Ethics form completion guide

All research projects at Newcastle University require the ethics form to be completed, this does not mean the submission will require full ethical review but does ensure the activity is logged and provided an ethics number required for publications and student course completion. This applies to staff and student projects, funded or unfunded. If you are unsure if your project requires ethical approval, please email res.policy@ncl.ac.uk.

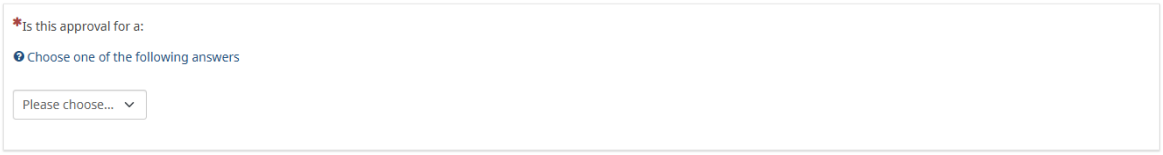
Reviewing this guide in advance of completing the form will allow you to have all the information ready.

More detailed guidance can be found at Research Ethics | Our Research | Newcastle University. It is recommended that all staff and students complete the ethics e-learning Course: Research Ethics which covers how ethics works at NU. Frequently Asked Questions | Our Research | Newcastle University.

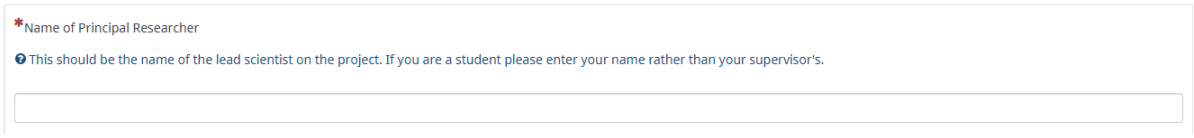
Key points:

- At the point of submission please save a pdf copy of the form as you will **not** be able to access your answers once you close the browser window.
- You are unable to make any amendments directly to your application once it has been submitted. Any amendments to low-risk projects including extensions to the end date of the project, need to be sent to res.policy@ncl.ac.uk. For high-risk projects, amendments need to be sent to the relevant faculty ethics committee that reviewed the original application.
- No research should begin on a project until ethical approval has been granted.
- Retrospective ethical approval cannot be granted; please ensure a future project start date.
- Projects involving animals (live or dead), their tissue or animal derived data will require review by AWERB (Animal Welfare Ethical Review Body) and may also require approval from a Faculty Research Ethics Committee (FREC) if there are other high-risk areas in addition to the animal research. Work cannot begin until approval has been granted AWERB **and** the relevant FREC. You will be informed by email from AWERB if your project requires FREC approval.
- All questions marked with a red asterisk * are compulsory and the form will not allow you to continue if these questions are not completed.
- Projects assessed as low risk must still follow good ethical practice.
- Intentionally completing the ethics form in a way designed to avoid or bypass full ethical review is considered a form of research misconduct. Ethical review is a safeguard, not a barrier, and attempting to circumvent it undermines both participant protection and research integrity.

Form Guidance



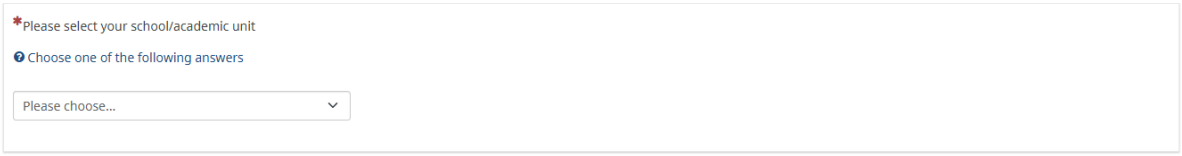
Options: Staff project; student project or course approval.
The course option is for undergrad and PGT modules which may be granted blanket ethical approval via the relevant Faculty Ethics Committee.



If you are completing the form on behalf of the lead researcher, enter their name here and make sure they are fully aware of the responses to each question. It is the responsibility of the PI or lead researcher to ensure that this form is filled out correctly and that appropriate ethical approval is in place.



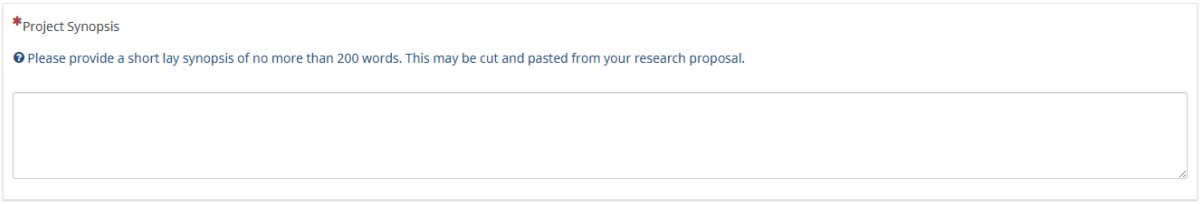
Email used for all correspondence, confirmation that low risk ethical approval or that is has been referred to a faculty ethics committee. If you do not receive a submission confirmation email, please check your junk folder. This email needs to be retained in the project records as evidence of ethical approval.



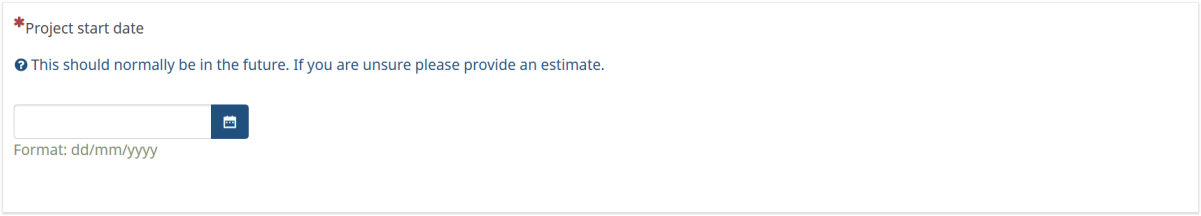
Please select from the list.
If you are a member of professional services, please choose an academic unit which belongs to the faculty where you work. If you are based in central services, please email res.policy@ncl.ac.uk for guidance on what to select.



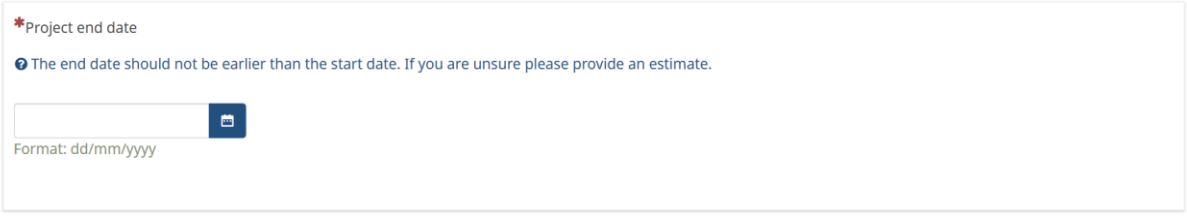
The project title should match what you have on NU Projects or your thesis to make the project easier to match.



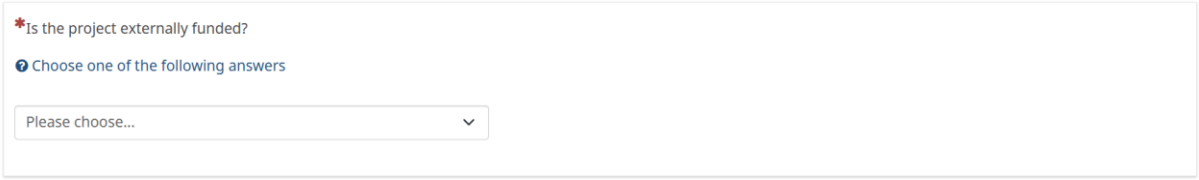
The synopsis should provide a brief summary of what you plan to do as part of this project. You should include, the project aims/objectives, benefits and why these are important as well as any planned outputs. The summary should be aimed at the general public and written in plain/lay English. The use of jargon should be avoided and any technical terms that do need to be used should be explained.



Ethical approval cannot be provided retrospectively; no research should begin until ethical approval has been granted.



This should be the current planned end date, if the project needs to be extended at a later date, email res.policy@ncl.ac.uk for low-risk projects or contact the relevant ethics committee for amendment guidance. Ethical approval should be treated as an iterative process - research regulations and expectations evolve, assumptions that a project is still low risk, particularly where similar work was acceptable in the past, may no longer be valid under current standards.

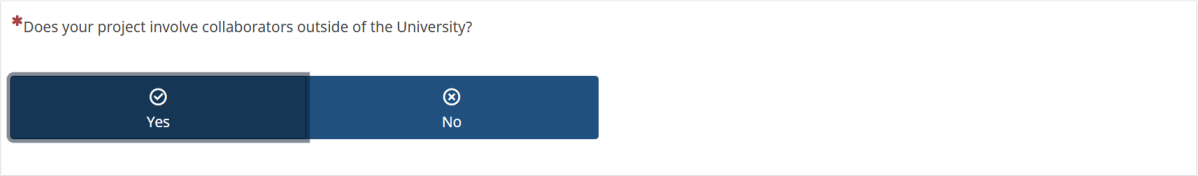


Externally and institutionally funded research projects require ethical approval. If you say yes to this option an additional box will appear in which you can add your NU Projects reference number.

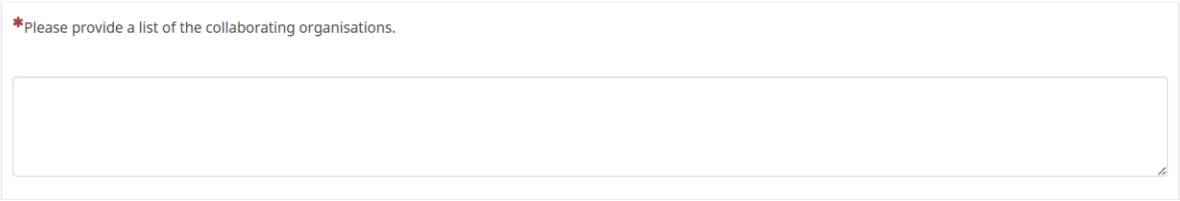


Enter your NUProjects/My Projects reference number exactly as provided to you

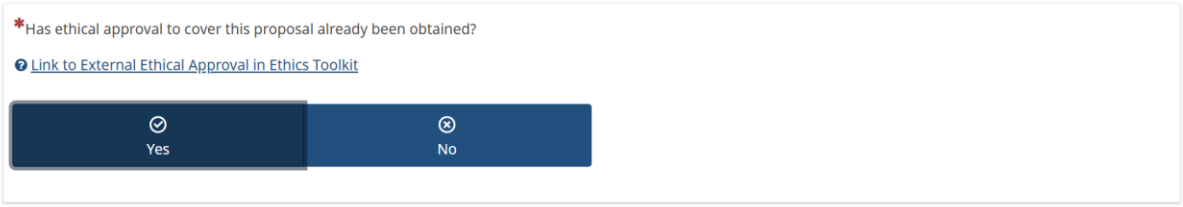
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If you select yes to this answer, an additional box will appear where you list collaborators.



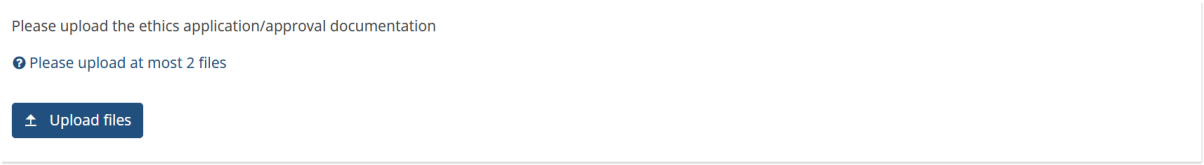
Please list all types of collaborators such as other universities, businesses and charities. If you are working with international collaborators, please read through the guidance [International Research | Our Research | Newcastle University] to ensure you are compliant with any relevant processes such as Trusted Research.



The purpose of this question is for those working with collaborators, it does **not** include approvals from biobanks or home office licences as these are separate compliance requirements – they do not constitute full ethical approval. Where Newcastle University is the research sponsor, Newcastle University may accept ethical approvals granted by external reviewers. Please read this guidance External Ethics | Our Research | Newcastle University **BEFORE** completing the NU ethics form and send evidence of the external ethical approval to your relevant Faculty Research Ethics Committee to check if they can accept it.



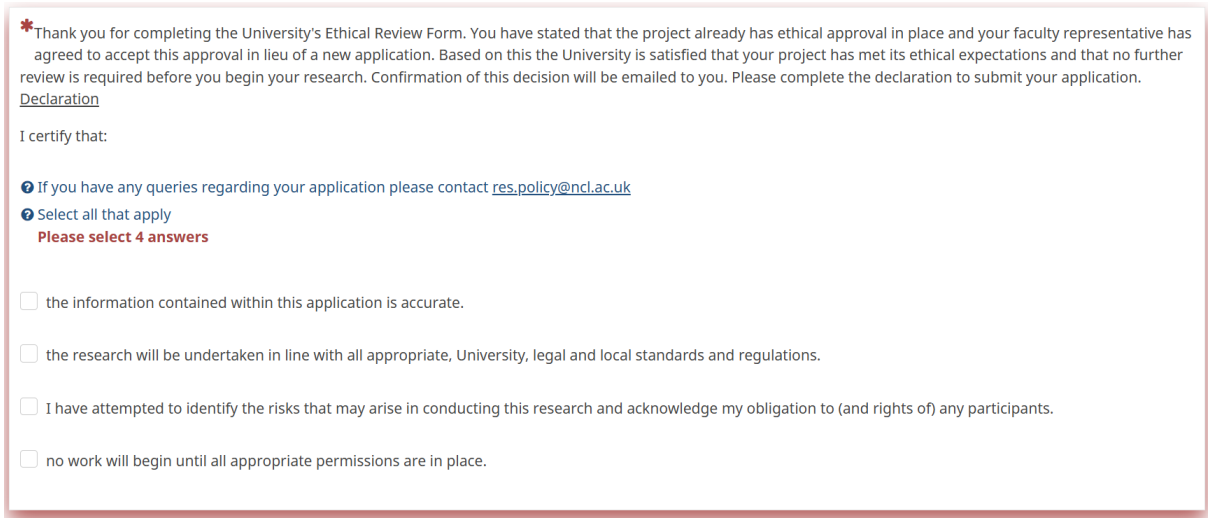
Select yes to this question if the external ethical approval was accepted by NU Ethics

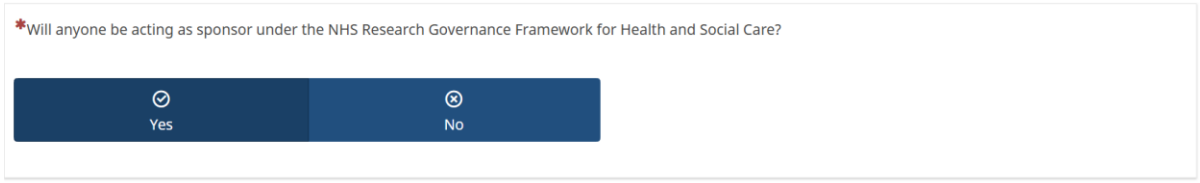


Upload the email confirmation from the Faculty Research Ethics Committee and complete the below information.



If you have valid external approval, you will not need to answer any of the remaining questions, but you will be asked to agree to the below statement.





If you are unsure about this question or if the answer is yes, please read this guidance NHS and Social Care | Our Research | Newcastle University. If you answer yes, please complete the below question.



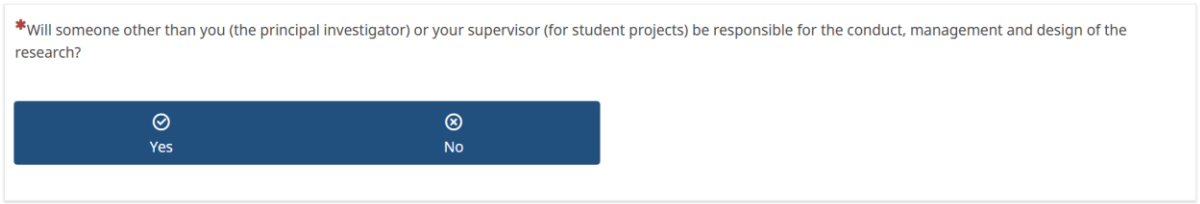
Enter sponsor name or institution. Use this link for more information on research sponsorship.



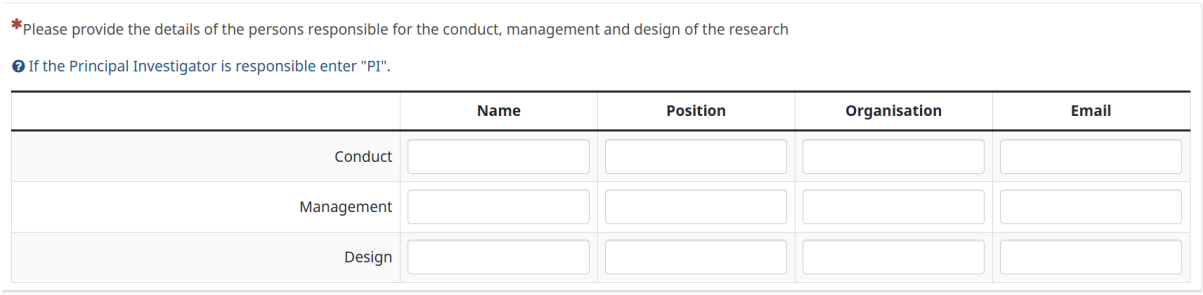
If your research involves the National Health Service (NHS) or a Health and Social Care (HSC) organisation, you may need to apply for Health Research Authority (HRA) approval. You can use the HRA decision tool to check if you need NHS ethical approval. If you answer yes, complete the additional questions



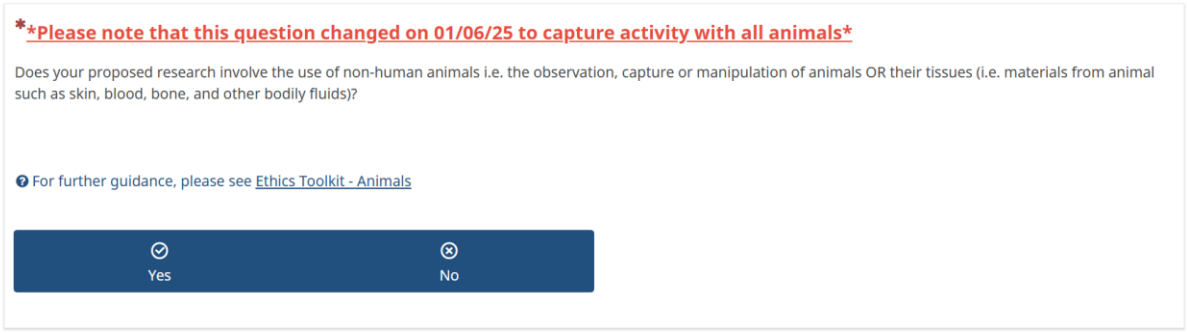
Enter reference number only



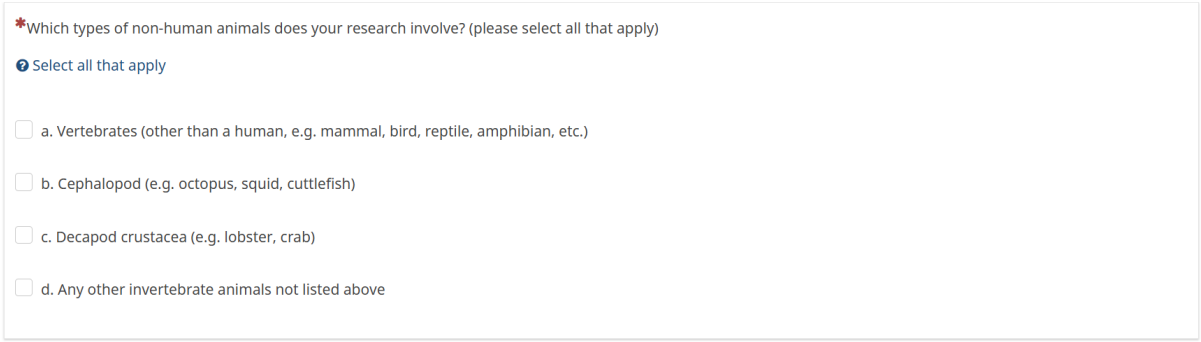
If you answer yes, complete the pop-up table:



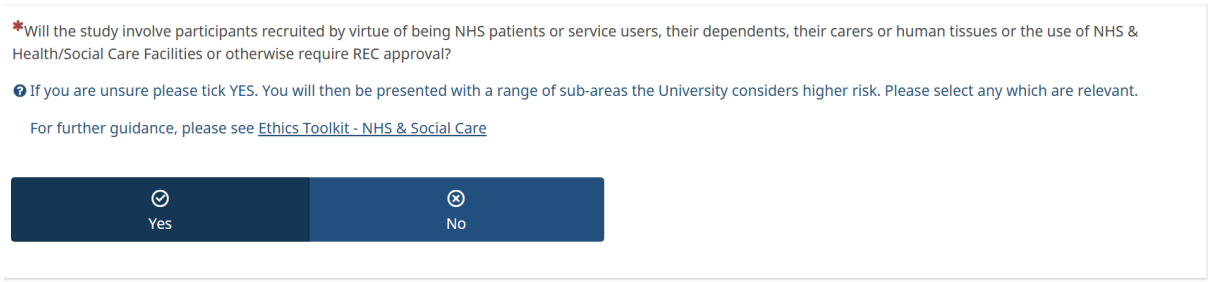
ANIMAL RELATED ACTIVITY



Answer yes to this question if your project involves the use of animals (alive or dead), their tissue or material (including faeces), or any animal derived data.

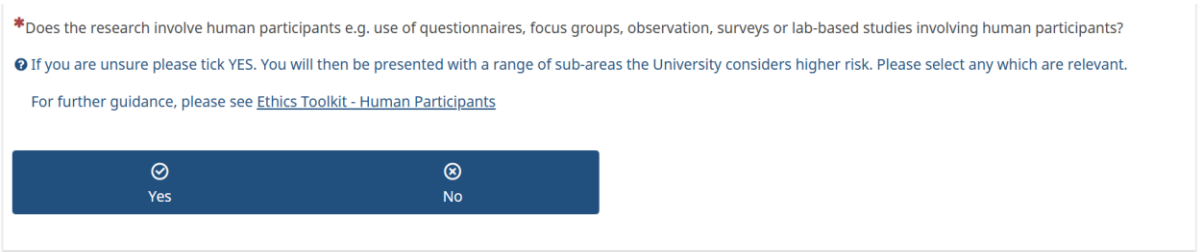


Select one or more of the animal classification checkboxes and complete the animal related questions. Ensure you write in lay terms and provide sufficient information to allow AWERB to consider your ethical application. Please link citations or organisations mention.



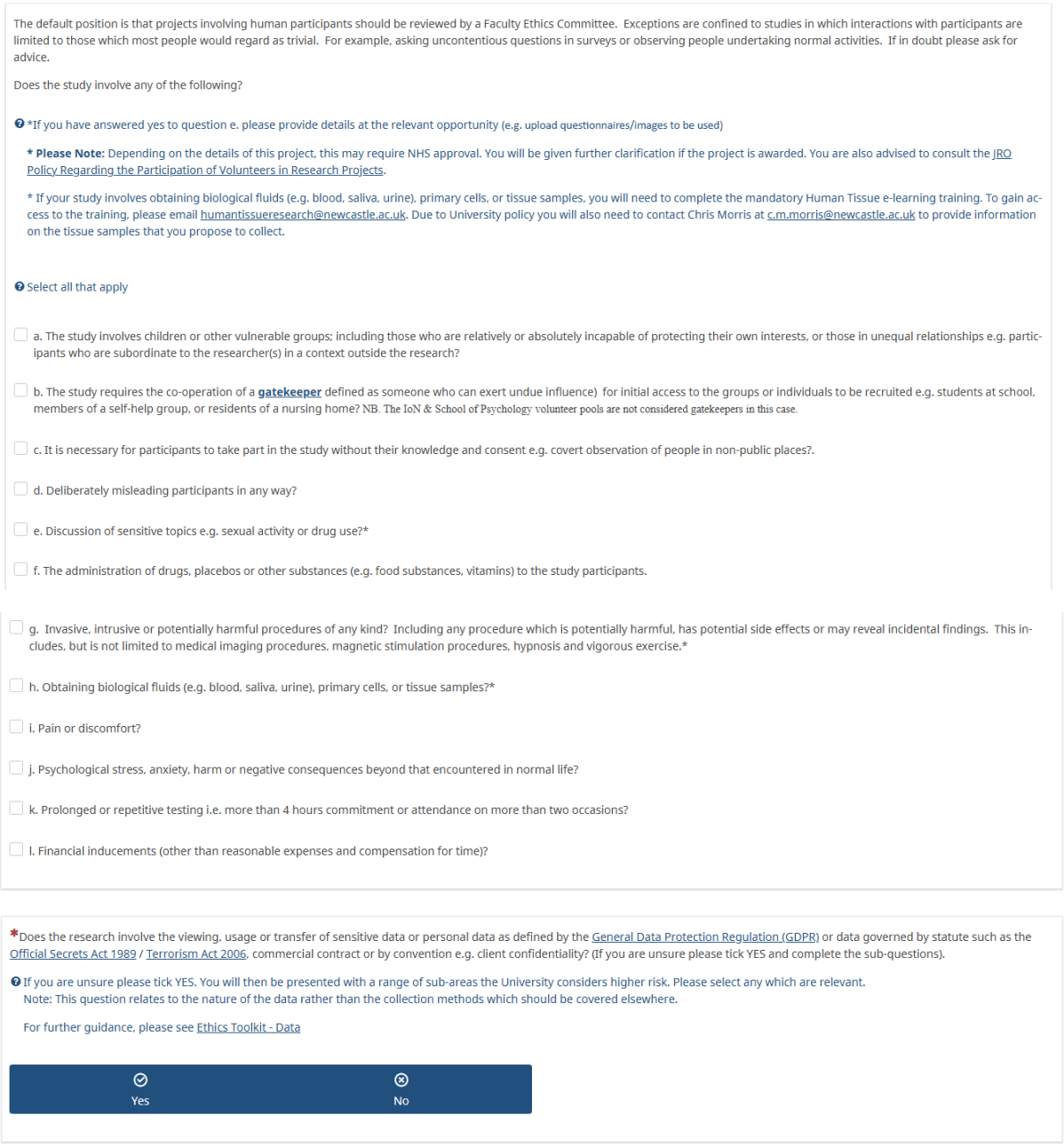
If you answer yes, please complete the relevant sub questions below.





If you answer yes, please complete the relevant sub questions below. Please note that ethical approval is separate to any compliance requirements as part of the Human Tissue Act Human Samples | Our Research | Newcastle University which applies to the collection, use and storage of human tissue. When existing tissue is being used (e.g. obtaining through a biobank, collaborators or commercial companies), the answer to this question should still be yes.

The list of sensitive topics is not exhaustive, a topic you may not consider sensitive could be extremely triggering for someone else, please refer to Human Participation | Our Research | Newcastle University for more information.



The default position is that projects involving human participants should be reviewed by a Faculty Ethics Committee. Exceptions are confined to studies in which interactions with participants are limited to those which most people would regard as trivial. For example, asking uncontentious questions in surveys or observing people undertaking normal activities. If in doubt please ask for advice.

Does the study involve any of the following?

*If you have answered yes to question e. please provide details at the relevant opportunity (e.g. upload questionnaires/images to be used)

Please Note: Depending on the details of this project, this may require NHS approval. You will be given further clarification if the project is awarded. You are also advised to consult the JRO Policy Regarding the Participation of Volunteers in Research Projects.

* If your study involves obtaining biological fluids (e.g. blood, saliva, urine), primary cells, or tissue samples, you will need to complete the mandatory Human Tissue e-learning training. To gain access to the training, please email humantissueresearch@newcastle.ac.uk. Due to University policy you will also need to contact Chris Morris at c.m.morris@newcastle.ac.uk to provide information on the tissue samples that you propose to collect.

Select all that apply

- a. The study involves children or other vulnerable groups; including those who are relatively or absolutely incapable of protecting their own interests, or those in unequal relationships e.g. participants who are subordinate to the researcher(s) in a context outside the research?
- b. The study requires the co-operation of a **gatekeeper** defined as someone who can exert undue influence) for initial access to the groups or individuals to be recruited e.g. students at school, members of a self-help group, or residents of a nursing home? NB. The IoN & School of Psychology volunteer pools are not considered gatekeepers in this case.
- c. It is necessary for participants to take part in the study without their knowledge and consent e.g. covert observation of people in non-public places?.
- d. Deliberately misleading participants in any way?
- e. Discussion of sensitive topics e.g. sexual activity or drug use?*
- f. The administration of drugs, placebos or other substances (e.g. food substances, vitamins) to the study participants.
- g. Invasive, intrusive or potentially harmful procedures of any kind? Including any procedure which is potentially harmful, has potential side effects or may reveal incidental findings. This includes, but is not limited to medical imaging procedures, magnetic stimulation procedures, hypnosis and vigorous exercise.*
- h. Obtaining biological fluids (e.g. blood, saliva, urine), primary cells, or tissue samples?*
- i. Pain or discomfort?
- j. Psychological stress, anxiety, harm or negative consequences beyond that encountered in normal life?
- k. Prolonged or repetitive testing i.e. more than 4 hours commitment or attendance on more than two occasions?
- l. Financial inducements (other than reasonable expenses and compensation for time)?

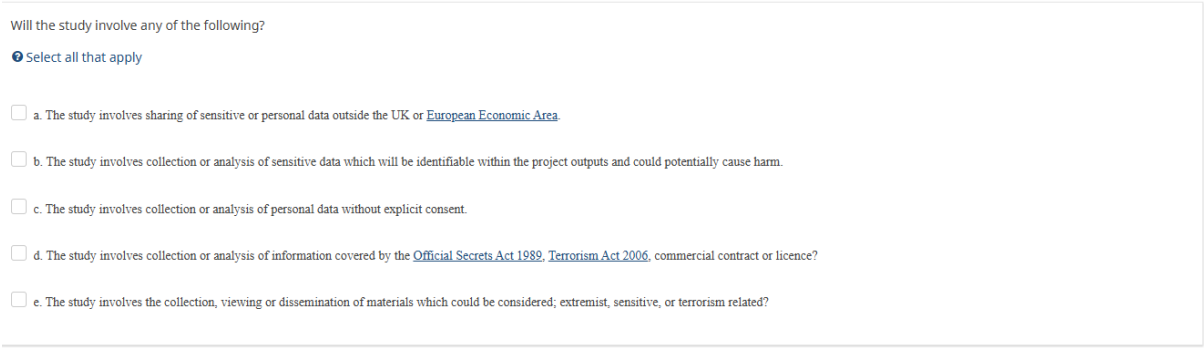
*Does the research involve the viewing, usage or transfer of sensitive data or personal data as defined by the General Data Protection Regulation (GDPR) or data governed by statute such as the Official Secrets Act 1989 / Terrorism Act 2006, commercial contract or by convention e.g. client confidentiality? (If you are unsure please tick YES and complete the sub-questions).

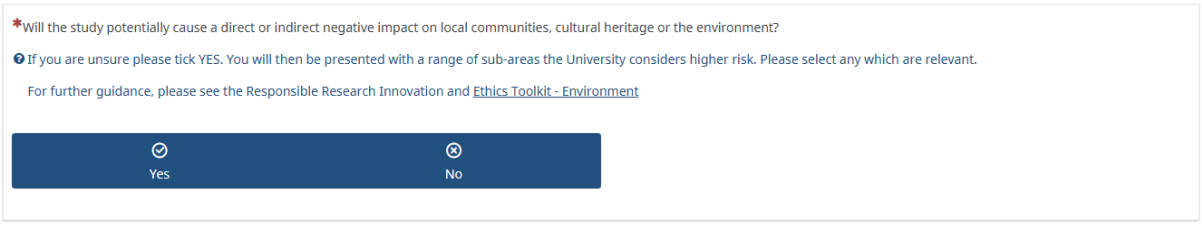
If you are unsure please tick YES. You will then be presented with a range of sub-areas the University considers higher risk. Please select any which are relevant.
Note: This question relates to the nature of the data rather than the collection methods which should be covered elsewhere.

For further guidance, please see Ethics Toolkit - Data

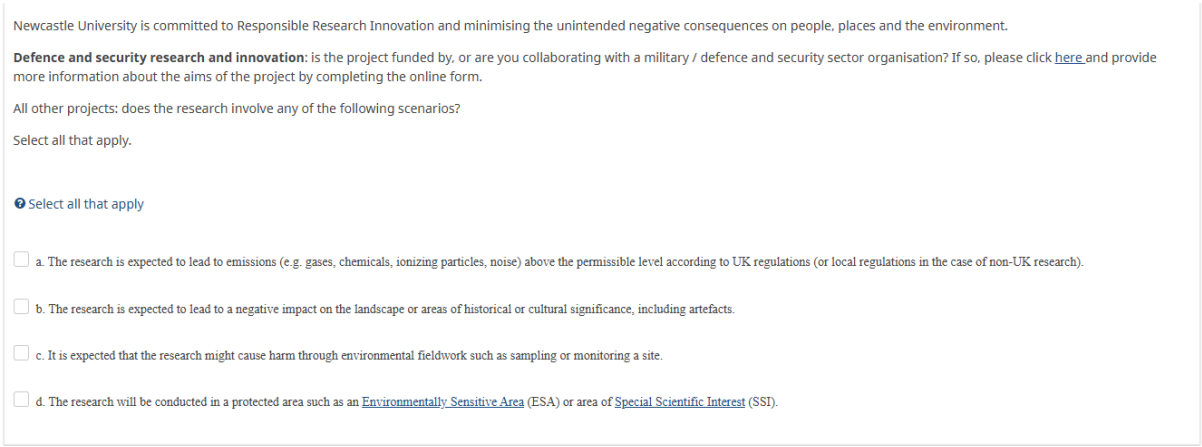
Yes | No

If you answer yes, please complete the relevant sub questions below.



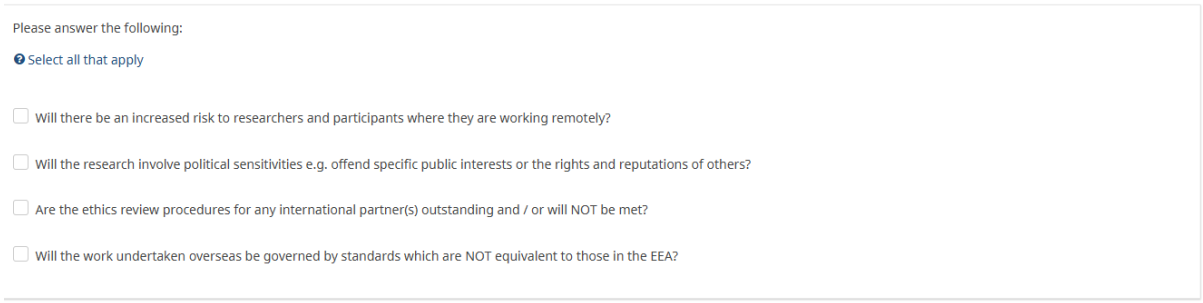


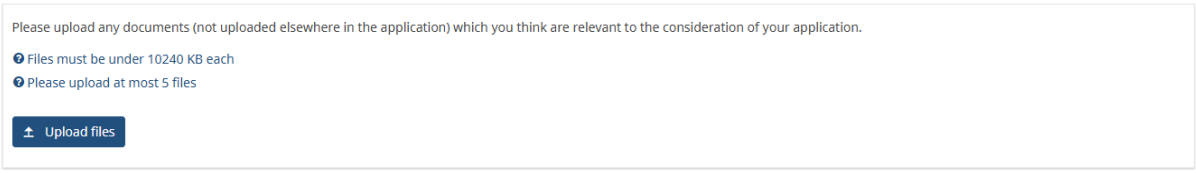
If you answer yes, please complete the relevant sub questions below. Please note that there is not a question relating to defence and security, there is a separate link in the description that you need to access which will re-direct you to a separate online form. For more information Defence and Security Research | Our Research | Newcastle University.





If you answer yes, please complete the relevant sub questions below.

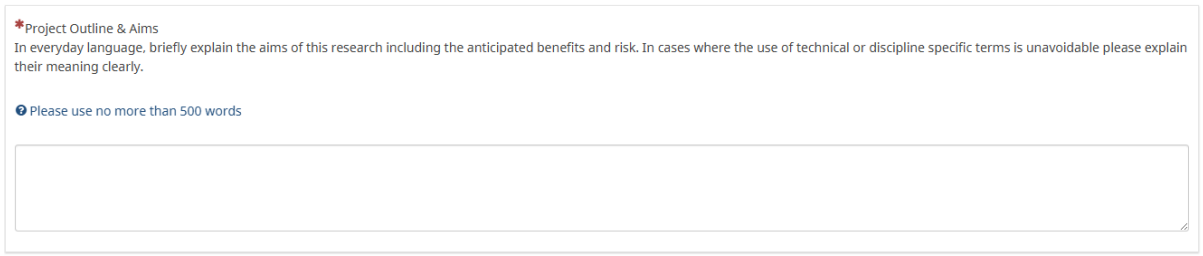


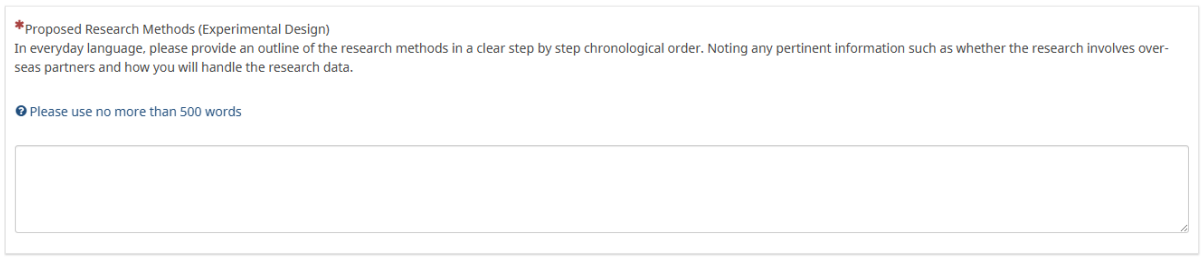


You can upload a maximum of 5 documents. These should include key information to allow and ethics reviewer to assess your application. Such as a project plan, participant information sheet, consent forms, risk assessment and data management plan.

Additional animal related questions

If you selected yes to the previous animal question, then the following additional questions will appear at the bottom of the form.





*Will the work be covered by an existing home office licence?

This can be an establishment licence, personal licence or project licence. Additional guidance is available here. If you are unsure please contact awerb@newcastle.ac.uk.

Yes | No

*Home Office Reference:

*Licences and Permissions

	Yes	No
Do you intend to apply for a Home Office Licence		
Have you discussed the project with the Director of the Comparative Biology Centre?		
Have you discussed the project with a Home Office representative?		
If your project uses wild caught animals, have you obtained the appropriate permissions? (Enter "no" if not applicable)		

*Why is the use of animals necessary in this project?

Please use no more than 500 words

*What kinds of animals will be used and how many of each?

Please use no more than 500 words

*What will happen to the animals during and after the project?

Please use no more than 500 words

*Who will be carrying out the project? Briefly describe the relevant experience and expertise of the persons involved?

Please use no more than 500 words

*Where will the animals be housed / located? If the animals are being observed in the wild or in establishments such as zoos, has permission been obtained from the appropriate authority? For any work outside the UK, do the standards of animal care and accommodation comply with UK codes of practice? If not explain how they differ.

Please use no more than 500 words

*What checks will be made on the animals, how frequently and by whom? What actions will be taken in the event of any adverse effects on the animals?

Please use no more than 500 words

*Please describe how data will be accessed, how participants' confidentiality will be protected and any other relevant considerations. Information must be provided on the full data lifecycle, from collection to archive.
Alternatively please upload a copy of your data management plan below.

If you do not have a data management plan, University approved funder-specific plans are available from the Digital Curation Centre.

Please upload a copy of your data management plan (if required).

Please upload at most one file

Upload file

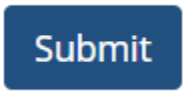
Please use the table below to record details of any licences or permissions required and / or applied for e.g. Local Authority District, Natural England etc. Ensure you include the reference, status and the date it was granted (if applicable).

If have not applied for a licence but you intend then please include but mark the status as 'to be applied for' or 'pending'. Evidence of any granted permissions should be provided to the relevant ethics committee via the upload question below..

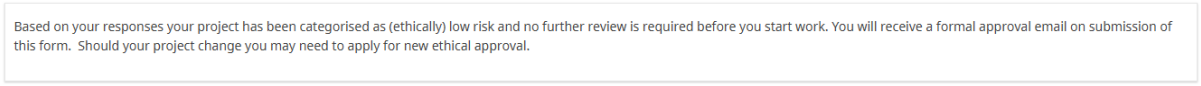
	Permission / Licence	Awarding Body	Reference Number	Date of Permission	Status e.g. Granted / Pending
1					
2					
3					
4					
5					

*What are the potential risks to the researchers themselves? This may include: personal safety issues, such as those related to lone working, out of normal hours working or to visiting participants in their homes; travel arrangements, including overseas travel; and working in unfamiliar environments. Please explain any risk management procedures that will be put in place and note whether you will be providing any risk assessments or other supporting documents.

Please use no more than 300 words. If you prefer you can upload any relevant risk assessments (travel, project etc.) below.



Once you have submitted your completed application, if the project has been assessed as low risk you will receive the following message and an email confirmation:


Based on your responses your project has been categorised as (ethically) low risk and no further review is required before you start work. You will receive a formal approval email on submission of this form. Should your project change you may need to apply for new ethical approval.

If your project is assessed as high risk, an automatic message will confirm which Faculty Ethics Committee it has been referred to or for animal research it will be sent to the Animal Welfare Ethics Review Board (AWERB). If your project is flagged as requiring further review from an NHS Research Ethics Committee, you will need to submit an application to the appropriate external health authority ethics committee through the National Research Ethics Service (NRES) - see http://www.hra.nhs.uk/research-community/ for further information.

At the point of submission please save a pdf copy of your answers as you will not be able to access it once you close the browser window.