Capacity and Capability Review Criteria for Research Approval

This document outlines the criteria by which applications to the BPAS Research Approvals Group (RAG) will be reviewed. Applications should be reviewed using the following rubric and corresponding checklist.

BPAS capacity and capability 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,*
    - *dissemination of findings.*
- Potential operational, reputational, or ethical sensitivities.

2. Study Team

- Suitable Principal Investigator (PI) and study team.
    - *Have the study team had GCP or other relevant training?*
- Conflicts of interest
    - *Do any of the staff have any conflicts e.g. with other roles, personal relationships?*
- Appropriate BPAS collaborator/point of contact available.

3. Ethical & Regulatory Compliance

- Evidence of external ethical approval (e.g., University REC, NHS HRA, MHRA if applicable).
- 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—who owns the study outputs?

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 (who is liable for what?).
- Health and safety considerations for staff and participants.

7. Participant Recruitment & Data Management

- Recruitment strategy—how will BPAS patients or staff be involved?
- Any additional burden on BPAS staff in 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—who is responsible for ongoing management?
- Exit strategy—how will BPAS be informed of study completion and outcomes?

BPAS Capacity & Capability Review Checklist

Required Documentation, with version numbers and dates

☐ BPAS Research Application (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 Data Sharing Agreement (if applicable) – If external institutions will access BPAS facilities, staff, or patient data.

☐ Proof of indemnity

1. Feasibility & Institutional Fit

☐ Study aligns with BPAS's mission, services, and ethical considerations.

☐ Justification for why BPAS is an appropriate research site is clear.

☐ Has built inclusion into all stages of the research cycle.

☐ BPAS has sufficient resources and capacity to support the study.

2. External Study team (if applicable)

☐ A suitable Principal Investigator (PI) has been appointed.

☐ The study team have the appropriate skills and experience to work on the study.

☐ All conflicts of interest have been declared

☐ An appropriate BPAS collaborator/point of contact has been appointed

3. Ethical & Regulatory Compliance

☐ Ethics approval obtained from appropriate REC (University/NHS HRA).

☐ Adherence to UK Policy Framework for Health and Social Care Research.

☐ Compliance with Good Clinical Practice (GCP) for trials.

☐ Adherence to MHRA regulations (if applicable).

☐ Fetal material research complies with Polkinghorne Report, Human Tissue Act (2004), and related guidance (if applicable).

4. Resource & Infrastructure Needs

☐ BPAS staff availability and workload impact assessed.

☐ Provision for training of BPAS staff has been made, if required.

☐ Physical space and facilities (consultation rooms, storage) available.

☐ IT infrastructure requirements met (software, data security, remote access).

5. Financial & Contractual Considerations

☐ Study is fully funded or funding sources are clearly identified.

☐ No unreasonable financial burden on BPAS (staff, facilities, training).

☐ Finance Department review required if major financial implications are anticipated.

☐ Contracts, MOUs, or data-sharing/information agreements in place (if applicable).

6. Risk & Impact Assessment

☐ Study does not pose major operational disruptions to BPAS services.

☐ Potential reputational risks have been assessed and mitigated.

☐ Insurance and indemnity coverage is in place and is of sufficient value

☐ Health and safety considerations for participants and staff are addressed.

7. Participant Recruitment & Data Management

☐ Recruitment strategy is ethical and appropriate for BPAS patients/staff (if applicable)

☐ Study places no unreasonable burden on BPAS staff for recruitment or data generation.

☐ Data protection measures comply with UK GDPR and Data Protection Act 2018.

☐ BPAS Data Privacy Impact Assessment approved, if required.

☐ Data security, anonymisation, and retention policies are clear [laid out in a data management plan].

8. Study Governance & Reporting

☐ Clear study oversight and accountability framework provided.

☐ Process for study closure and sharing outcomes with BPAS defined.

Approval Outcome

☐ Approved

☐ Approved with Conditions (Specify conditions below)

☐ Request Modifications (Specify required changes below)

☐ Not Approved (Provide justification below)

☐ Escalate to RICA/Board

☐ Escalate to Finance for further review

Comments / Conditions / Justification for Decision: