risk/benefit ratio of the study.			

8.	Does the study involve any physical risk (e.g. more than minimal pain, fatigue) that would not usually be encountered in everyday life? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐
If participants will be exposed to any physical risk as a result of taking part in the study this should be justified to the REC. You should fully outline any potential risks and if there may be potential benefits, these should also be described. This will allow the REC to make a judgement on the risk/benefit ratio of the study.			

9.	Does the study intentionally aim to result in a change in behaviour in the participant? *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects*	**Yes** ☐	**No** ☐

If the research aims to cause participants to alter their lifestyle or behaviour as a result of taking part in the study this should be justified to the REC. You should describe how this change will be generated and how long they may be expected to last. You should outline any potential risks associated with these changes and if there may be potential benefits, these should also be described. This will allow the REC to make a judgement on the risk/benefit ratio of the study. You should describe what measures, e.g. debriefing, you will employ to minimise any adverse effects.

Participants

		Experimental	Controls	Total
1.	How many participants will be involved in the study	Click here to enter text.	Click here to enter text.	Click here to enter text.
a.	How many will be students at QUB	Click here to enter text.	Click here to enter text.	Click here to enter text.
b.	How many will be adults outside QUB	Click here to enter text.	Click here to enter text.	Click here to enter text.
c.	How many will be individuals aged 15 and under	Click here to enter text.	Click here to enter text.	Click here to enter text.
d.	How many will be individuals with specific medical conditions	Click here to enter text.	Click here to enter text.	Click here to enter text.

2.	How will participants be recruited?

The REC will expect to see full and clear information on how prospective participants will be identified, approached and recruited. It should be noted that it is not acceptable for personally identifiable information, such as potential participant contact details, to be provided to a member of the research team without the consent of the individual concerned. An opt-in method of recruitment is preferred, and if this cannot be employed, the rationale for alternative recruitment methodologies should be given.

3.	What, if any, inclusion or exclusion criteria will be used?

If you will be using inclusion or exclusion criteria to select potential participants, then these should be outlined and justified. You should describe how the criteria will be applied, who will make the assessment of whether a participant should be included or excluded and if this is not the researcher, and how this will be communicated with the research team. It should be noted that it is not acceptable for personally identifiable information, such as potential participant contact details, to be provided to a member of the research team without the consent of the individual concerned.

4.	What, if any, is the relationship between the investigators and participants (e.g. fellow students, club members, family friends)?

If there is a relationship between investigators and potential participants, there is the potential for perceived coercion as potential participants may not feel they can refuse to take part in the project. Any potential perceived coercion should be acknowledged, and details given of how this will be avoided or reduced. Participants should be made aware that they do not have to take part in a study and that refusal to take part will have no adverse impact on any relationship they have with the researcher.

5.	How and what will individuals be told about the research? *(a copy of the Participant Information Sheet must be attached to this application)*
Provide details on what information will be given to prospective participants, and when this will be done. Separate guidance on the content of Participant Information Sheets and Consent Forms is available from the Faculty REC website.	

6.	How will participants provide consent? *(a copy of the Consent Form (if applicable) must be attached to this application)*
Explain how you will obtain informed consent from participants, how this will be recorded and when it will occur. Separate guidance on the content of Participant Information Sheets and Consent Forms is available from the Faculty REC website.	

7.	If individuals are unable to give consent, e.g. through age or incapacity, how will consent be obtained?
If you need to include participants in your study who are unable to provide consent for themselves, you should fully justify why this is required. The justification should include an explanation why the research question could not be answered without the involvement of these participants. You should also outline what methods will be used to obtain consent or assent. In circumstances where the participant is legally incapable of providing consent or is a minor, you should: (i) Explain the research and the participants' role and requirements; (ii) Seek the participants' agreement; (iii) Ensure the person's best interests are served; (iv) Obtain assent from the participants' legal guardian. Any research involving children should comply with Articles 3 and 12 of the United Nations Convention on the Rights of the Child. Article 3 requires that in all actions concerning children, the best interests of the child must be the primary consideration. Article 12 requires that children who are capable of forming their own views should be granted the right to express their views freely in all matters affecting them, commensurate with their age and maturity. Children should therefore be facilitated to give fully informed consent.	

8.	Can the participants withdraw from the research at any time? *How and when are individuals informed of this?*	**Yes** ☐	**No** ☐
Every participant has the right to withdraw from a study with no detrimental effect on them.			

9.	If individuals wish to withdraw, what will happen to them and their data?
There should be a clear understanding of what should happen and how any data, samples, information previously collected will be managed. Sometimes it will not be possible to remove data/destroy data in particular when it has been incorporated into a larger dataset and identifiers removed. If this is the case, participants should be fully informed and it should be clear at what point withdrawal will no longer be feasible.	

10.	Are participants being offered any financial inducements (other than reasonable expenses and compensation for time) to participate? *If yes, explain why this is necessary*	**Yes** ☐	**No** ☐
If it is proposed to offer participants any financial inducements, e.g. vouchers, prize draw entries etc. this should be outlined and justified. Careful consideration should be given to the value of any offer as this could be seen coercive. The reimbursement of expenses and any compensation for inconvenience should be detailed.			

11.	Does the research involve access to records of a personal nature or confidential information (including genetic, health or other biological information) for which specific consent has not been granted for its use for the purposes of the research and it is not anonymised or potentially sensitive data through third parties (such as employee data)? *If yes, explain how the confidentiality of the information will be preserved*	**Yes** ☐	**No** ☐
If it is necessary to obtain access to this type of information, this should be justified and a clear process for preserving confidentiality should be outlined. It should be noted that it is not generally acceptable to have access to such information without explicit consent for research purposes. You should clearly explain why it is not possible to obtain consent, and why it is necessary to access identifiable data for the purposes of research. If it would be possible to answer the research question by using alternative means, then this should be done.			

12.	Could the study result in 'labelling' either by the researcher (e.g. categorisation) or by the participant (e.g. 'I am stupid', 'I am not normal'), or an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information)? *If yes, explain how the confidentiality of the information will be preserved*	**Yes** ☐	**No** ☐
If there is potential for the above, this should be justified and a clear method for preserving confidentiality should be outlined.			

13.	Could the study reveal findings relevant for an individual participant's health and well-being? *If yes, please state what information the individual will be given, what*	**Yes** ☐	**No** ☐

	permission will be obtained, and describe how the information will be handled, e.g. who will it be passed on to.		
If it is known that the study could generate findings which may have implications for a participant's health and well-being, a protocol for managing this should be clearly described. It is unlikely that a research project will generate diagnostic findings, however it is possible that during the course of a study results may be generated which warrant further exploration by a clinical specialist. If this is known to be a possibility, then participants should be advised of this possibility in the Information Sheet and it should be made clear how any such findings will be handled.			

Methods

1.	Will you be administering any substances to participants?	**Yes** ☐	**No** ☐
	Will you be asking participants to refrain from taking any substance they would usually take?	☐	☐
If you have answered yes to either of the above provide the following information for each substance to be administered or withheld: *a) substance, b) amount to be administered or withheld, and for how long; c) desired effect, d) possible side effects, and e) what will be done to minimise risks.* Provide the requested information if applicable.			

2.	Will you be administering any questionnaires to participants?	**Yes** ☐	**No** ☐
	Will you be undertaking any interviews or semi-structured interviews?	☐	☐
If you have answered yes to either of the above *i) for each questionnaire state a) title, b) reference or for unpublished questionnaires provide a copy with the application, c purpose of questionnaire, and/or ii) provide a schedule for the interview.* Provide the requested information if applicable.			

3.	Is permission required from any other source before commencing the research or for the use of equipment? *If yes, state what permission is required and provide evidence*	**Yes** ☐	**No** ☐

Any equipment to be used in the study that belongs to an external party and is not certified by the University should be declared. This must include any checks that have been conducted by the research team. When the research is conducted in another organisation the management permission required must be provided or the intention to apply for this must be detailed. For example, research conducted within a Housing Fold or airport. Please contact researchgovernance@qub.ac.uk for further information.

Data security and participant confidentiality

		Yes	No
1.	Will data be anonymised such that individual responses cannot be identified? *If yes, describe how you will do this*	☐	☐
Provide a clear explanation of how data will be anonymised so that personal information is not identifiable.			

2.	If data is not anonymised describe what steps will be taken to preserve the confidentiality of the data.
Clearly outline how data will be held confidentially. If there are limits to the confidentiality which can be assured, then participants must be made aware of this in the Information Sheet and a clause inserted in the Consent Form to this effect.	

3.	Where will all forms of the data be stored?
Provide full information on what forms of data will be created, how these will be retained, backed up and disposed of.	

4.	Who will have access to the data?
It should be clear who will require access to study data and how this will be managed.	

5.	Where will Consent Forms be stored?
Provide details on where the study Consent Forms will be stored.	

		Yes	No
6.	Will individually identifiable information be given to third parties or available through publications, etc? *If yes, state why this is necessary and demonstrate that participants are made aware of this.*	☐	☐
If identifiable information may be given to third parties or used in publications this should be justified. The Information Sheet should clearly describe how the participant's information will be used and distributed and the Consent Form should include specific clauses in relation to these.			