BPAS
Centre for Reproductive Research & Communication

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 a BPAS governance group. The approval of the Research Approvals Group (RAG) will be required for any study classed as research and any type of project undertaken by a researcher external to BPAS.

Applicants should reach out to the research team (research@bpas.org) in the early stages of study design to determine appropriate venue for approval. The research team will also work with the applicant to identify a named individual at the study site who will act as a contact for the researcher in the process of project development and for the research team or RAG for queries about the research and its progress. It is suggested that the contact person is invited to co-author any published articles derived from the research work, provided their contribution to the work satisfies the requirements of the journal concerned and merits inclusion as an author.

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

Applicants may be invited to attend the RAG meeting.

INSTRUCTIONS FOR COMPLETING APPLICATION FOR APPROVAL OF RESEARCH FORM

Parts 1, 3 and 4 of the Application for Approval of Research form 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.

In addition to this form, **all submissions must also include the following documents**. Please include version numbers and dates:

- A full study protocol including a detailed summary, project timeline showing milestones, and flow chart of procedures.
- Ethics Approval Letter. This could be provided by a Higher Education Institution Research Ethics Committee (REC), an NHS REC, and / or the Health Research Authority (HRA).

- If applicable, provide letters of support from additional study sites.
- One page CV for Principal Investigator (PI) and all members of the research team.
- Data Management Plan, which may include a Data Privacy Impact Assessment approval and/or a BPAS Information Sharing Agreement or a Collaboration Sharing Agreement.
- Recruitment materials, Participant Information Sheets (PIS), and research instruments, interview guides, or questionnaires, if applicable. Please refer to the BPAS Application for Approval of Research form for a full checklist of documents.

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

PROCEDURE FOR BPAS CAPACITY AND CAPABILITY ASSESSMENT FOR RESEARCH APPROVAL

The Research Approvals Group (RAG) gives advice on and approval for research applications involving patients, staff or patient data from BPAS.

The RAG does not provide ethical reviews, rather they conduct Capacity and Capability assessments. All submitted BPAS Application for Approval of Research forms will be reviewed to ensure that projects have received external research and ethics approval(s). Researchers will be directed to seek ethics committee approval if not in place at the time of submission.

BPAS Application for Approval of Research forms are reviewed using the following criteria:

1. **Feasibility & Institutional Fit**
   - Alignment with BPAS's mission, values, and strategic priorities.
   - Justification for why BPAS is an appropriate site for the study.
   - Evidence that inclusion has been built into all stages of the research lifecycle, including: the research question and design, the participants recruited, the research methods, data collections, analysis, and dissemination of findings.
   - Potential operational, reputational, or ethical sensitivities.

2. **Study Team**
   - Suitable Principal Investigator (PI) and study team.
   - Conflicts of Interest.
   - Appropriate BPAS collaborator/ point of contact available.

3. **Ethical & Regulatory Compliance**
   - Evidence of ethical and / or regulatory approvals (e.g., University REC, NHS REC, HRA, MHRA).
   - Adherence to the UK Policy Framework for Health and Social Care Research.
   - Compliance with Good Clinical Practice (GCP) guidelines for clinical trials.
   - Consideration of fetal tissue research regulations if applicable.

4. **Resource & Infrastructure Needs**
   - Availability of BPAS staff time and expertise to support the study.
   - Need for training or special qualifications for BPAS staff involved in the study.
   - Space and facilities required (e.g., consultation rooms, lab space).
   - Data storage and security requirements (e.g., BPAS vs. external servers).

- IT infrastructure needs, including software or system integration.

5. **Financial & Contractual Considerations**
   - Costs to BPAS (staff time, resources, equipment use).
   - Funding source(s) and whether BPAS needs financial reimbursement.
   - Need for a contract or formal agreement (e.g., collaboration agreement, data-sharing agreement).
   - Intellectual property (IP) considerations.

6. **Risk & Impact Assessment**
   - Assessment of any major operational risks (e.g., disruption to patient services).
   - Potential reputational risks to BPAS.
   - Insurance and indemnity coverage.
   - Health and safety considerations for staff and participants.

7. **Participant Recruitment & Data Management**
   - Participant identification and recruitment strategy.
   - Any additional burden on BPAS staff in identifying, recruiting, or consenting participants.
   - Data protection compliance under UK GDPR and the Data Protection Act 2018.
   - Anonymisation and confidentiality measures for participant data.

8. **Study Governance & Reporting**
   - Study oversight mechanisms and ongoing management.
   - Exit strategy and how will BPAS be informed of study completion and outcomes.

A corresponding checklist is included in the 'Capacity and Capability Review Criteria for Research Approval' document, which can be accessed from the BPAS website at: https://www.bpas.org/resources/research/instructions-for-researchers/.

SPECIFIC QUESTION INSTRUCTIONS

TYPE OF PROJECT

Projects can take the form of internal BPAS projects, external projects, collaborative projects, co-investigations with BPAS, or student-led projects.

Please review the following definitions to help designate which degree of BPAS involvement your project requires.

i. **Internal Research:** Research conducted by BPAS staff, using BPAS resources. This includes data, patients, and staff.

ii. **External Research:** Research conducted by external researchers, using BPAS resources. This includes data, patients, staff, or using BPAS as a study site. BPAS are typically only involved in the research to facilitate its execution; BPAS staff are not listed as key personnel.

iii. **Collaborative Research:** Research conducted by external researchers but involves BPAS staff. The two levels of collaboration are **Co- Investigation** (BPAS staff are involved in the development, execution and dissemination of the project, and are listed as key personnel) and **Collaboration** (BPAS staff are involved in the execution of the project and are listed as key personnel).

iv. **Student-led projects:** when students propose their own project and act as PI overseen by an educational supervisor from a higher educational institution. A BPAS member of staff will also act as an advisor on the project.

PROCEDURE FOLLOWING C&C ASSESSMENT

The decision and any requests for clarification or changes will be communicated by email to the PI by the Research Administrator. The RAG's decision will be final.

AMENDMENTS TO THE PROTOCOL

As the RAG does not grant ethical approvals, amendment reporting should follow the procedure of the governing, external ethics committee. However, all amendments must be initially discussed with BPAS (Research and Engagement Lead or Director of Research and Innovation) prior to submission to the approving external ethics committee.

The outcome of the amendment review by the ethics committee should then be communicated to BPAS via email with accompanying approval documentation. Amendments will be reviewed by the Director of Research and Innovation and RAG Chair; amendment approval from the external ethics committee does not guarantee approval from BPAS.

Amendments altering the nature of research of the project may need consultation with RAG and could result in the withdrawal of BPAS support.

PROTOCOL VIOLATIONS AND/OR BREACHES OF GOOD CLINICAL PRACTICE

The PI must inform the Research Administrator of any deviation from the protocol and/or breaches of good clinical practice. This will be communicated to the RAG.

If an amendment is required following a protocol deviation this must be initially discussed with BPAS (Research and Engagement Lead or Director of Research and Innovation) prior to submission to the approving external ethics committee. However, if the RAG is providing research oversight or the project involves BPAS staff, any violations should be reported to BPAS at the same time.

The RAG will make the decision as to whether an application for protocol amendment, cessation, or suspension of the study should be made.

REPORTING SERIOUS ADVERSE EVENTS

A serious adverse event (SAE) should be reported immediately to the researcher's home institution/ ethics committee, and to BPAS in writing. However, if the RAG is providing research oversight or the project involves BPAS staff, an SAE should be reported to BPAS

and the researcher's home institution/ ethics committee at the same time. The Research Administrator will acknowledge receipt of the report and communicate it to the Director of Research and Innovation and RAG Chair.

The RAG will make the decision as to whether an application for protocol amendment, cessation, or suspension of the study should be made.

PROGRESS REPORTS

Bi-annual interim reviews should be submitted by the PI electronically on the **BPAS Research Progress Report form** provided or when requested by BPAS. A final report must be submitted on the **BPAS Research Final Report form** at the conclusion of the study and the PI may be asked to attend the RAG meeting where it is discussed. PIs will be asked to submit a lay summary and/or give a seminar for BPAS staff on findings. 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. Suitable acknowledgement of BPAS in articles for publication is encouraged.

Further information may be found in BPAS Research Policy and all research forms available on BPAS website https://www.bpas.org/resources/research/instructions-for-researchers.