

This template must be completed for all research grant applications and should accompany the University's Research Proposal form (RS1) for approval by the Head of Department.
(Additional departmental information may be incorporated as appropriate, for example from an existing resources form).

Please note that this procedure is intended to help researchers consider ethical implications of research activity. Researchers are responsible for deciding, in conjunction with their departmental guidelines and professional disciplinary standards, whether a more extensive review is necessary.

To be completed by Principal Investigator/Staff member

Brief Title of Project	
Names of Principal/other Investigators	

SECTION 1: COMPLETION FOR ALL RESEARCH

Are there ethical implications concerned with the following general issues? If yes, please provide details below	
1. Data storage (eg Confidentiality, availability, length of storage, etc)	
2. Are you free to publish the results? eg Are there any restrictions raised by contractual issues?	
3. Effect on/damage to the environment eg Hazardous waste may be produced; water or air might be polluted; injurious pathogens might be released; damage to ecological systems/habitats.	

Specific Issues		
4. Does the research involve human participants in any way? (Please note if you are processing personal data you need to tick 'Yes'.)	No	Complete only Section 1
	Yes	Complete Sections 1 and 2
5. Does the research involve animals in any way?	No	Complete only Section 1
	Yes	Complete Sections 1 and 3

Demonstration of Ethical Considerations <i>Please outline the ethical issues which will need to be managed during the course of the activity.</i>

Declarations

I confirm that the statements in Sections 1-3 describe the ethical issues that will need to be managed during the course of this research activity.

Principal Investigator	Signature: Date:
Second reader (This will normally be a person <i>external</i> to the project team.)	Signature: Date:
Head of Department	Signature: Date:

Please return this form to your Departmental Research Ethics Officer. (Issues will be monitored for incorporation into an annual departmental report to be submitted to the University Ethics Committee.)

SECTION 2: FOR COMPLETION IF YOUR RESEARCH INVOLVES HUMAN PARTICIPANTS

If any of the answers to these questions are 'yes', please confirm in the space below how the ethical issues will be managed during the course of the activity.

Compulsory question for consideration by all disciplines:

	Yes	No
<p>Will the study involve obtaining or processing personal data relating to living individuals, (eg involve recording interviews with subjects even if the findings will subsequently be made anonymous)?</p> <p><i>Note: If the answer to this question is 'yes' you will need to ensure that the provisions of the Data Protection Act are complied with. In particular you will need to seek advice to ensure that the subjects provide sufficient consent and that the personal data will be properly stored, for an appropriate period of time). Information is available from the University Data Protection Website and dataprotection-queries@lists.bath.ac.uk</i></p>		

Departments may amend the following list to include topics of particular relevance to their discipline(s).

	Yes	No
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (eg children, people with learning disabilities)		
2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (eg students at school, members of self-help group, residents of a nursing home)		
3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non-public places)		
4. Will the study involve discussion of sensitive topics? (eg sexual activity, drug use)		
5. Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants and/or will the study involve invasive, intrusive or potentially harmful procedures of any kind?		
6. Will blood or tissue samples be obtained from participants? <i>Note: If the answer to this question is 'yes' you will need to be aware of obligations under the Human Tissue Act, see further information at http://www.bath.ac.uk/internal/ethics/committee/HTA.html</i>		
7. Is pain or more than very mild discomfort likely to result from the study?		
8. Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?		
9. Will the study involve prolonged or repetitive testing?		
10. Will financial inducements (or other expenses and compensation for time) be offered to participants?		
11. Will the study involve recruitment of patients or staff through the NHS? <i>Note: If the answer to this question is 'yes' you will need to submit an application to the NHS through IRAS, see: http://www.nres.npsa.nhs.uk/applications/integrated-research-application-system/</i>		

Section 2: Demonstration of Ethical Considerations

Please complete this section if any of the answers to the above questions are 'yes'.

SECTION 3: FOR COMPLETION IF YOUR RESEARCH INVOLVES ANIMALS

	Yes	No	In progress
1. Has the project been submitted to and approved by the Ethical Review Committee for the purposes of Home Office approval under the Animals (Scientific Procedures) Act 1986?			
2. If the research is outside the scope of the Animals (Scientific Procedures) Act 1986 is it controlled by any other UK legislation? If so, please give details below.			
3. If the research is not controlled by UK legislation have the ethical implications of the project been considered by the Ethical Review Committee? http://www.bath.ac.uk/research/docs/nonlicencedthicareviewformfinalmay2010-2.doc			

Section 3: Demonstration of Ethical Considerations

This section is available for submission of further details relevant to Section 3.

PROCESS

The University of Bath requires staff to consider the potential ethical implications of all research undertaken. The template is designed to be completed and accompany all research grant applications for consideration by the Head of Department.

(Researchers may also wish to consider using this ethics template for any additional research-related activities, or as an aid to the consideration of ethical implications of student projects.)

1. This template *Ethical Implications of Research Activity* should be completed by Principal Investigators (PIs) for all research proposals. The PI will pass the completed template to a Second Reader and then on to the Head of Department (to accompany RS1 and the research grant proposal). The completed signed template should then be passed to the Departmental Research Ethics Officer (DREO), who will review issues for action and inclusion in Departmental Annual Monitoring Report. (The DREO is also available to advise on identifying/assessing ethical issues and completion of this form.) Where significant ethical issues arise on which additional guidance is required, this can either be given within the Faculty/School (particularly where there is an Ethics Committee) or exceptionally by the University Ethics Committee.
2. If any significant issues arise during the project they should be investigated by the Department and, if appropriate, forwarded for guidance within the Faculty/School/University (see 1 above). At the end of the project, to reflect good departmental practice, the PI will advise the Departmental Research Ethics Officer if ethical issues changed during the course of the project.
3. The DREO will prepare an Annual Monitoring Report for submission to the Head of Department via any relevant Committees for review and to the University Ethics Committee for monitoring purposes (standard template EIRA2). The University Ethics Committee reports to Senate via minutes.

Queries on the University ethics process can be sent to: ethics@lists.bath.ac.uk