UNIVERSITY OF STRATHCLYDE

**GENERIC FRAMEWORK APPLICATION FORM**

APPLICATION FOR GENERIC FRAMEWORK ETHICAL APPROVAL FOR A SERIES OF INVESTIGATIONS AND/OR TEACHING EXERCISES INVOLVING HUMAN PARTICIPANTS

**This form should be used for an application for ethical approval for a set of teaching activities or a group of investigations involving human subjects and can be used whether the teaching activities or group of investigations fall within the remit of the University Ethics Committee (“UEC”) or a Departmental Ethics Committee (“DEC”) (Section B1 a and b of the Code of Practice on Investigations involving Human Beings (the “Code of Practice”) sets out the criteria for studies to be considered by the UEC).**

**Research & Knowledge Exchange Services can advise on whether an application should be considered by the UEC or a Departmental Ethics Committee. Please contact** **ethics@strath.ac.uk** **for advice.**

**1. Chief Investigator / Course Leader, (**grade 7 member of staff or above)

Name:

Status (professor, senior lecturer, lecturer):

Department:

Contact details: Telephone:       E-mail:

**2. Other Investigators**

Please list any other investigators who may be involved and give details of any conditions (e.g. professional/medical qualifications) that will be a prerequisite for involvement

Undergraduate students [ ]

Postgraduate students [ ]

External students [ ]  specify external institution

Professor [ ]

Reader [ ]

Senior Lecturer/Lecturer [ ]

Research Assistants [ ]

Teaching Assistants [ ]

Admin and Professional support [ ]

Technical support [ ]

External investigators [ ]  specify external institution/organisation

**Any conditions that apply:**

**3. Title of this research/teaching activity**:

**4. Where will the investigation/teaching activity be conducted?**

If not fixed, please specify range/area/type of premises.

**5. Duration of the investigation/teaching activity (years/months):**

 (Expected) start date:        (Expected) completion date:

**6. Sponsor:**

**7. Funding body (if applicable):**

**Status of funding application:-**

**In preparation** [ ]

**Submitted** [ ]  **Date of submission of proposal**

**Accepted** [ ]  **Date of start of funding**

**8. Objectives / Justification of Investigation/Teaching Activity:**

**9. Details of participants (please provide details for *each* group of participants who will be recruited to take part in the investigations/teaching exercise by answering the following questions):**

1. What are the principal inclusion criteria (please justify)?
2. What are the principal exclusion criteria (please justify)?
3. Will any of the participants be from any of the following groups?

|  |  |
| --- | --- |
| Are unable to consent for themselves or have significant learning difficulties and/or cognitive impairment of a nature and extent that would affect their ability to give informed voluntary consent | [ ]  |
| Are severely ill or have a terminal illness | [ ]  |
| Are prisoners or young offenders, or are awaiting trial for a crime or offence that is relevant to the project | [ ]  |
| Are potentially subject to coercive measures by government, such as detention, restrictions on movement, deportation or repatriation | [ ]  |
| Live in or are connected to an institutional environment | [ ]  |
| Are in a situation of special vulnerability, e.g. women of childbearing potential where the investigation might carry any risk to pregnancy or to a foetus, or persons with addictions | [ ]  |
| Have a physical disability or a chronic physical condition relevant to the subject of the investigation. | [ ]  |

Have the appropriate Participant Information Sheets and Consent Forms been prepared for each group? Yes[ ]  No[ ]

If ‘NO’, please explain

**Remember to complete the checklist of documents at the end of this application form.**

**10. Recruitment (Please refer to the guidance in Section B4b of the Code of Practice):**

How will participants be recruited:

**Letter** [ ]

**Advertising notice** [ ]

**In person: to groups** [ ]  **to individuals** [ ]

If ‘In person to Individuals’, please give details:

**Other:**

Are recruitment procedures consistent with the need to obtain informed consent? [ ]

**11. What consents will be sought and how? Please refer to the guidance in Section B4c of the Code of Practice .**

**12. Methodology**

Are any of the categories mentioned in the Code of Practice Section B1a (project considerations) applicable to this investigation/teaching exercise?

Yes [ ]  No [ ]

If yes please detail:

**PLEASE NOTE: This application will be assessed on the appropriateness and necessity of the methodologies and techniques described herein. If approved, ethical approval is only given to the methodologies and techniques described in this application.**

Design: Please list all methodologies you can reasonably foresee being part of this generic framework application:

Techniques: Please list all techniques you can reasonably foresee being part of this generic framework application. With as much detail as possible, describe what is required of participants.

**13. Data collection, storage and security:**

Please explain how data is handled, specifying whether it will be fully anonymised, pseudo-anonymised, or just confidential, and whether it will be destroyed after use.

Please state how and where data will be stored, who has access to it, and for how long it will be stored.

Will anyone other than the named investigators have access to data?

Yes [ ]  No [ ]

If yes please detail:

**14. Potential risks or hazards:**

(Details of all risks, hazards and discomforts to participants and researchers and efforts to ameliorate these before, during and after the participant’s involvement)

**15. Ethical issues**

**16. Any payment to be made:**

**17. What debriefing, if any, will be given to participants?**

**18. How will the outcomes of the study be disseminated?**

**Will you seek to publish the results?**

**19. Nominated person/s (and contact details) to whom participants’ concerns/questions should be directed before, during or after the investigation.**

**20. Minimum previous experience of the investigator(s) with the procedures involved.**

**Investigator and Head of Department Declaration**

I have read the University’s Code of Practice on Investigations involving Human Beings and have completed this application accordingly.

 Signature of Chief Investigator/Course Leader Please also print name below

..……………………………………………

 Signature of Head of Department Please also print name below

 ……………………………………………

 Date:

**Head of Dept statement on Sponsorship**

**(only for university sponsored projects under the remit of the DEC with no external funding and no NHS involvement)**

This application requires the University to sponsor the investigation. I am aware of the implications of University sponsorship of the investigation and have assessed this investigation with respect to sponsorship and management risk. As this particular investigation is within the remit of the DEC and has no external funding and no NHS involvement, I agree on behalf of the University that the University is the appropriate sponsor of the investigation and there are no management risks posed by the investigation.

If not applicable, cross here

 Signature of Head of Department Please also print name below

 ……………………………………………

Date:

\* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \*

For applications to the University Ethics Committee the completed form should be sent (electronically with signed hard copy to follow) to Research & Knowledge Exchange Services in the first instance*.*

***Checklist of enclosed documents***

It is appreciated that in the case of generic framework applications that it is not always possible to give examples of every possible document within the framework. Supporting documentation may therefore fall within one of the following categories:-

Examples - full documentation is not provided, but examples given.

Standardised documents – these may be used where the investigator/course leader is able to produce a standard set of documentation which will not vary substantially for each investigation/teaching exercise.

Devolve to DEC (where investigation/teaching activities within remit of UEC): where it is not possible for documents to be produced at the application stage, the UEC may devolve approval of supporting documents to the relevant DEC.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Examples Enclosed** | **Standardised documents enclosed** | **Devolve to DEC** | **N/A** |
| Participant information sheet(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Consent form(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Sample questionnaire(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Sample interview format(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Sample advertisement(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| PDF of completed eRisk assessment: https://safetysystems.strath.ac.uk/ | [ ]  | [ ]  | [ ]  |  |
| Any other documents (please specify below)                | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  |

**Please check your documentation specifications before submitting this application:**

Has a consent form and a participant information sheet been developed for every *group* of participants ? [ ]

Has a consent form been developed for each relevant procedure? [ ]

Does all advertisement and correspondence carry the University Logo? [ ]

Are questionnaires pitched at the appropriate level for participants? [ ]

Does the consent form make clear that participants are free to withdraw at any time without giving reason, and (if appropriate) without effecting their situation (school/work/care etc)? [ ]

Do participants have adequate time to consider involvement prior to giving informed consent? [ ]