INSTRUCTIONS FOR RESEARCH APPLICANTS

Approval of Research

All requests for research, audits, surveys, and academic projects with BPAS clients or staff will require the advice and approval of the Research and Ethics Committee. Applicants should reach out to the research team (research@bpas.org) in the early stages of study design.

All applications, whether internal of external, should be done on the BPAS Application for Ethical Approval of Research form. Applications should be submitted to the Research Administrator by email to research@bpas.org. An electronic version of the Application and all other forms may be accessed from BPAS website at https://www.bpas.org/resources/research/instructions-for-researchers/. Applicants may be invited to attend the REC meeting.

INSTRUCTIONS FOR COMPLETING APPLICATION FOR ETHICAL APPROVAL OF RESEARCH FORM

Parts 1 and 4 of the REC application must be fully completed by **all** investigators wishing to carry out research at BPAS. All applications that involve use of fetal tissue must also complete Part 2. Part 3 must be completed by all applicants with the exception of those applicants who have already received NRES approval. A copy of the full NRES application (available http://www.nres.npsa.nhs.uk) with the approval letter may be submitted in lieu of Part 3.

In addition to the BPAS Application form, **all** submissions must also include:

- A full research protocol including a detailed summary, project time chart showing milestones, and flow chart of procedures
- Proposed client information leaflets, consent forms, instruments, interview guides and questionnaires to be used in the research, with dates and version numbers
- If applicable, a letter of approval from a NHS REC, and letters of support from additional sites
- A Data Protection Impact Assessment, in line with the BPAS Privacy by Design & by Default Procedure Policy

For any queries, email **research@bpas.org**

SPECIFIC QUESTION INSTRUCTIONS

QUESTION 1.8 LEVELS OF ETHICAL REVIEW

Please review the definitions and tick the box designating which kind of review your project requires.

i) Exempt

Examples of studies which may fall into the exempt category include:

- Evaluation of training strategies, curricula, or classroom management methods;
- Anonymous surveys or observations of public behaviour;
- Existing database analysis:
- The planned activity does not involve human subjects.
- Clinical audit and service evaluation.

General characteristics of all exempt activities include the following:

- Private identifiable information ***is not*** recorded by the investigator or members of the research team
- Participants **do not** sign a consent form but are informed about the nature of the study via the use of an information sheet
- Tests, surveys, interviews, or observations of public behaviour are limited to adults 18 years of age and older.

Performance standard for a response to the applicant is within 21 working days.

ii) Expedited

Studies that don't fall into the exempt category may be expedited if two criteria are met:

- The potential for risk of harm to participants and others affected by the proposed research is minimal as confirmed by the REC Chair

- Examples of studies which may fall into the expedited category include:

    - Clinical studies of drugs or medical devices where an investigational new drug or device application is NOT required
    - Collection of blood samples by finger stick, heel stick, ear stick, or venipunctures from healthy non pregnant adults. The amounts drawn may not exceed 55 ml in an 8 week period and collection may not occur more frequently than 2 times a week.
    - Prospective collection of biological specimens for research purposes by non invasive means. Examples, hair and nail clippings, excreta and external secretions (including sweat)
    - Collection of data through non invasive procedures routinely employed in clinical practice. Examples: ultrasound results, body mass index
    - Research involving materials (data, documents, records) which include client identifiable data
    - Collection of data from voice, video, and/or digital recordings made for research purposes.
    - Research on individual or group characteristics or behaviour

- Continuing analysis of data from completed research previously approved by the REC

If the REC Chair determines that there are no ethical issues requiring REC input, then the research can go ahead, with minimum delay under the supervision of the Research Administrator and Medical Director. It may be possible for the PI to make minor amendments to bring it in line with the "no ethical issues requiring REC input" criterion. The Chair of the REC carries responsibility for this decision on behalf of the whole REC.

Performance standard for a response to the applicant is within 21 working days.

iii) Full REC

All other studies will be circulated to the full REC for ethical review by email or at the REC quarterly meetings.

Performance standard for a response to the applicant is within 30 working days to the applicant.

iv) Full REC and Board

Issues here include those that may impact on the organisation itself, where corporate ethical responsibility may become an issue. It may also include matters of principle e.g. whether payment should be made and, if so, how much; what sort of research may or may not be carried out on tissues provided through BPAS.

Performance standard is not imposed as it is likely to be of serious significance and require a time for reasonable deliberations.

QUESTION 1.9 TYPE OF COLLABORATION WITH BPAS

Please review the definitions and tick the box designating which type of collaboration your project requests.

i) Co-Investigator: BPAS staff are involved in the development, execution and dissemination of the project and are listed as key personnel.
ii) Collaborator: BPAS staff are involved in the execution of the project and are listed as key personnel.
iii) Facilitator: BPAS staff are involved in the execution of the project but are not listed as key personnel.

PROCEDURE FOLLOWING REVIEW

The decision and any requests for clarification or changes will be communicated by email to the Principal Investigator. The committee's decision will be final.

AMENDMENTS TO THE PROTOCOL

All amendments to a study must be submitted to the Research Administrator on the appropriate BPAS form. Substantial amendments must also be submitted to the Investigator's local NHS REC and/or NRES.

The following amendments should normally be regarded as substantial:

- changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value;
- changes to the procedures undertaken by participants;
- changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
- a change of sponsor(s) or sponsor's legal representative;
- appointment of a new chief investigator
- a change to the insurance or indemnity arrangements for the study;
- a CTIMP or regulated investigation of a medical device wishing to add a new Non-NHS/HSC site
- appointment of a new principal investigator at a non-NHS/HSC trial site in a CTIMP or regulated investigation of a medical device
- temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- a change to the definition of the end of the study;
- any other significant change to the protocol or the terms of the REC application.
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Examples of non-substantial amendments:

- Correction of typographical errors in the protocol or other study documentation;
- Other minor clarifications of the protocol;
- Updates of the Investigator's Brochure (unless there is a change to the risk/benefit assessment for the trial);
- Changes to the Principal Investigator's research team (other than appointment of key collaborators);
- Changes to the research team at particular trial sites (other than appointment of a new principal investigator at a Non-NHS/HSC site in a CTIMP or a regulated investigation of a medical device);
- Changes in funding arrangements;
- Changes in the documentation used by the research team for recording study data;
- Changes in the logistical arrangements for storing or transporting samples;
- Inclusion of new sites and investigators (other than a CTIMP or a regulated investigation of a medical device wishing to add a new Non-NHS/HSC site);
- Extension of the study end date.

PROTOCOL VIOLATIONS AND/OR BREACHES OF GOOD CLINICAL PRACTICE

The PI must inform the BPAS Research Administrator and/or the Medical Director of any deviation from the protocol and complete the Protocol Violation and/or Serious Adverse Event Form.

A breach should be regarded as serious if it is likely to affect to a significant degree the safety or physical or mental integrity of the subjects or scientific value of the trial. A minor deviation from the protocol to deal with unforeseen circumstances is not considered a serious breach provided that it is approved by the Principal Investigator, either in advance of, or after, the event and reasonable attempt was made to contact BPAS personnel.

The BPAS Research Administrator will notify the Medical Director and REC Chair of any protocol deviations and they will make the decision as to whether application for protocol amendment, cessation, or suspension of the study of should be made.

REPORTS OF SERIOUS ADVERSE EVENTS.

A serious adverse event (SAE) either related to the research procedures or unexpected from that listed in the protocol should be reported to the BPAS Research Administrator and/or Medical Director immediately. The PI must complete the Protocol Violation and/or Serious Adverse Event Form. They should also be reported to the NHS REC where applicable.

A serious adverse event is an untoward and unexpected occurrence that:

1. Results in death;
2. Is life-threatening;
3. Requires hospitalisation or prolongation of existing hospitalisation;
4. Results in persistent or significant disability or incapacity;
5. May result in a congenital anomaly or birth defect.

PROGRESS REPORTS

Bi-annual interim reviews should be submitted by the PI electronically on the BPAS form provided or when requested by BPAS. A final report must be submitted on the BPAS form at the conclusion of the study and the PI may be asked to attend the REC meeting. PIs will be asked to submit a lay summary and/or give a seminar for BPAS staff. Permission will be sought from the PI to put a summary of the findings on the BPAS website. All publications must be reported to BPAS, even if the final report has already been submitted.

Further information may be found in BPAS Research Policy and Procedure, which is available with a check list for applicants, and all research forms on BPAS website https://www.bpas.org/resources/research/instructions-for-researchers.