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Medical and Health Sciences Academic Ethics Committee

Ethics Guidance and Procedures

2022/23

INTRODUCTION

Research carried out in the School of Medical and Health Sciences (MHS) requires ethical approval from the MHS Academic Ethics Committee (AEC). This requirement forms part of the process governed by the University Research Ethics Committee (UREC) as specified in the University Ethics Policy

Following approval by MHS AEC, where appropriate, permissions through the Ethics Committee for external host organisations in which the study takes place and NHS R&D may be required. For further information, see NHS Guidance section

All staff and students conducting investigative research studies outside of the UK also need to seek approval from MHS AEC.

Background

This document includes guidance for applicants regarding the processes of submitting an ethics application through the electronic system. Additional guidance is available on the webpage

The ethics review process is generally conducted as an expedited process unless a full review by the committee is required. This would include (i) if the MHS AEC reviewers raise concerns regarding the application or (ii) the applicant decides to appeal the decision made on the basis of the initial expedited review. In general these are exceptional circumstances.

The **expedited review** is made by two independent reviewers and the recommendations (if any) are forwarded electronically to the applicant for action. If there are differences in the feedback or recommendations provided by reviewers then these will be subject to further scrutiny and reviewed by the Chair of the AEC: Diane Seddon (d.seddon@bangor.ac.uk)

If you have any problems or queries, please contact the Ethics Administrator

Application paths

Complete the electronic submission process once you have reviewed the information provided in the policy. Please refer to the information on the submission procedure in section 2.2 below prior to initiating the submission process. Additional guidance is included as additional supportive resources.

For the applicant, a number of pathways exist for the submission of an application. These are as follows:

- ***Student applications*** - In the case of student applications, these may include undergraduate, PGT or PGR students - MSc, MSc by Research, MPhil, PhD or Professional Doctorate submissions. As part of such applications please ensure that supervisors are labelled as 'collaborators'. This ensures they have reviewed the application prior to submission. They will need to collaborate in the submission process and the review will only take place once all parties have agreed the submission

  Academic Staff applications – The application process is required for both educational-focused projects and research-based work that may be undertaken by academic staff members. Please ensure that all relevant Investigators are labelled as 'collaborators'. This ensures they have reviewed the application prior to submission. However care should be exercised in only identifying core team members as they will need to collaborate in the submission process and the review will only take place once all parties have agreed the submission.

Please remember that you can only begin your study once approval has been granted. If external approval is also required, your study can only commence once this has been granted too. Approval from an Ethics Committee is separate from the Research Governance approval process for undertaking research in the NHS. You may require additional ethics approval from an NHS Research Ethics Committee (REC). Further

information can be obtained by contacting the R&D department in the NHS organisation where you are planning to do your research. Further information on the Integrated Research Application System (IRAS) can be found here

Submitting your application

1. Access the electronic system using the submission link on the MHS AEC webpage
2. Log on to the online system using your Bangor University username and password in order to access the MHS AEC ethics page
3. Click on "Start New Ethics Application" or "Submit amendment". For undergraduate projects, clicking on "Start by Proxy" will allow you to start an application for another researcher using your login.
4. Fill in the title and start and end dates of the project. Note projects are only approved for a three-year period. If you enter an end date that extends beyond three years, you will get an error message. For studies that have a longer timespan please contact us
5. The system will automatically generate an application number and will assign you as PI according to your BU login. In the next window you will be able to add other researchers. BU researchers are identified by username or surname.

   To create a login for an external collaborator click on the line "Add External Collaborator (Create a login for non BU collaborators). The buttons to the right of the names under the word "Editor", when checked, will grant editorial rights to the application to specific collaborators.
6. At this point you will see a screen with tabs across the top. You can navigate to any part of the application by clicking on the tabs.
7. Complete all the relevant sections of the online form in sequence, using the tabs. You can move between each section by clicking on the relevant tab at the top of the screen, save the document at regular intervals before moving to the next tab.

Important: Attach all relevant information by uploading supporting documents (e.g. research proposal, external NHSethics/governance forms, IRAS draft applications, applications to other regulatory bodies, draft consent forms and participant information sheets, draft questionnaires, interview schedules etc) in the final tab- called "Supporting Documents". Please ensure all drafts have version number and date in footer.

8. Once you are finished with the form, submit using the "Submit for Review" button.

Approval Process

The application is sent to your collaborators for approval. Once every collaborator has approved the application it will be sent for review. Guidance for reviewers is included here. This provides guidance for all reviewers of applications and also enables applicants to reflect on their application to ensure all relevant information is provided prior to submission. The Ethics system administrators will forward your application to two reviewers for consideration. We aim to respond regarding your application within 20 working days of the application being made. If you have not heard after 20 days, please contact the Chair.

Outcomes

There are several outcomes to the approval process**.**

- Your application is approved. Research may commence when you receive notification of this from the ethics administrators, unless external permissions are required. If external permissions are required then these must be secured before the research can commence.
- Your application is approved subject to minor changes. In these cases, you will be contacted by the ethics administrators and asked to submit the minor changes but these will not need to be reviewed again.
- Ethics reviewers may request that some changes or additions to

your proposal are made. In these cases, you will be contacted by the ethics administrators and asked to resubmit the amended proposal for further review.

- Your application is not approved.

Please remember that research may only commence once approval has been given. Substantial amendments or change to the protocol will require an amendment. Projects lasting more than 3 years will be subject to re-review after 3 years.

It is important to ensure that your proposal is compliant with all relevant legislation, in particular: GDPR (2018); Data Protection Act (1998); Data Protection Bill (2017); Mental Capacity Act (2005); Safeguarding children and young people, Human Tissues Act (2004).

Amendments to Previously Approved Projects

It is often the case that approved projects undergo a change, or a change becomes necessary. For example, new researchers join or leave the project or where it becomes necessary to change the way in which participants are recruited or consent is gained. Where such modifications to the approved study are substantial, then they must be submitted for Ethics Committee approval. Examples of substantial amendments are:

- introduction of a new condition or new measures (such as a change to the inclusion or exclusion criteria to increase/decrease sample size or the use of a different questionnaire)
- change in participant population (e.g., the change from working with students to working with patient representatives or patient groups such as a local diabetes group, or the change from only staff participants to also include patients)
- change of investigators, especially where there is a change in the qualifications of the investigators to carry out the study (e.g., a project originally carried out by staff or PhD students will now be carried out by undergraduate students)
- change in ways in which participants are recruited

- major changes to equipment or research environment or venue (originally planned to interview patients while they attended out-patient appointments to interviewing them in their own homes)
    - changes relevant to any of the key questions presented on the tick box sections to the ethics/risk assessment form (i.e. consent, deception, confidentiality, participant payment, potential for distress to participants).
    - Changes in relation to the delivery of an intervention e.g. how/ where/by whom an intervention/treatment is delivered.

In the case of student projects, please discuss any such changes with your supervisor in the first instance. For clarification or more information you can contact the Ethics Administrator or AEC Chair for advice.

Complete and submit an *Ethical Approval Substantial Amendment Request Form* (Form 3) and submit to mailto:hcmsethics@bangor.ac.uk

We aim to send a response within 14 working days.

OR

- In the case of a number of more substantial changes, submit a **new** proposal on the standard ethical approval form. This second option is generally required where your previous approval was based on there being no significant ethical implications of the study (i.e. you ticked box A on the original ethical approval form), and where you now wish to do one or more of the following:

a. Pay participants;

b. Work with children or other vulnerable populations (for example, patients, people in custody, physically vulnerable adults, people engaged in illegal activities, people with learning or communication difficulties);

c. Deliberately mislead participants;

d. Utilise procedures that carry a realistic risk of participants experiencing physical or psychological distress or discomfort.

Clinical Trials and Sponsorship Arrangements

The area of clinical trials has a particular pathway relating to sponsorship arrangements MHS AEC Process of scrutiny, approval and monitoring (Bangor University) As a consequence there is a dedicated set of reviewers for trials and additional guidance is provided. Please ensure that all relevant Investigators are labelled as 'collaborators'. This ensures they have reviewed the application prior to submission. However care should be exercised in only identifying core team members as they will need to collaborate in the submission process and the review will only take place once all parties have agreed the submission. The approval processes for Clinical Trials are positioned within the MHS AEC as part of a wider approval and governance process, including particular arrangements for sponsorship by the University and governance arrangements. For further information, see detail here

Responsibility for approval and monitoring of a Clinical Trial

The approval and subsequent monitoring and oversight processes are focused on close working relationships between three Sponsor's representatives from Bangor University, (Bangor University Insurance, MHS AEC and UREC). These representatives will work closely with the researchers delivering the clinical trial. These seek to ensure appropriate ethical and governance standards are evidenced in the development of the application ready for submission to MHS AEC and following approval external ethics and governance.

2.4.1 Approval and monitoring procedures

The process of approval and monitoring is outlined here. The activities of clinical trials are to be run in accordance with joint Bangor University-BCUHB SOPs which can be accessed via here. **All** relevant documentation must be submitted by the research team to the MHS AEC as outlined in the general guidance, including draft NHS Research Ethics Committee and R&D documentation. Following approval the Sponsor's representatives (Bangor University) complete and 'sign off' approval and notify UREC and its Standing Trials Sub-Committee.

2.4.2 Adverse Incidents Reporting

In the event of an adverse incident the research team will immediately inform (1) Dr Huw Roberts or (2) Dr Elizabeth Mason and the information will be immediately provided to (3) Gwenan Hine. An extraordinary meeting of the Standing Trials Sub-Committee of UREC will be held to complete a review and further risk assessment.