

BPAS Research and Ethics Committee Terms of Reference

1. Role

The REC maintains an overview of all research conducted at BPAS.

It will examine proposals for research, audit or service evaluation involving clients, or materials derived from clients, or which are to be carried out within BPAS units or by BPAS staff as appropriate and to ensure that such activities conform to generally accepted ethical principles and standards, and are appropriately indemnified.

The Research and Ethics Committee (REC) will also from time to time provide advice on ethical issues that affect BPAS and which the REC elects to consider or which are referred for its consideration by the Clinical Governance Committee, the Clinical Advisory Group, the Finance and General Purposes Committee or the BPAS Board. Due notice that such issues will be receiving consideration should be given to the Chair of the Clinical Governance Committee by the REC Chair, where possible in advance of the relevant REC meeting.

2. Accountability

The REC is a sub-committee of the Clinical Governance Committee (CGC). The REC will report to the Clinical Governance Committee and so, indirectly, to the BPAS Board of Trustees. The REC Chair will be a core member of the CGC.

3. Conduct of Business

All applications for approval in relation to proposals for research, clinical audit or service evaluation must be submitted to the BPAS Senior Research Nurse or Medical Director on BPAS application forms.

The REC should normally consider every correctly completed application form that it receives at its next meeting providing that the application is received 14 days before the scheduled date of the meeting. Applications may also be eligible for consideration via email between REC members.

The REC will manage conflicts of interest in the same manner as the BPAS Board.

The REC may:

- Request the applicant to supply further information in relation to an application and/or request the applicant to attend a meeting of the REC at which the application will be considered for the purpose of providing further information and answering questions;
- Investigate the competence or qualifications of anyone involved in a research project and, if required, inspect relevant facilities;
- Delegate consideration of certain scientific, medical, technical, procedural or any other matters to a sub-committee, or appropriate persons; and
- Take into account the views on the same or similar proposal of another REC or the National Research Ethics Service (NRES).

Following approval of a study, the REC will also have responsibility for approving all substantial amendments to it.

The REC Chair, or his/her nominee, shall be empowered to approve all minor amendments to a study. The REC Chair may also exceptionally give a provisional opinion on any application or a substantial amendment of an existing approved application, which should be subject to ratification at the next scheduled meeting or by email.

The BPAS Senior Research Nurse, Medical Director and/or the REC Chair shall notify the investigator promptly, in writing, of the REC's opinion. If the opinion is unfavourable the reasons for this should be clearly stated.

The BPAS Senior Research Nurse shall maintain a register of all applications which are made to the REC.

4. Responsibilities of the Principal Investigator

The REC will hold the Principal Investigator(s) accountable for following the BPAS Policy and Procedure for research. This includes reporting any changes to the research protocol for consideration and approval prior to implementation, protocol violations, and provision of interim and final reports.

5. Committee Membership

REC will be composed of core members and additional members who meet the skills-based requirements of the REC.

The core membership of the REC will be the:

- REC Chair
- Medical Director
- Director of Operations
- Associate Director of Research
- Senior Research Nurse

The BPAS Board Chair and the BPAS Chief Executive will be ex officio members of the REC.

Skill requirements of the REC are:

- Expertise in the ethical principles involved in areas of BPAS activities, particularly the conduct of research
- Expertise in operational issues involved in the conduct of research at BPAS facilities
- The ability to act as an advocate for and support BPAS clients
- Methodological expertise in qualitative and quantitative research designs, including clinical trials
- Expertise in law and political issues related to BPAS clients, staff and work
- Medical expertise and experience in the provision of medical and surgical abortion
- Knowledge of press and broadcast media and the implications for BPAS.

Additional members of the REC may be appointed or co-opted by the REC on an ad hoc basis.

Ethical Review Group (ERG)

This sub-committee of the REC will be composed of the BPAS REC Chair, Chief Executive, Medical Director, Associate Director of research, Director of Operations, and Senior

Research Nurse. The ERG may be asked to decide what level of ethical review is required and will perform an expedited review of those applications which, in its judgment, do not raise any ethical issues which require the input of the full REC. In all cases where the research poses more than minimal risk of harm to participants and any others affected, the application will be referred for review by the full REC.

6. Election Procedure

- The REC Chair will normally be a member of the Board of Trustees
- The REC Chair will be appointed by the Clinical Governance Committee
- The BPAS Medical Director, Associate Director of Research, Director of Operations, and Senior Research Nurse will be standing members
- Appointment of other members will be made by a selection subcommittee consisting of the REC chair and two other REC members elected by the committee. The subcommittee will review of letters of interest and curriculum vitae solicited through calls for membership posted internally at BPAS and disseminated externally through appropriate networks in order to determine appointments. If the Chair of the REC so wishes, an interview process may also be conducted to assess applicants for inclusion on the REC.

7. Quorum

A quorum must be reached in order to hold a REC meeting. This will include 1) the REC Chair or another REC member who is not be an employee of BPAS; 2) either the Medical Director or the Director of Operations; 3) either the Chief Executive or Board Chair; and 4) one other member.

8. Frequency of meetings

The REC will meet two times per year typically with one meeting on the same date as a Clinical Governance Committee meeting. Extra meetings may be held on an as needed basis and applications or any other issues may be considered by the REC via email.

9. Term of Office

The membership of the Chief Executive, Medical Director, Associate Director of Research, Director of Operations and Senior Research Nurse are fixed positions on the BPAS REC and not subject to rotating appointment.

The Chair and other REC members will be appointed for one year in the first instance, extendable to a term of three years, and then for a further three years up to a maximum of two terms or 6 years.

If a current member of the REC is appointed as Chair, their membership term will start over once they assume the Chair position (i.e., initial one year extendable to 3 years and then a further 3 years to a maximum of 6 years).

10. Review

Terms of reference Membership and frequency of meetings shall be reviewed every three years.

