

BPAS Research and Ethics Committee Terms of Reference

1. Role

The Research and Ethics Committee (REC) maintains an overview of research, clinical audits and service evaluations conducted at BPAS.

It will examine proposals for research, clinical audits and service evaluations involving clients, staff, client data or materials derived from clients carried out within or via BPAS units by BPAS staff or researchers from other organisations. The REC will ensure that such activities conform to sound ethical principles and standards, regulatory guidance, are appropriately indemnified and operationally feasible.

The 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 (CGC) or its sub-committees, the BPAS Board, or individual members of staff. Due notice that such issues will be receiving consideration should be given to the Chair of the CGC by the REC Chair, where possible in advance of the relevant REC meeting.

2. Accountability

The REC is a sub-committee of the CGC. The REC will report to the CGC and so, indirectly, to the BPAS Board of Trustees.

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 Research Administrator 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. Exceptionally, applications may also be eligible for consideration via email between REC members.

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

After review of an application, 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
- Consider 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 their 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 Research Administrator, 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 and clear guidance will be offered if a resubmission is appropriate.

The BPAS Research Administrator 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

The REC will be composed of core members and additional members who meet the skills-based requirements of the REC. The committee will include BPAS staff and members independent of the organisation.

The core membership of the REC will be the:

- REC Chair
- BPAS Medical Director
- BPAS Deputy Chief Executive, Client Services
- BPAS Research and Engagement Lead
- BPAS Head of Clinical Policy and Evaluation
- BPAS Director of Embryology
- A representative for the patient perspective
- A layperson

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/or quantitative research designs, including clinical trials
- Expertise in law and political issues related to BPAS clients, staff and work

- Medical expertise in the services provided at BPAS
- 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.

The BPAS Research Administrator will serve as the secretariat for the REC.

5.1 Ethical Review Process

The REC Chair and BPAS Research Administrator will decide what level of ethical review is required and will perform an expedited review of those applications which, in their judgment, do not raise any ethical issues which require the input of the full REC. They may nominate a member of the REC to advise on the level of ethical review. 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 may be a member of the Board of Trustees or externally appointed
- The REC Chair will be appointed by the CGC
- The BPAS Medical Director, Head of Clinical Policy and Evaluation, Research and Engagement Lead, Director of Embryology and Deputy Chief Executive, Client Services will be standing members
- Appointment of other members will be made by a selection sub-committee consisting of the REC Chair and two other REC members elected by the committee. The sub-committee will review of letters of interest and curriculum vitae solicited through calls for membership posted internally at BPAS and disseminated externally through appropriate networks 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 to hold a REC meeting. This will include 1) the REC Chair or another REC member who is not an employee of BPAS; 2) either the Medical Director or the Deputy Chief Executive, Client Services; 3) either the Chief Executive or Board Chair; and 4) one other member.

8. Minutes

The Research Administrator will provide minutes of the meeting to the committee Chair for initial approval and will distribute them to REC members within two weeks of the meeting.

Meeting minutes will be submitted to the CGC.

9. Frequency of Meetings

The REC will meet quarterly typically with two meetings on the same date as a CGC meeting. Two of the meetings will be held on an ad hoc basis to review research applications. Any other issues may be considered by the REC via email.

10. Term of Office

Standing members are 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).

11. Review

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