# ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS, THEIR PERSONAL DATA OR TISSUE, AND ITS CONDUCT

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# 1 General Principles and Statements

The ethics policy of the University of Bradford (UoB) for research involving human participants, their biological material (tissue) or data, is to treat all participants with respect and protect their rights according to the principles of the Declaration of Helsinki and the specific requirements of UK legislative and regulatory bodies with oversight of our work, as well as ensuring ethical conduct of research by UoB researchers. This will also provide protection for participants, UoB researchers and the University. It is part of the policy to operate and monitor systems to scrutinise the design and conduct of all such research for appropriate ethics. It is expected that ethics will be considered by researchers from the inception of their research through to its conclusion; education and training are used to support them in this.

# 2 Scope and applicability of the Research Ethics Policy

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue applies to:

- all University staff and registered students who conduct, or contribute to, research activities involving human participants, personal data or human tissue, whether these take place within or outside University premises and facilities; and

- all individuals who, although they are not members of the University, conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises and facilities.

This specifically includes research undertaken by non-academic departments of the University of Bradford, and administrative research undertaken within academic departments or faculties. For further definition and discussion of these activities and the procedures for their ethical review, see Research Ethics Policy Note no. 7, 'Administrative research within the University'.

The University of Bradford's Policy is designed to complement the National Health Service (NHS) ethics review system administered via the Health Research Authority (HRA) using its Integrated Research Approval System (IRAS) and NHS Research Ethics Committee (NREC) system. HRA have a requirement that submissions via IRAS must have been scrutinised for quality by the submitting institution. The University's Ethics Review Procedure therefore complements the functions and remit, of the HRA ethics review system. It is thus required to work alongside IRAS to ensure that submissions from the University have been checked for completeness, sense and fundamental ethical issues. (A full ethics review is not required as that is the remit of the NREC.) For further detail about ethics review via the NHS ethics review system, and information about which University research requires NHS, rather than University, ethics approval, see Annex II.

Other external bodies, such as some public-sector social care providers or the armed forces, also have their own research ethics policies and review procedures. In the case of social care research, see Research Policy Note no. 5. In all other cases, contact the Chair of the relevant REP for guidance.

Research funding bodies may have their own research ethics policies and/or requirements, which must be met as a condition for receiving research funding. In most cases, such as the Concordat on research ethics policy of the governmental Research Councils, these have informed the University's Research Ethics Policy and Governance documents. This reinforces the need for observance of the University's Policy and its associated procedures. In some cases, there may be external policies and requirements that represent an *extra* layer of research ethics governance. Adherence to these must be in addition to, not an alternative to the University's Policy.

The final external stakeholders to be considered are professional bodies and learned societies, which may also have their own research ethics policies, guidelines and requirements. While learned societies' research ethics guidelines are useful resources that may offer supplementary guidance, the University's Policy must, in the first instance, take precedence for University staff and student members and with respect to research conducted on University premises. External bodies that have professional licensing or registration responsibilities are, however, a different matter and their external principles have a different weight. Although it is unlikely that professional ethical codes will conflict with the University's Policy, in the event of a perceived conflict of this kind, the member of staff concerned should contact the Chair of the CER for guidance. Conflict between ethical requirements of overseas authorities and the policy of the University of Bradford (UoB) for work involving UoB researchers will usually be resolved in favour of the overseas authorities but again, guidance will be given through the CER and its Research Ethics Panels.

Legislative and regulatory requirements for ethics in research require that an institution's ethical policies are implemented by statutory procedures and processes with appropriate oversight and monitoring. The mechanisms by which this is achieved at UoB are detailed in Annexes II and III.

## 3 Fundamental principles of research ethics

The University of Bradford's vision is 'Making Knowledge Work'. The University's mission is to conduct fundamental and translational research having positive impact on the communities with which it engages. The University currently makes a huge contribution to some of the most important and challenging issues facing the world today with its work having particular impact on the areas of Advanced Health Care, Innovative Engineering, and Sustainable Societies. The University seeks to sustain this impact and to make further significant improvements in these areas for the benefit of mankind.

The paramount principles governing all University of Bradford research involving human participants, personal data and human tissue derive from the Declaration of Helsinki (most recent update: 2013). This includes but is not limited to respect for the participants' autonomy, dignity, rights, safety and well-being. All such research is therefore to be scrutinised to ensure that it maintains respect for autonomy, is beneficent, non-maleficent, just and proportionate.

### 3.1 Participants' rights

In May 2018 the General Data Protection Regulation (GDPR) replaced the Data Protection Act 1998 (DPA). Guidance on this new law are provided on the University of Bradford's web pages at the following link: https://www.bradford.ac.uk/data-protection/gdpr-explained/ Participants have a right to:

- consent to participate, withdraw from, or refuse to take part in research projects;
- confidentiality: personal information or identifiable data should not be disclosed without participants' consent;
- security of their data: data and samples collected should be kept secure and anonymised where appropriate; and
- safety: participants should not be exposed to unnecessary or disproportionate levels of risk.

### 3.2 Researchers' obligations

According to the principles of this Policy, researchers have an obligation to ensure that their research is conducted with:

- honesty;
- integrity;
- minimal possible risk to participants and to themselves; and
- respect for other people, their values and their cultures.

Guidance on the interpretation and application of these principles is detailed in this Policy document.

These principles of research ethics are recognised in international and regional treaties, as well as national laws. Breach of these principles may be, in some instances, a civil or criminal offence. The principles and requirements outlined in this Policy reflect the principles of research ethics but do not displace a researcher's obligation to comply with any relevant legal and regulatory requirements. Furthermore, all staff are bound by the codes of the University to behave in an ethically appropriate manner in all aspects of their employment, not only research.

Ethical research conduct does not require the avoidance of potentially high-risk research. An ethical approach to research involves, rather, proper recognition of, and preparation for, risks, and their responsible management. Ethical research is therefore a matter of being risk aware, not risk averse.

Finally, if research ethics are to be more than merely formulaic and procedural they must be meaningful and relevant to - and accepted by - researchers. To this end, this Policy specifies an ethics review procedure that is devolved to a Committee for Ethics in Research (CER), and Research Ethics Panels (REPs) answerable to that Committee in the first instance, and which depends on ethically aware, self-reflective researchers taking responsibility for implementing the principles and requirements embodied in the Policy. To that end, it is also expected that every member of staff actively involved in research and all students will attend appropriate training or education in research ethics.

## 4 Introducing research ethics

The University's definition of research is taken from the Research Excellence Framework 2014: **'a process of investigation leading to new insights, effectively shared'**. This applies to all research undertaken by, or on behalf of, the University, across the full range of academic disciplines, from the arts and humanities to the natural sciences (whether funded or not), and also encompassing administrative research (undertaken within, or on behalf of, professional services departments or academic faculties/departments), and research undertaken by or within University research centres/institutes, advisory/consultancy services and subsidiary companies. This definition includes:

- work of educational value designed to improve understanding of the research process;
- work of relevance to commerce and industry;
- work of relevance to the public and voluntary sectors;
- scholarship supporting the intellectual infrastructure of subjects and disciplines (such as dictionaries, scholarly editions, catalogues, and contributions to research databases);
- the invention, design and generation of ideas, images, performances and artefacts, where these lead to new or substantially improved understanding; and
- the experimental use of existing knowledge to develop, design and construct new or substantially improved materials, devices, products and processes.

This definition of research excludes:

- the routine testing and analysis of materials, components and processes - e.g. for the maintenance of national standards - as distinct from the development of new analytical techniques;
- routine audit and evaluation, within the established management procedures of organisations; and

- the development of teaching materials that do not embody original research.

The University of Bradford's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, applies only to research involving human participants, personal data and human tissue. What is understood by these terms is discussed in Research Ethics Policy Note no. 1. It does not cover broader ethics or integrity issues that may apply to any type of research (e.g. ethical issues surrounding the source of funding for research), or ethical issues surrounding the use of animals in research.

## 5 Research ethics at the University of Bradford

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue recognises that the responsibility for maintaining ethical conduct lies, in the first instance, with researchers themselves. If researchers do not take responsibility for the ethical conduct of their own research, defensible research ethics will be an unrealisable goal. To this end, responsibility for operating the University's Ethics Review Procedure, informed by the Policy, is devolved to the CER and REPs.

Within this devolved framework, the University recognises that diversity enriches and strengthens its research culture and performance. Diversity means that research activities involving human participants, personal data and human tissue may differ widely from one department or funding unit to another. Thus the ethical issues relating to human participation in research may also differ considerably from one academic department or funding unit to another. Nevertheless, they should be assessed within a common framework accepted by all departments or funding units.

This means that the formal ethical review of research proposals involving human participants, personal data or human tissue is best carried out by the REPs on behalf of the CER, within the broad parameters provided by this Policy and the Research Ethics Approval Procedure.

The key principle underlying the Research Ethics Approval Procedure is that researchers should reflect on the ethical issues that are raised by their research and be able to justify, in ethical terms, the practices and procedures that they intend to adopt during their research. Matters of research ethics are often not 'black and white', and there is no 'one size fits all approach'. This Policy therefore aims to set a clear framework and guiding principles to assist researchers in addressing the ethical issues that may arise in the course of their research.

## 6 Research governance and responsibilities

According to this Policy, Deans and Heads of School are responsible for the conduct of the research that is undertaken in their departments. They are therefore responsible for ensuring that departmental researchers have access to appropriate ethics review procedures for research activities that involve human participants, personal data or human tissue, in line with the University's Ethics Policy Governing Research Involving Human Participants, Personal

Data and Human Tissue. They are also responsible for ensuring that all research-active staff and students are familiar with the content of the Policy. As in all other matters, individual researchers are expected to follow the leadership of their Dean and Head of School.

In everyday research practice, however, the first responsibility for considering, respecting and safeguarding the dignity, rights, safety and well-being of human participants involved in research lies with the lead researcher (e.g. the principal investigator or supervisor). Nevertheless, this practical principle does not absolve more junior, or more senior, staff, or students, from personal responsibility in this respect, or from their responsibility to disclose any failure to meet the principles of conduct required by the Policy.

All researchers at the University of Bradford, whether staff members or students, are responsible to a range of stakeholders for their conduct during, and delivery of, their research activities involving human participants. These are:

- the human participants involved (as defined by this Policy);
- society in general;
- the University of Bradford;
- fellow researchers, whether colleagues or students;
- colleagues who undertake research support activities;
- their department or funding unit;
- the research funder; and
- their academic profession or discipline.

The University Committee for Ethics in Research (CER) is responsible to the University's Ethics Committee and the terms of reference for this committee are provided in section 4.1. The purpose of the Committee is to recommend to the University Ethics Committee policies and procedures for the ethical conduct of research. This Committee will oversee all research ethics activity for the University and will approve actions for the same purpose.

Service user representatives are members of the CER and play a leading role in decision-making. Service user representatives are also members of the Biomedical, Natural, Physical and Health Sciences (BNPHS) Research Ethics Panel (REP), the Humanities, Social and Health Sciences (HSHS) REP, and the IRAS sub-panels.

### 6.1 Terms of Reference for the University Committee for Ethics in Research (2021-2022):

The Committee will consider all research undertaken under the purview of the University and will be responsible for policy and strategy for research ethics.
For the purpose of these Terms of Reference, ethical consideration and conduct will include

research involving human participants, tissue and data, research integrity and sources of research funding. It will exclude research involving animals.

- The Committee will operate procedures no less rigorous than those suggested or required by relevant statutory or professional bodies.
- The Committee will be impartial, supportive, and developmental and dedicated to the promotion of ethical standards in research.
- The Committee will liaise with external research ethics committees, including those governed by the Health Research Authority.
- The Committee will subject its own activities to continuous review and present an annual report on its activities to University Ethics Committee.
- The Committee will raise awareness of research ethics amongst staff and students by providing training and relevant events across the University.

The Committee will advise or recommend in the following areas:

| **Detail** | **Power Delegated From:** |
|---|---|
| Advise University bodies, staff and students as appropriate on all matters pertaining to research ethics within the remit of this Committee | University Ethics Committee |
| Recommend the necessary administrative arrangement for operating the policies and procedures | University Ethics Committee |
| Monitor the activities of delegate committees | University Ethics Committee |

The Committee will make the following decisions:

| **Detail** | **Power Delegated From:** |
|---|---|
| Approve the Terms of Reference, membership, policies and procedures of the delegate committees | University Ethics Committee |
| Act as an appeals body for delegate committees | University Ethics Committee |
| Issue guidelines and codes of practice, where appropriate on any matter pertaining to research ethics and review | University Ethics Committee |

## 7 The objectives of the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue

This Policy is intended to:

- protect the dignity, rights, safety and well-being of human participants;
- codify the University's position on research ethics for research involving human participants, personal data and human tissue;
- demonstrate a commitment to high quality, transparent and accountable research ethics throughout the University, from senior management policy-making to the practicalities of individual staff and student research projects;
- warrant and inform the operation of the University's Ethics Review Procedure within departments and funding units;
- provide guidance and training on research ethics involving human participants, personal data and human tissue for all staff and students;
- encourage an organisational research culture based upon defensible standards of research practice;
- reduce risks to the University, departments and funding units, and individual researchers;
- strengthen the eligibility and quality of University research funding applications; and, not least,
- enhance the University's reputation with the general public and wider society, within the academic professions, and with funding bodies and external auditors.

## 8 Good research practice

Observing recognised research ethics principles is basic to good research practice in general. The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue should, therefore, be read alongside:

- the University's Good Research & Innovation Practices Policy; and
- the University's Research Misconduct Guide.

Upholding ethical standards in the conduct of research means accepting and respecting

principles of integrity, honesty and openness. Conducting research with integrity means embracing intellectual honesty and accepting personal responsibility for one's own actions.

Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the cultural, economic, psychological, physiological, political, religious, spiritual and social consequences of it for the human participants involved. Researchers must be aware that impact may differ according to the participants' protected characteristics, i.e. age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

Researchers should always consider their research from the perspective(s) of the participants and any other people who may possibly be affected by it. Researchers can undertake the University's unconscious bias e-learning training module to assist with this.

Research misconduct will be monitored via the University's management structure or via the University's whistleblowing procedures. Both routes involve reporting of misconduct to the Chair of the Committee for Ethics in Research and via that body, to the University's Ethics Committee. An annual research misconduct report is produced by the Chair of the Committee for Ethics in Research; this is presented to University Council and made publically available via the University website, in accordance with the concordat to research integrity, to which the University is a signatory.

Comprehensive training in the application of research ethics is available at the University. There is mandatory training for newly appointed researchers as part of their induction process. New staff are required to undertake a training session, which is available twice a year and an e-learning module is under development. Once the e-learning module is available, all staff involved in research will be expected to complete it. All taught courses at the University, both post-graduate and undergraduate, are expected to contain an element of research ethics. All staff and students involved in research are thus expected to have undertaken appropriate research training. This is reinforced by Research and Innovation Services.

## 9 Safety and wellbeing

Issues of safety and wellbeing are at the heart of research ethics. According to this Policy, researchers have a responsibility to protect all participants as well as they can from avoidable harm arising from their research. Researchers also have a responsibility to consider their own safety and that of any co-researchers or collaborators.

As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those they encounter in their normal lifestyles. If it is expected that harm, unusual discomfort or other negative consequences might occur in prospective participants' future lives as a result of participation in a research project, the researcher should highlight this during the ethics approval process, and discuss the matter fully with participants during negotiations about informed consent. Further detailed discussion of informed consent, and safety and well-being, can be found in Research Ethics Policy Notes nos. 2 and 3.

## 10 Equality and diversity

All research undertaken at the University of Bradford must comply with University policies on equality and diversity.

The University's Equality and Diversity Committee has responsibility for the development, implementation, monitoring and review of policy and procedures and practice.

**Reference**

World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. JAMA November 27, 2013 Volume 310, Number 20

University of Sheffield, Ethics Policy Governing Research Involving Human Participants Personal Data and Human Tissue: General Principles And Statements. Retrieved from https://www.sheffield.ac.uk/polopoly_fs/1.755691!/file/Ethics_Policy_Senate_Approved.pdf

# Appendix I - Expectations of Researchers (staff and students)

The University expects the researcher to follow a particular code of practice, so have developed the good research practice guide (GRP).

The GRP outlines the University's position on research practice and its expectation of research staff and students.

## University

The University of Bradford expects the researcher to carry out the research effectively and accurately, in accordance with the Research Ethics Panel (REP) and the University's Code of Practice.

The University is represented by the researcher on any research study, consequently affecting the University's credit and reputation.

## Research Team

The research team is expected to conduct themselves in accordance with the GRP and adhere to the research ethics policy and University regulations.

The research team is expected to carry out research in agreement with internal and external stakeholders, to ensure smooth running of the research projects.

## Principal Investigator/Lead Researcher

The primary responsibility for considering, respecting and safeguarding the dignity, rights, safety and wellbeing of participants involved in research lies with the lead researcher.

## Participant

Participants should expect: to be treated with respect; only to be involved with research that has novelty and is designed to gain beneficial knowledge.

The ethical implications of the work should not have any unduly adverse effect on the people involved.

# Appendix II - Research Ethics Approval Process

**Ethics Website:**

https://unibradfordac.sharepoint.com/sites/research-and-knowledge-transfer-support-intranet/SitePages/Homepage-Ethics.aspx?web=1

**Ethical approval must be obtained before any research begins and before potential participants are approached. Retrospective approval cannot be given.**

For guidance on whether you will need NHS or University approval, please see https://unibradfordac.sharepoint.com/sites/research-and-knowledge-transfer-support-intranet/SitePages/University-or-NHS-Approval.aspx?web=1

Please submit all completed ethics checklists and application forms for review to: ethics@bradford.ac.uk

Please submit all completed IRAS checklists and application forms for review to nhs-ethics@bradford.ac.uk

## Stages of UoB Ethics Approval via HSHS or BNPHS REP

NB Correct at time of writing. Please see https://unibradfordac.sharepoint.com/sites/research-and-knowledge-transfer-support-intranet/SitePages/Stages-of-UoB-Ethics-Approval-via-HSHS-or-BNPHS-REP.aspx?web=1 for the current version.

### Stage 1

If the study involves human participation, then the Ethics checklist needs to be completed. All questions on the checklist should be completed.

If no ethical implications are identified the checklist should be signed by the principal investigator (PI) and sent to the Ethics Administrators in the Research Support Unit at ethics@bradford.ac.uk

The checklist will be reviewed by the Chair of the appropriate Research Ethics Panel (REP), the PI will be informed of approval.

### Stage 2

If the checklist highlights that the project needs ethical approval, then the Ethics Application should be completed using the Guidance Notes for Ethics Application. Both the signed Ethics Checklist and Ethics Application form should be sent to the Ethics Administrators in the

Research Support Unit at ethics@bradford.ac.uk along with any supporting documents as ticked on the application form.

If you are planning on traveling to a high risk area, as advised by the Foreign and Commonwealth Office, in the course of your research project then the risk assessment form for traveling to high risk areas which can be found on the Finance Insurance webpage, needs to be completed, signed by your Dean and submitted to finance. A copy of this form must also accompany your ethics checklist and application form when seeking approval.

**(STAFF ONLY: If the application is for generic approval (covers similar projects with no ethical difference done over a number of years), you will need to complete a Generic Ethics Application form)**

## Stage 3

The Ethics Administrators in the RSU will check the form for completeness. If it is incomplete it will be sent back, this will delay the process.

## Stage 4

The Ethics Administrators will select two Ethics Reviewers from the appropriate Research Ethic Panel (REP). Reviewers will be members of the REP.

## Stage 5

The Ethics Administrators in the RSU receive the Research Ethics Reviewers Comments Form back (reviewers are given a timeframe of two weeks to complete and return the form).

## Stage 6

The Reviewers will recommend in their judgment one of the following:

## Approved

This means you will receive a formal email to indicate that you have ethics approval from the University - the reviewers may have indicated some recommendations but these are for information only and do not need to be acted on.

## Minor Amendments Required

If one or more of the reviewers indicate that minor amendments are required, then you will receive a 'Required' email with both reviewers' comments forms, and will be asked to make the required changes and resubmit your application. A list of changes made and a track changes copy of each altered document should be returned when the application is resubmitted. Your amendments will be reviewed by both reviewers, even if one approved it originally, as any changes you have made, may alter their opinion. If both reviewers disagree with the changes made then they will discuss between them until it is resolved. If it cannot

be resolved between the reviewers, then the REP Chair will discuss with the lead researcher and/or reviewers as appropriate. You would then be informed of the outcome.

## Major Amendments Required

(This could be issues regarding comprehensibility, institutional reputational risk, risk to life etc.) If one or more of the reviewers indicate that major amendments are required, then you will receive a 'Required' email with both reviewers' comments forms, and will be asked to make the required changes and resubmit your application. A list of changes made and a track changes copy of each altered document should be returned when the application is resubmitted. Your amendments will be reviewed by both reviewers, even if one approved it originally or asked for minor amendments, as any changes you have made, may alter their opinion. If both reviewers disagree with the changes made then they will discuss between them until it is resolved. If it cannot be resolved between the reviewers, then the REP Chair will discuss with the lead researcher and/or the reviewers as appropriate. You would then be informed of the outcome. It may be that it would need to be discussed at a Panel meeting, to which you would also be invited.

## Application to be Seen by Panel

If for any reason either of the reviewers feel that your application would benefit from being seen by the Panel, then this will first of all be checked via the Chair of the REP, and if agreed, you will be invited to attend the next Panel meeting which are usually held monthly, where you will be able to discuss your research in more depth and answer any questions that the reviewers/panel members have about your study, to help the panel come to a decision on next steps. You will be informed after the Panel meeting of the outcome.

## Application not adequately completed – please discuss with supervisor and re-submit

If for any reason one or both of the reviewers feel that your application has not been adequately completed, then they may wish your application to be sent back to you and for you to spend time with your supervisor ensuring it is completed to a higher and more complete standard. You will then be expected to resubmit your application for full review.

## NOT be approved for the reason(s) given

If one or more of the reviewers indicate that they do not feel that your application should be approved, then this will be taken to the Chair to check whether they agree. If they do then you will not be able to proceed with your study. It may be that they ask for your application to come to the Panel, where it can be discussed further and a second assessment made.

# Stages of UoB Ethics Approval via the IRAS Application Review Panel

Please see https://unibradfordac.sharepoint.com/sites/research-and-knowledge-transfer-support-intranet/SitePages/Stages-of-UoB-Ethics-Approval-via-the-IRAS-Application-Review-Panel.aspx?web=1 for the current version.

## Stage 1

If you are unsure whether your research needs IRAS approval; first of all please complete this HRA Decision Tool, which will help you decide.

## Stage 2

If after completing the HRA Decision Tool above you feel that you will need IRAS approval, please complete the IRAS Checklist in the first instance, this will highlight further if you need to complete an IRAS application. If you feel after completing the IRAS Checklist that you do not need IRAS approval, then please complete and submit the Ethics Checklist instead and submit as per the instructions on the form and the process outlined in the tab above for approval via the BNPHS REP.

## Stage 3

If the checklist highlights that the project needs IRAS approval, you should login to the IRAS Portal or create yourself an account if you do not have one. You will then be able to complete the online IRAS application form. **Please use the free e-learning module to familiarise yourself with IRAS.** New users are advised to use the free e-learning tool to familiarise themselves with the layout, functionality and navigation that is available in IRAS. You do not need to register to use this tool and you can choose whether to work through the whole training module, which will take about 1 hour, or just dip into particular sections of the training. Both the signed IRAS Checklist and a downloaded copy of the IRAS Application form should be sent to the Ethics Administrators in the Research Support Unit at nhs-ethics@bradford.ac.uk along with any supporting documents as indicated on the IRAS Checklist.

The Ethics Administrators in the RSU will check the form for completeness and that all necessary supporting documents are included. If it is incomplete or anything is missing it will be sent back, which will delay the process.

## Stage 4

The Ethics Administrators will select two IRAS Reviewers from the IRAS Application Review Panel to review your checklist, application and documents.

## Stage 5

The Ethics Administrators in the RSU receives the IRAS Application Reviewer Comments Form back (reviewers are given a time frame of two weeks to complete and return the form).

## Stage 6

The Reviewers will recommend in their judgment one of the following:

## Approved

This means you will receive a formal email to indicate that the reviewers feel that your IRAS application and documents are ready for submission via the IRAS Portal - the reviewers may have indicated some recommendations but these are for information only and do not need to be acted on.

## Approved once the Minor amendments required have been satisfactorily addressed and approved by the reviewers

If one or more of the reviewers indicate that minor amendments are required, then you will receive a 'Required' email with both reviewers' comments forms, and will be asked to make the required changes and resubmit your application. A list of changes made and a track changes copy of each altered document should be returned when the application is resubmitted. Your amendments will be reviewed by both reviewers, even if one approved it originally, as any changes you have made, may alter their opinion. If both reviewers disagree with the changes made then they will discuss between them until it is resolved. If it cannot be resolved between the reviewers, the Chair will discuss with the lead researcher and/or reviewers as appropriate. You would then be informed of the outcome.

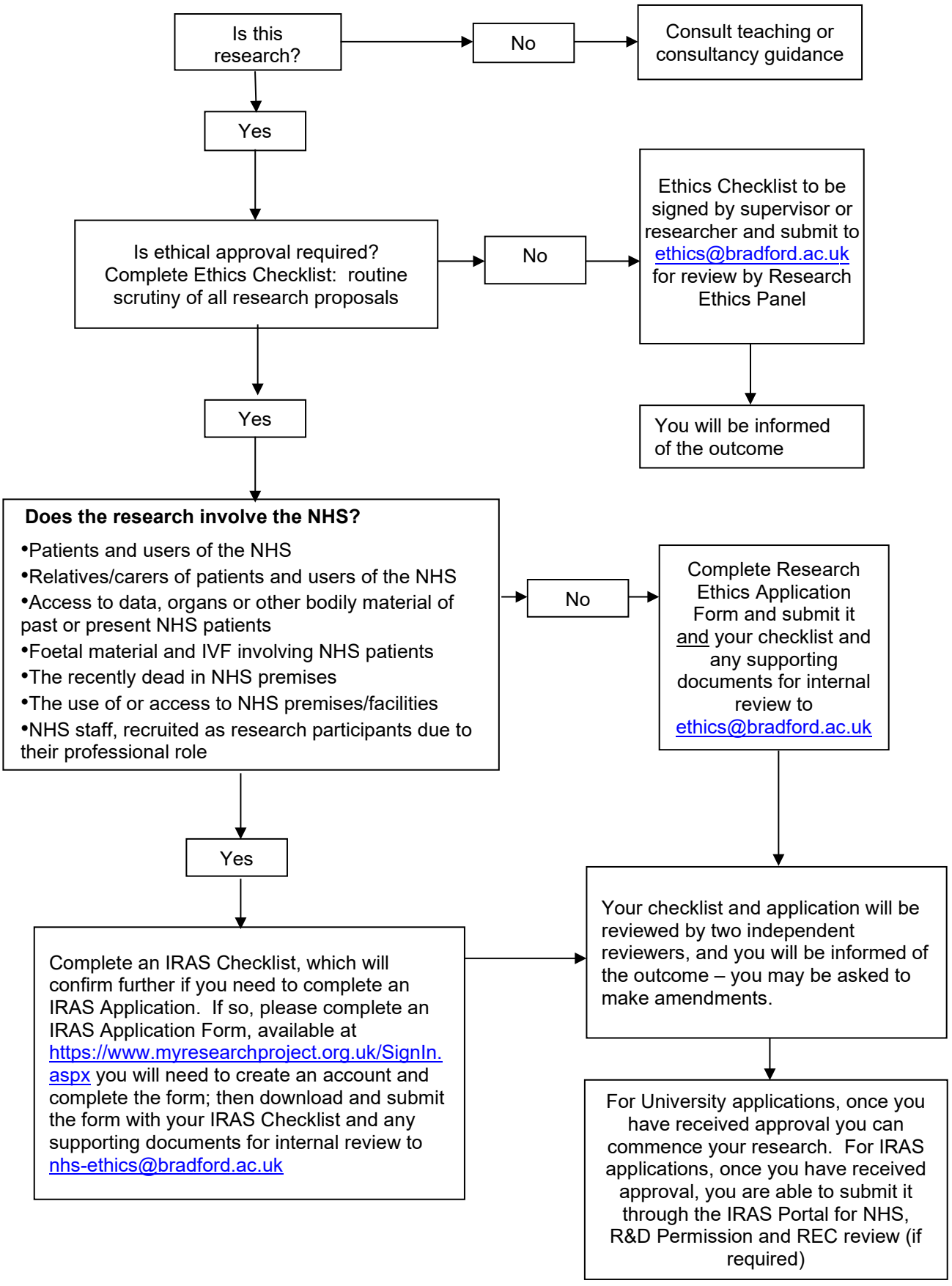
## Major Amendments Required, Application to be Seen by Panel

If the reviewers feel that major amendments are required and that your application would benefit from being seen by the Panel, this will first be checked via the Chair of the IRAS Panel, and if agreed, you will be invited to attend the next Panel meeting, which are held quarterly and ad-hoc where required, where you will be able to discuss your research in more depth and answer any questions which the reviewers/panel members have about your study, to help the panel come to a decision on next steps. You will be informed after the Panel meeting of the outcome.

## Application Incomplete for the reason(s) given

If for any reason one or both of the reviewers feel that your application has not been adequately completed, then they may wish your application to be sent back to you and for you to spend time with your supervisor ensuring it is completed to a higher and more complete standard. You will then be expected to resubmit your application for full review.

# Appendix III - Workflow Overview for Ethical Approval



# Process

# Appendix IV - Key Contacts

## RSU

Research and Innovation Administrator - Nazreen Akhtar, N.Akhtar67 @bradford.ac.uk, 01274 236554

Research Performance Administrator – Jagruti Lad, j.lad1@bradford.ac.uk, 01274 236225

## University Ethics Committee

Chair - Baroness Anne Taylor

Secretary – Katherine Wass, k.wass@bradford.ac.uk, 01274 23260

## Humanities, Social and Health Sciences Research Ethics Panel (REP)

Chair – Dr Clare Beckett-Wrighton

Administrators – Nazreen Akhtar, N.Akhtar67 @bradford.ac.uk, 01274 236554, and Jagruti Lad, j.lad1@bradford.ac.uk, 01274 236225

## Biomedical, Natural, Physical and Health Sciences Research Ethics Panel (REP)

Chair – Dr Martin Brinkworth

Administrators – Nazreen Akhtar, N.Akhtar67 @bradford.ac.uk, 01274 236554, and Jagruti Lad, j.lad1@bradford.ac.uk, 01274 236225

## IRAS Application Review Panel

Chair – Dr Martin Brinkworth

Administrators – Nazreen Akhtar, N.Akhtar67 @bradford.ac.uk, 01274 236554, and Jagruti Lad, j.lad1@bradford.ac.uk, 01274 236225