

**Application for Approval of Research**

BPAS Reference Number (internal use only):

**Instructions for applicants**

Parts 1, 3 and 4 of this 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.

Please refer to the BPAS Research Policy for guidance in completing this application. In addition to the BPAS Application form, **all** **submissions must also include the following documents**. Please include version numbers and dates:

[ ]  BPAS Application for Approval of Research *(mandatory)*

[ ]  Study Protocol *(mandatory)*

[ ]  Ethics Approval Letter *(mandatory)*

[ ]  One page CV for PI and all members of research team *(mandatory)*

[ ]  Letter of approval from NHS REC, HRA and letters of support from additional study sites *(if applicable)*

[ ]  Evidence of relevant training *(if applicable)*

[ ]  Participant Information Sheet (PIS) *(if applicable)*

[ ]  Recruitment materials, including email/text content, posters, and flyers *(if applicable)*

[ ]  Consent Forms *(if applicable)*

[ ]  Research instruments, interview guides, or questionnaires *(if applicable)*

[ ]  Data Management Plan *(mandatory)*

[ ]  Data Privacy Impact Assessment Approval *(if applicable)*

[ ]  BPAS Information Sharing Agreement *(if applicable)*

[ ]  MHRA Approval *(if applicable)*

[ ]  Collaboration or Information Sharing Agreement *(if applicable, where external institutions will access BPAS facilities, staff, or patient data)*

[ ]  Proof of indemnity

**Please return all application materials by email to:** **research@bpas.org**

**Consideration of research proposals to BPAS**

All requests for research, audits, surveys, and academic projects with BPAS patients of staff will require the advice and approval of a BPAS governance group. 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 approval of the Research Approvals Group (RAG) will be required for any study classed as research and any type of protect undertaken by a researcher external to BPAS. The RAG uses the BPAS Capacity and Capability Criteria to assess applications.

The BPAS 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. **PART 1**

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| **1.1 Title of project**  |
|  |
| **1.2 Date of application** |
|  |
| **1.3 Principal Investigator****Does this project form part of an educational qualification, including a masters or doctorate? Yes 🞎 No 🞎****Please attach a one-page CV.** |
|  |
| **1.4 Job title** |
|  |
| **1.5 Co-investigators and/or Collaborators.****If this is an educational project, please list all supervisors.****Please attach a one-page CV for all co-investigators.** |
|  |
| **1.6 Has external funding been sought? Yes 🞎 No 🞎****If Yes, please give details. Please include information on whether BPAS will receive any funding.**  |
|  |
| **1.7 Has internal funding been sought? Yes 🞎 No 🞎****If Yes, please give details** |
|  |
| **1.8 Type of project:** **Internal BPAS Project 🞎 External Project 🞎 Collaboration 🞎 Co-investigation with BPAS 🞎 Student-led project 🞎**  |
| **1.9 Contact Information**  |
| Email address:Postal address:Telephone number:Extension:Email: |
| **1.10 Name and site(s) of the institution(s) at which you intend to carry out the project** |
|  |
| **1.11 Proposed study dates and duration** |
| Start date: |  |
| End date: |  |
| Duration: |  Years Months |
| **1.12 Primary purpose of the research (Tick as appropriate)**  |
| 🞎 Commercial product development and/or licensing🞎 Publicly funded trial or scientific investigation🞎 Educational qualification🞎 Establishing a database/data storage🞎 Other (describe):  |
| **1.13 Implications for BPAS and Staff Involvement Plan.****Please describe the role of BPAS in this research, clearly explaining the implications for BPAS staff time and use of facilities that will be required.**  |
|  |
| **1.14 What use could the results be to the public, to BPAS patients and for BPAS policy?** |
|  |
| **1.15 What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, BPAS patients of staff for negligent harm?****Please also attach copies of the relevant documents.** |
|  |
| **1.16 What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, BPAS patients or staff for non-negligent harm?****Please also attach copies of the relevant documents.** |
|  |
| **1.17 Will this project require approval of a Data Protection Impact Assessment (DPIA) according to BPAS’ Privacy by Design policy?****Yes [ ]  No [ ]**  |
|  |
| **1.18 Will this project require an Information Sharing Agreement?****Yes [ ]  No [ ]**  |
|  |

**PART 2**

**This section is to be completed where the proposed research involves a request for the supply of fetal tissue.**

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| **2.1 Please estimate the amount and integrity of tissue needed (e.g. gestational age, viability, intactness, freedom from chemical contamination).** |
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| **2.2 Please indicate the process of proposed disposal of the fetal tissue at the end of the project.** |
|  |
| **2.3 Please describe the experience of Principal and Co-investigators in handling and disposal of fetal tissue.** |
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**Please attach:**

1. A detailed synopsis or diagram (flow chart) detailing the proposed operational procedure(s) for obtaining specimens at the BPAS Treatment Unit, including transport of the tissue.
2. The Material Transfer Agreement.
3. The Human Tissue License.

**PART 3**

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| **3.1 What is the principal research question/objective?**  |
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| **3.2 What are the secondary research questions/objectives (if applicable)**  |
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| **3.3 Abstract of the proposed research**Maximum 300 words in lay terms; (including the purpose of the research, and a short summary of the theoretical framework, methodology, design, outcome measures and analytical methods that will be used to achieve the objectives, the role of BPAS, and the potential benefits, if any, to BPAS and its patients. Attention should be paid to how inclusion is built into all stages of the research cycle). |
|  |
| **3.4 Background and significance of the project, with supporting literature. Please include references.** |
|  |
| **3.5 Will any intervention or procedure, which would normally be considered a part of routine care, be withheld from the research participants?** 🞎 **Yes** 🞎 **No** If yes give details and justification: |
|  |
| **3.6 Will the research participants receive any clinical intervention(s) or procedure(s) including taking samples of human biological material over and above that which would normally be considered a part of routine clinical care?** |
| Describe the additional intervention | Average number of interventions per patient | Average time taken (minutes/hours/days) | Details of additional intervention of procedure, who will undertake it, and what training they have received |
|  | Routine Care | Research |  |  |
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|  |  |  |  |  |
| Additional rows may be added to the table above as needed.In addition, please attach a detailed flow chart or research plan.  |
| * 1. **Will the research participant be subject to any non-clinical research related intervention(s) or procedure(s) (includes use of interviews, non clinical observations and use of questionnaires)?**

🞎 **Yes** 🞎 **No** If yes, attach any interview tools, and questionnaires. Include a flow chart or research plan which describes the research procedure or intervention. Detail who will undertake it and what training they will receive. |
|  |
| **3.8 Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during the interviews/group discussions, or use of screening tests for drugs)?**  |
| 🞎 **Yes** 🞎 **No**If yes provide details of procedures in place to manage these issues: |
| **3.9 What is the expected total duration of participation in the study for each participant?** |
| 1. during treatment:
 |
| 1. pre or post-treatment:
 |
| **3.10 What is the potential for, and likelihood of, risk and burden for the participants (e.g. withholding medications, devices, ionising radiation, pain, discomfort, emotional distress, inconveniences, or changes in lifestyle)? How will you minimise these?** |
|  |
| **3.11 Is follow up support available (e.g. medical care, counselling) for participants if research uncovers underlying unresolved issues?** |
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| **3.12 What is the potential for benefit if any to research participants?** |
|  |
| **3.13 What are potential risks to the researchers themselves? (If any). How will you minimise these risks?** |
|  |
| **3.14 How will potential participants, records or samples be:**  |
| a) identified: |
| b) recruited or obtained: |
| **3.15 How many participants will be recruited and by whom? How many of these participants will be in a control group? If randomised please give the method of randomisation.**  |
|  |
| **3.16 Please provide your inclusion and exclusion criteria** |
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| **3.17 Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?**  |
| 🞎 **Yes** 🞎 **No** 🞎 **Not Known**If yes, give details and justify their inclusion. If not known, what steps will you take to find out? |
|  |
| **3.18 Will valid consent be obtained from the research participants?** |
| 🞎 **Yes** 🞎 **No**If yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos or interactive material. Supply copies of the consent and information sheets. |
|  |
| **3.19 Will the participants be from any of the following groups?**  |
| 🞎 Children under 16🞎 Adults with learning disabilities🞎 Adults who are unconscious or very severely ill🞎 Adults in emergency situations🞎 Adults with mental illness (particularly if detained under Mental Health Legislation)🞎 Adults suffering from dementia🞎 Prisoners🞎 Young Offenders🞎 Other vulnerable groups (please specify) |
| **3.20 If participants are to be recruited from any of the potentially vulnerable groups listed in 3.19, say how you will ensure that consent is voluntary and fully informed. Where applicable, describe the procedure for ensuring willingness to participate in participants where consent is provided by a legal representative.** |
|  |
| **3.21 If consent is not to be obtained, please explain why not.** |
|  |
| **3.22 How long will the participant have to decide whether to take part in the research? What arrangements are in place to answer any questions they may have during this period?** |
|  |
| **3.23 What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters).** |
|  |
| **3.24 Will individual research participants receive any payments, reimbursement of expenses or any incentives or benefits for taking part in the research?**  |
| 🞎 **Yes** 🞎 **No**If yes, indicate how much and on what basis this has been decided: |
|  |
| **3.25 How will the results of research be made available to research participants and communities from which they are drawn? How will this be done and within what time frame?** |
|  |
| **3.26 What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or any other anonymisation procedures have been used and what stage.** |
|  |
| **3.27 Where will the analysis of the data from the study take place and who will undertake it?** |
|  |
| **3.28 Who will have control of and act as the custodian for the data generated by the study?** |
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| **3.29 Who will have access to the participant’s personal data and other data generated by the study?**  |
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| **3.30 How long will data from the study be stored? At what point will it be destroyed, by whom and how? Please supply rationale.**  |
|  |
| **3.31 How has the scientific quality of the research been assessed? Please include any available critiques and /or assessments.**  |
|  |
| **3.32 Has the size of the study been informed by a formal statistical power calculation?**  |
| 🞎 **Yes** 🞎 **No**If yes, indicate the basis upon which this was done, giving sufficient information to allow the replication of the calculation. If no, how was the size of the sample decided?  |
|  |
| **3.33 Has a statistician given an opinion about the statistical aspects of the research?**  |
| 🞎 **Yes** 🞎 **No**If yes, give a brief summary of advice offered and attach a copy of comments if available: |
|  |
| **3.34 What arrangements are in place for monitoring and auditing the conduct of the research?** |
|  |
| **3.35 Will a data monitoring committee (DMC) be convened?**  |
| 🞎 **Yes** 🞎 **No**If yes, give details of the membership of the DMC and its standard operating procedures. Forward summary interim analyses to BPAS REC. |
|  |
| **3.36 What are the criteria for electively stopping the trial or other research prematurely?** |
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| **3.37 How will any incidental findings be reported and addressed?**  |
|  |
| **3.38 Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?**  |
| 🞎 **Yes** 🞎 **No** |
| If yes, give details including:Name of Research Ethics Committee or regulatory authorityDecision and date takenResearch Ethics Committee reference numberIf no, please provide the letter of approval as an appendix. |

**Part 4**

 **Declaration by Principal Investigator(s)**

**In compliance with the policies established by BPAS Research Approvals Group (RAG), the Principal Investigator(s) agree that:**

1. The information in this form is accurate to the best of my (our) knowledge and I (we) take full responsibility for it.
2. I (we) undertake to comply with the ethical principles of the current Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the application is approved, I (we) undertake to adhere to the study protocol.
4. Approval will be obtained from BPAS prior to instituting any change in this research project.
5. Development of any unexpected events will be immediately reported to BPAS RAG.
6. An annual review and progress report will be completed and submitted.
7. Signed valid consents and all research documents will be kept for the duration of the project and for at least three years thereafter at a location approved by BPAS RAG.
8. *For projects involving fetal tissue only*. I have considered the feasibility of achieving the purpose of the project by means not involving fetal tissues, and in my opinion no such alternatives exist. I undertake responsibility for the management of the project and that it will be carried out in accordance with any guidance from the Department of Health including the recommendations of the Polkinghorne Report, the Human Tissue Act and the Associated Code of Practice.
9. *For projects where a Data Management Committee has been convened only.* I undertake to forward summary interim data analyses to BPAS RAG.
10. I undertake responsibility for the management of the project and that it will be carried out in an ethical manner.
11. I understand that the lay summary of this study may be published on BPAS website

**SIGNATURES**

ALL SIGNATURES MUST BE ORIGINAL**.** Type the name of each individual above the appropriate signature line.

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Co-Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Student Adviser (if any): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**