

Research Policy



Category	Policy
Summary	This policy outlines BAPAM's principles and procedures which ensure that any research involving BAPAM, its patients, service users and staff achieves the highest standards of conduct and ethics.
Valid from	March 2016
Version	1.0
Date of next review	May 2016 Under Review
Approval date/ via	BAPAM Medical Committee
Distribution	BAPAM clinicians e-mail & online forum Staff e-mail and meetings Public website
Related documents	<i>Clinical Governance Policy</i> <i>Equality & Diversity Policy</i> <i>Information Governance Policy</i> <i>IT Usage Policy</i>
Author	Dr Deborah Charnock
Further information/contacts	

1. Aims and Context of this Policy

The aim of this Research Policy is to ensure that any research involving BAPAM, its patients, service users and staff achieves the highest standards of conduct and ethics. The policy is also designed to ensure that BAPAM meets legislative requirements whereby healthcare providers are aware of all research taking place within their organisation or drawing on their patients and users (or their data).

The policy involves adherence to the principles outlined in the Department of Health Research Governance Framework (2005), the Private and Voluntary Health Care Regulations (2001) and other relevant national legislation, and to BAPAM's own policies, particularly Clinical Governance, Data Protection and Confidentiality, Access to Medical Records, Safety and Security, and Child Protection policies.

All BAPAM research activity is overseen by the BAPAM Service Evaluation and Research Advisory Group (SERAG) which is a subgroup of the BAPAM Medical Committee. Operational issues are managed by the SERAG Chair and Clinics Development Officer (see Appendix A for Terms of Reference). The responsible person is the BAPAM Chair.

2. Key terms

For the purposes of this policy, the following definitions are used:

- **BAPAM:** the British Association for Performing Arts Medicine acting corporately i.e. through approved actions of the Board and Chief Officer
- **BAPAM staff:** all paid and voluntary staff working for, with or on behalf of BAPAM. This includes **BAPAM clinicians** - medical and allied healthcare professionals providing clinical assessment and therapeutic services for BAPAM patients, including

AMABO¹ doctors. Further details of BAPAM clinics and clinic personnel are outlined in the BAPAM Clinical Governance Policy.

- **BAPAM service user:** anyone who uses BAPAM’s health advice and clinical services. This includes telephone advice line users, visitors to the website, and participants attending BAPAM health promotion courses (professionals and performers). A specific category of service users is **patients** – performers who receive assessment and care from BAPAM clinicians through BAPAM clinics or as members of an orchestra supported by an AMABO doctor. As BAPAM patients are in receipt of clinical services, they have detailed personal information and medical records held within BAPAM.

Note: this policy does not extend to patients who are referred on to professionals listed in BAPAM’s Practitioner Directories (i.e. secondary referrals and self-referrals)

- **Research:** there are two levels of research relevant to this policy:
 - Service audit and evaluation:* activity that involves assessing the quality, efficacy, and accessibility of BAPAM services through analysis of patient and service user profiles and feedback and of organisational activity
 - Empirical research:* activity that involves collection and use of information arising from direct interaction with BAPAM patients and service users, and which is designed to enhance Performing Arts Medicine (PAM) knowledge and best practice, as per the definition from the Dept of Health (Dept Health Research Governance Framework, 2005, 1.1, P.3):

“Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods (this definition includes studies that aim to generate hypotheses as well as studies that aim to test them)”

Types of empirical research relevant to this policy include:

- *biomedical research*, including mechanisms of disease, therapeutics, and development of new technologies
- *demographic and epidemiological surveys*
- *behavioural studies*
- *health outcomes and health services research*

Note that invasive clinical procedures are not usually carried out within BAPAM clinics, and BAPAM cannot independently support clinical research involving invasive techniques (see 3.2.2 and 3.3.3).

¹ Association of Medical Advisers to British Orchestras

- **Research Ethics Committee (REC):** All research projects involving BAPAM patients and clients need to conform to high ethical principles and standards, and will need to have been approved by an appropriate, independent REC.² Exceptions may include in-house activities such as patient feedback and clinical practice evaluations (see Section 3 and flow chart in Section 4) which will be approved by SERAG and managed by the SERAG Chair.

Note: BAPAM SERAG is not an authorised or recognised REC (see 3.3.3).

3. Scope

Most research conducted at BAPAM will fall under (i) above. However, BAPAM may also be involved in empirical research as outlined under (ii) through either in-house projects or collaborative projects involving other organisations.

In summary, the types of research that may involve BAPAM are as follows:

- in-house audit and evaluation (3.1)
- in-house empirical research (3.2.1)
- empirical research involving BAPAM as sponsors, partners, funders or co-ordinators (3.2.2)
- requests for access to BAPAM patients and service users for empirical research being conducted by independent researchers and organisations. This may include requests to publicise research projects via BAPAM clinics, websites and newsletters, mailing lists, and so on.

The BAPAM Clinics and Development Officer and the SERAG Chair will be responsible for handling all enquiries and recommendations relating to research at BAPAM, including decisions about which projects need to be forwarded to SERAG for more detailed input or approval. They will also maintain a record of all such activities which will be reported regularly to SERAG, the Medical Committee and BAPAM Board.

3.1 In-House Audit and Evaluation

BAPAM's in-house audit includes data on service quality, efficacy and accessibility, and is part of an ongoing programme of service evaluation and improvement. Key activities are:

- collecting and analysing a database of patients' demographic details

² In the UK, there are two types of RECs which consider proposals for research involving NHS patients which are relevant to this policy: *Authorised* and *Recognised* RECs. Both act in accordance with Governance Arrangements for NHS Research Ethics Committees (GAfREC). *Recognised* RECs are also legally recognised by the UK Ethics Committee Authority (UKECA) to provide ethical opinions on clinical trials of an investigational medicinal product (CTIMP)).

- collecting and analysing patient and service user satisfaction and feedback
- collecting and analysing website and telephone advice line activity data
- collecting and analysing clinician and practitioner information: e.g. qualifications and training needs, activity and referral patterns, demographic data

All in-house audit activity is conducted by BAPAM staff and the collection and storage of this information is in accordance with Data Protection legislation as outlined in the BAPAM Clinical Governance Policy. In particular, no personal information is collected and recorded without the consent of the individual, and any reports arising from this work will consist of anonymised data so that no individual can be identified (either by name or description). Audit activity is monitored through SERAG and the Medical Committee to ensure that it is carried out in accordance with these standards.

3.2 Empirical Research

3.2.1 In-house Empirical Research

BAPAM's audit and evaluation activities may sometimes be extended to gather more specific information about patients' and service users' needs and experiences e.g. postal or interview surveys about BAPAM's services, health outcomes, performance issues, and longterm followup.

The SERAG Chair, in consultation with BAPAM staff and SERAG members, will develop an annual workplan of topics that need further investigation and will make recommendations on the most appropriate means of data collection – i.e. through changes to auditing practice or through development of empirical research projects. Proposals for in-house research projects will be developed by the SERAG Chair or BAPAM staff and submitted to SERAG for approval and registration on the Research Register as per the flowchart and protocol outlined in Section 4. SERAG will also be available to provide advice on research design, including the possible need for REC approval, and will monitor progress of research projects through regular reports from the SERAG Chair and Clinics and Development Officer.

The results of research conducted in-house will enable the SERAG Chair and members to make recommendations for changes in BAPAM's administrative and clinical practice where appropriate. The SERAG Chair and Clinics and Development Officer will also be responsible for developing procedures for using and sharing this information outside the organisation to enhance broader understanding of performers' health needs and care. In-house research will therefore be a standing item on the SERAG agenda.

3.2.2 Independent Empirical Research involving BAPAM, its patients and service users

BAPAM may be involved in empirical research as a partner, sponsor, funder or co-ordinator, or as a “gate-keeper” providing access to BAPAM patients and service users as potential recruits into independent PAM research projects. In each case, the Clinics and Development Officer and the SERAG Chair will be responsible for accepting and registering projects, and the Officer will also manage issues around implementation and liaison. The Chair and Officer will also provide regular reports to SERAG of all recorded research activities. The flowchart and protocol in Section 4 outlines this process.

Any empirical research involving invasive or experimental clinical procedures, biomedical interventions, randomised controlled trials, or psychiatric assessment and treatment would require appropriate REC approval and external clinical management responsibility. This would not necessarily preclude BAPAM involvement³, but at present, BAPAM staff or other researchers wishing to engage BAPAM patients in such research must ensure that it is conducted as follows:

- the patients are seen as secondary referrals (following informed consent) to professionals working for an independent organisation
- the research is conducted at an external location
- the research has been approved by an appropriate REC

3.2.3 Independent PAM Research: Developing a Knowledge hub

As part of good governance and with the aim of developing BAPAM as a UK PAM knowledge hub, SERAG will encourage all PAM researchers, including BAPAM staff and their colleagues, to inform BAPAM of their independent PAM research activities. SERAG will therefore develop opportunities for broader research dissemination and networking.

3.3 Key Points and Exclusions:

3.3.1. Access to BAPAM patients, service users, and their personal information:

BAPAM patients and service users cannot be invited to participate in any research that has not been accepted and registered by the BAPAM Clinics and Development Officer and the SERAG Chair

Access to BAPAM patients’ and service users’ personal information, including contact details, is confined to authorised BAPAM staff – primarily the Clinics and Development Officer. **There will be no instances where BAPAM patients’ or service users’ information can be released or used without their informed consent.**

³ SERAG will seek research partnerships to develop BAPAM’s role as a PAM knowledge hub

3.3.2 Access to Medical Records: Medical records contain sensitive patient information which is covered by a separate BAPAM policy and is overseen by the Medical Committee. SERAG cannot approve research involving access to medical records without the prior approval of the Medical Committee and informed patient consent.

3.3.3 Research involving invasive or experimental clinical procedures biomedical interventions, randomized controlled trials, psychiatric assessment: this research cannot be conducted in BAPAM clinics, and requires independent management and appropriate REC approval

3.3.4 Sensitive survey research: Some forms of audit and survey research may not employ methodologies requiring REC approval but may still have the potential to elicit emotional discomfort or distress e.g. questions about personal issues such as career path, employment status, disability.

BAPAM staff, clinicians and practitioners intending to conduct this type of research need to provide SERAG with assurance that the research will be conducted in accordance with British Psychological Society (BPS) guidelines, particularly issues of informed consent and participant discomfort (www.bps.org.uk). Relevant information to submit to SERAG prior to conducting the survey should include:

- a rationale outlining the potential benefits of the research
- full details of the questions to be asked and how, where and by whom
- details of the qualifications of personnel involved in the design, management and administration of the survey
- an action plan for dealing with distress/mental health issues arising from or detected during the course of the research (including procedures for participant drop-out and onward referral)

3.3.5 Children: BAPAM does not conduct research involving patients and service users under 18 years of age.

4. Summary & Protocol

(See separate Flowchart)

4.1 Principles

The SERAG Chair and members encourage researchers to consider the following guiding principles when developing their proposals:

- the research will provide a positive contribution to the quality, efficacy and accessibility of BAPAM services or to broader PAM knowledge and practice
- the research will be conducted in accordance with the Department of Health Research Governance Framework, particularly in terms of:
 - ethical practice, particularly informed consent and confidentiality
 - clarity about project management, responsibility and accountability and the role of BAPAM within the project
 - clarity about ownership of any publications or products arising from the research, and about the process for dissemination
 - evidence of REC approval where appropriate

Further details of national legislation and guidance relating to research can be found in Appendices B and C.

4.2 SERAG Recommendations

SERAG exists as a resource for all PAM researchers. The Chair and members welcome enquiries and requests for advice from anyone involved in such research, particularly researchers wishing to work with BAPAM. SERAG Members will always aim to make constructive recommendations, including signposting for proposals that require REC approval.

The SERAG Chair and members are entitled to request additional information about any research involving BAPAM, its patients and service users, and may refuse or halt a research project if deemed necessary. In all cases, SERAG will act in the interest of BAPAM patients and service users and will seek to ensure that the highest standards of clinical governance and ethical behaviour are followed.

Version 1.0 = May 2012

Review = May 2016