

FMHS REC Ethical Review Request Form

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*Required

This form must be completed to request ethical review from the FMHS Research Ethics Committee

Before completing this form, ensure the following:

You are applying to the correct Ethics Committee (see

<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/>)

You are familiar with the Application process as described on the FMHS FREC webpage

(<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/howtoapplyforkeeleuniversityreview/fmhsfrec/>)

All documents requiring REC review are complete, contain version control and are ready to be uploaded to this form

Where applicable, you should obtain authorisation for submission from your Supervisor before submitting an application

For amendments; any changes to documents are clearly tracked or highlighted and justified where necessary

Once you can confirm the above, you are ready to complete the application process. Failure to ensure any of the above may result in your application being rejected or delayed. Part-completed submission forms can not be saved.

1. What type of submission is this? *

Mark only one oval.

- New application *Skip to question 6.*
- New application (for a NEW programme of work) *Skip to question 36.*
- New application (falling under an existing programme of work) *Skip to question 2.*
- Registration of previous approval from another REC *Skip to question 4.*
- Amendment *Skip to question 52.*

Programme of Work Reference

If you are applying under an existing approved programme of work, you must declare that your project does not alter it in any way. Where you are changing or adding to a programme of work, you must submit this as an Amendment and receive authorisation from a Programme Lead before submitting.

2. Programme of work reference *

If the Programme of Work reference you are looking for is not listed below then check that you are submitting this application to the correct ethics committee. If necessary, contact research.governance@keele.ac.uk to obtain correct codes.

Mark only one oval.

- Option 1

3. Declaration that this project does not fall under any of the security sensitive information criteria *

For guidance on security sensitive information:

<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/securitysensitiveinformation/>

Mark only one oval.

This project does not fall under any of the security sensitive information criteria.

Skip to question 65.

Previous approval

4. Does the project already have a favourable opinion from an ethics committee at a UK Higher Education Institution (HEI) OR NHS REC OR from another approved organisation. *

A list of approved organisations can be found on the main Ethics webpage

(<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/#research-with-external-ethical-approval>).

Mark only one oval.

Yes *Skip to question 5.*

No *Skip to "Previous approval by non-approved organisation."*

Previous approval upload

5. Upload a pdf copy of the favourable ethical opinion. *

You maybe contacted for further information about this project and/or approval at a later date.

Files submitted:

Skip to question 47.

Previous approval by non-approved organisation

If your previous approval is not from another UK HEI, an NHS REC, or an organisation on the approved list, you will need to make a full submission. Please return to the start of this form and select New Application.

Start this form over.

REC Review Criteria

6. Does the research involve potentially vulnerable people or groups/individuals in a dependent or unequal relationship? *

This can include but is not limited to children, criminal suspects, domestic violence victims, etc.

Mark only one oval.

Yes

No

7. Does the research involve individuals or groups where permission of a gatekeeper is required for initial or continued access to participants? *

This includes children, care homes, and any access to participants which requires permission of another adult or a community leader (e.g., community groups, employees, students in a module, etc.). Note: This does NOT include students recruited through the Keele Psychology RPT.

Mark only one oval.

Yes

No

8. Does the research involve sensitive topics? *

This includes but is not limited to participants' sexual behaviour, illegal behaviour, political opinions, abuse, physical or mental health, personal finances, genetic or biological material, etc.

Mark only one oval.

Yes

No

9. Does the research involve collecting/storing participant data which cannot be anonymised? *

This includes visual images, videos, or sound recordings of the participant and any other identifiable records (e.g., structural MRI images). This does not include consent forms with names as long as it is not linked to the data files in any way.

Mark only one oval.

Yes

No

10. Does the research involve processing of data beyond that for which informed consent has been given? *

This includes linking to participant's data from other studies or other use of the data for answering research questions beyond those addressed in the information sheet.

Mark only one oval.

Yes

No

11. Will data be gathered through social media channels or online groups/websites without the explicit informed consent of each individual? *

This includes any online forum in which participants' posts/behaviour will be observed without providing explicit consent to participate regardless of whether the forum is public or private.

Mark only one oval.

Yes

No

12. Will the research involve blood/saliva/tissue samples, MRI imaging, or other methods which involve careful screening or specialist skills of the researchers in order to maintain safety? *

If your methods require specialist training/qualifications for the experimenters or screening procedures in order to maintain the safety or hygiene of the procedure (for both participants and experimenters) then you should select "yes" here. This, for example, might include screening for metal implants for MRI, hygiene/training for phlebotomy or tissue samples, or safety awareness for gathering data in public events such as protests. This is not an exhaustive list.

Mark only one oval.

Yes

No

13. Could the research involve more than minimal psychological stress, anxiety, or humiliation for the participant? *

When answering this, you should consider the likely effect of your procedures on the intended sample and how they will react. For instance, a story about political unrest may cause a very negative reaction in refugees but not in non-refugees.

Mark only one oval.

Yes

No

14. Will the research involve deception? *

Deception includes misleading or incomplete information about the nature/procedures of the study during the consent process. Withholding the hypothesis is not deception as long as participants are fully informed of the procedures and purpose when giving informed consent.

Mark only one oval.

Yes

No

15. Will the research involve data collection without informed consent at the time the data is collected? *

This includes covert or naturalistic observation studies in public?

Mark only one oval.

Yes

No

16. Does the research involve a risk to the safety and well being of the researchers and other staff? *

This can be physical or psychological risks.

Mark only one oval.

Yes

No

17. Does any of the data collection take place outside of the UK, EU or the list of accepted countries? *

This includes online data collection which will or could be completed by participants outside of the UK, EU or list of accepted countries. The list of accepted countries can be found here: <<insert link>>

Mark only one oval.

Yes

No

Skip to question 36.

Light touch place holder section

18. Q13

Mark only one oval.

Yes

No

19. **Q14**

Mark only one oval.

Yes

No

20. **Q15**

Mark only one oval.

Yes

No

21. **Q16**

Mark only one oval.

Yes

No

22. **Q17**

Mark only one oval.

Yes

No

23. **Q18**

Mark only one oval.

Yes

No

24. **Q19**

Mark only one oval.

Yes

No

25. **Q20**

Mark only one oval.

Yes

No

26. **Q21**

Mark only one oval.

Yes

No

27. **Q22**

Mark only one oval.

Yes

No

28. **Q23**

Mark only one oval.

Yes

No

29. **Q24**

Mark only one oval.

Yes

No

30. **Q25**

Mark only one oval.

Yes

No

31. **Q26**

Mark only one oval.

Yes

No

32. **Q27**

Mark only one oval.

Yes

No

33. **Q28**

Mark only one oval.

Yes

No

34. **Q29**

Mark only one oval.

Yes

No

35. **Q30**

Mark only one oval.

Yes

No

Skip to question 18.

Central REC Review Criteria

CREC Review Criteria

Research involving the following criteria requires review by CREC; please identify all that apply.

36. *

Mark only one oval per row.

	Yes	No
Activity which exposes participants to potential civil, criminal or other proceedings. (e.g. through disclosure of past events or prospective activity)	<input type="radio"/>	<input type="radio"/>
Administering a substance to participants including drugs, nutritional supplements and challenge agents or other intrusive intervention e.g. hypnotherapy, transcranial magnetic stimulation.	<input type="radio"/>	<input type="radio"/>
Human exposure to ionising radiation / X-Ray.	<input type="radio"/>	<input type="radio"/>
A risk of significant or permanent physical, mental or emotional harm, psychological stress, anxiety or humiliation requiring medical attention, treatment or other amelioration/mitigation/alleviation.	<input type="radio"/>	<input type="radio"/>
Prisoners and/or young offenders.	<input type="radio"/>	<input type="radio"/>
Participants without their consent in activity that will have a direct impact upon those participating.	<input type="radio"/>	<input type="radio"/>
Activity which may bring the reputation of the University or other body into question (eg controversial sources of funding, engaging with issues that may cause offence to groups or individuals, or engaging in areas that might be misconstrued as endorsing illegal practices)	<input type="radio"/>	<input type="radio"/>
Generation of knowledge that could potentially be weaponisable	<input type="radio"/>	<input type="radio"/>

If you have answered 'Yes' to any of the above then this project should be reviewed by the Central Research Ethics Committee. Return to the Selecting a REC flow diagram (<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/>) to establish the correct committee for your application.

Skip to question 37.

Security Sensitive Information

For guidance on security sensitive information:

<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/securitysensitiveinformation/>

37. Does the research include: *

Mark only one oval per row.

	Yes	No
Materials that are covered by the Official Secrets Act (1989) and the Terrorism Act 2006	<input type="radio"/>	<input type="radio"/>
Materials that could be considered 'extremist' or incompatible with British values	<input type="radio"/>	<input type="radio"/>
Materials used for research projects commissioned by the military or under an EU security call	<input type="radio"/>	<input type="radio"/>
The acquisition of security clearances to undertake the research	<input type="radio"/>	<input type="radio"/>

Human Biomaterial

38. Does your project involve use of Human Biomaterial? *

Mark only one oval.

- Yes
 No

Nature of research

39. Is the research pedagogic or educational in nature? *

(The term "educational" in this context does NOT refer to research being conducted to gain an undergraduate or postgraduate degree qualification. In this context "educational" means research undertaken in such areas as educational methodologies and techniques, e.g. teaching evaluation, innovation-based, TEL, etc)

Mark only one oval.

- Yes *Skip to "This application should be submitted to the KIITE EREC."*
 No *Skip to question 40.*

This application should be submitted to the KIITE EREC

<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/howtoapplyforkeeleuniversityrecreview/kiiteerec/>

Skip to "This application should be submitted to the KIITE EREC."

Educational purpose

40. Is the project being undertaken to gain an educational qualification? *

Mark only one oval.

- Not educational *Skip to question 43.*
 Undergraduate degree *Skip to question 41.*
 Masters in research *Skip to question 41.*
 Masters in teaching *Skip to question 41.*
 PhD *Skip to question 41.*

Academic Supervisor

41. Who is your academic supervisor? *

Give the name(s) and Keele email address of your academic supervisor(s).

Declaration

Your supervisor should approve your application before it is submitted. If your supervisor has not reviewed and approved this application it is strongly advised that you do not submit it until they have.

42. My academic supervisor is aware of this submission.

Mark only one oval.

- My academic supervisor (named above) has reviewed and approved this submission.
Skip to question 43.

Skip to question 41.

External Funding

43. Does the project have external funding? *

Mark only one oval.

- Yes Skip to question 44.
 No Skip to question 46.

External Funding

44. If yes, what is the RAISE reference ID?

Format: PID-#####. If you don't know this reference please contact your Raise Project Lead or email research.raise@keele.ac.uk with a copy of the grant award letter/contract and request confirmation of the PID reference.

45. If yes, is this Economic and Social Research Council (ESRC) funded? *

Mark only one oval.

- Yes
 No

Mandatory Documents

The following document must be submitted for your application to be considered for review.

46. Application form upload *

Upload must be in pdf format.
Files submitted:

Skip to question 47.

Other Documents

These must be included if they are required in the project but are not necessarily relevant to all projects.

47. Document checklist

Tick all that apply.

	Included	Not applicable
Participant consent form	<input type="checkbox"/>	<input type="checkbox"/>
Participant information leaflet/sheet	<input type="checkbox"/>	<input type="checkbox"/>
Letters of invitation to participants	<input type="checkbox"/>	<input type="checkbox"/>
Participant questionnaires	<input type="checkbox"/>	<input type="checkbox"/>
Advertisement materials for participants	<input type="checkbox"/>	<input type="checkbox"/>
Letter from sponsor	<input type="checkbox"/>	<input type="checkbox"/>
Letter from funder	<input type="checkbox"/>	<input type="checkbox"/>
Letter from statistician	<input type="checkbox"/>	<input type="checkbox"/>
Protocol	<input type="checkbox"/>	<input type="checkbox"/>
Other documents not listed (list below)	<input type="checkbox"/>	<input type="checkbox"/>

48. If documents are being submitted that are not listed above list them here.

49. Upload all documents indicated above (1 - 10):

Must be in pdf format.

Files submitted:

50. Upload all documents indicated above (11 - 20):

Must be in pdf format.

Files submitted:

51. Upload all documents indicated above (21 - 30):

Must be in pdf format.

Files submitted:

If you have more than 30 additional documents then email them directly to health.ethics@keele.ac.uk immediately after completing this submission.

Skip to question 65.

Amendment Type

52. Is this an amendment to a programme of work or to a stand alone project? *

Mark only one oval.

- Stand alone project *Skip to question 56.*
- Programme of work *Skip to question 53.*

Amendment to a programme of work

53. **Is this a new project requiring an amendment to the programme or an existing project operating under the programme? ***

Mark only one oval.

New project *After the last question in this section, skip to question 65.*

Existing project (operating under the programme of work) *After the last question in this section, skip to question 56.*

54. **Programme of work reference ***

Mark only one oval.

Option 1

55. **Upload the Application to Amend a Programme of Work Form ***

Upload in pdf format

Files submitted:

Amendment Details

56. **Project Title ***

57. **Original REC ID ***

This format: MH-#####

58. **Does this amendment change the proposed start or end dates of the project? ***

Mark only one oval.

Yes *Skip to question 59.*

No *Skip to question 61.*

Amended Timeline

59. **New start date**

Example: 15 December 2012

60. **New end date**

Example: 15 December 2012

Skip to question 61.

Mandatory Documents

61. **Amendment Form ***

Upload must be in pdf format.

Files submitted:

Skip to question 62.

Other Documents

These should only be included if they are being revised by this amendment.

62. Documents revised by this amendment

Tick all that apply.

	Revised	No change	Not applicable
Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant consent form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant information leaflet/sheet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letters of invitation to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant questionnaires	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advertisement materials for participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter from funder	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter from statistician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other documents not listed (list below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

63. If revised documents are being submitted that are not listed above list them here.

64. Upload all revised documents indicated above

Files submitted:

If you have more than 10 additional documents then email them directly to health.ethics@keele.ac.uk immediately after completing this submission.

Skip to "Submission."

New Application Details

65. Applicant Name: *

66. Project Title: *

Academic Unit

67. Faculty *

Mark only one oval.

Faculty of Medicine and Health Sciences

68. School *

Mark only one oval.

- School of Allied Health Professions
- School of Medicine
- School of Nursing and Midwifery
- School of Pharmacy and Bioengineering
- School of Primary, Community and Social Care

Project timeline

If exact start date is not known, please provide a realistic estimate

69. Proposed Start Date: *

Example: 15 December 2012

70. Proposed End Date: *

Example: 15 December 2012

Skip to "Submission."

Submission

By clicking submit below you are confirming that the information contained in this form and associated documents is accurate and complete. Incomplete submissions will result in delay to the review of your application.

Contact information for FMHS FREC

FMHS Faculty Research Ethics Committee Administrator: health.ethics@keele.ac.uk

Timelines and further information

For further information please refer to the FMHS Faculty Research Ethics Committee webpage (<https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/howtoapplyforkeeleuniversityreview/fmhsfrec/>)

A copy of your responses will be emailed to research.governance@keele.ac.uk

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