

RESEARCH POLICY

(Core Standard 32)



Documents

- Policy
- Posted on Website
- Standard documents (letters etc – to be done?)
- Review date – January 2012

RESEARCH

(Care Standard 32)



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 (see Appendix A for Terms of Reference). The responsible person is the BAPAM Chair.

2. Definitions

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 subcategory 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 Specialist or Practitioner Directories (i.e. secondary referrals and self-referrals)

- **Research:** there are two levels of research relevant to this policy:
 - i. Service audit and evaluation:* assessing the quality, efficacy, and accessibility of BAPAM services through analysis of patient and service user profiles and feedback and of organisational activity (including marketing and publicity)
 - ii. 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):** two types of Research Ethics Committee which consider proposals for research involving NHS patients in the UK 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).

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

3. Scope

Most research conducted within BAPAM falls under (i) above. However, BAPAM may also be involved in empirical research as outlined under (ii), either as extended in-house audit activity or as research projects conducted in conjunction with other organisations. SERAG is responsible for approving all research involving BAPAM, its patients and service users and developing a research register in accordance with the legislation outlined in Appendix B. The types of research to be registered 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 (3.2.2)

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
- collecting and analysing patient and service user satisfaction and feedback
- collecting and analysing website and telephone advice line activity 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 consist of anonymised data so that no individual can be identified (either by name or description). Audit activity is monitored by SERAG 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).

SERAG will advise BAPAM staff on topics that need further investigation and the most appropriate means of data collection – i.e. through changes to auditing practice or undertaking discrete, empirical research projects. Proposals for in-house research projects will be developed by BAPAM staff and submitted to SERAG for approval and registration on the Research Register as per the protocol outlined in Section 4. SERAG will provide advice on research design, including the possible need for REC approval, and will monitor progress of approved research projects.

The results of research conducted in-house will enable SERAG to make recommendations for changes in BAPAM's administrative and clinical practice where appropriate. SERAG will also be responsible for developing protocols 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, SERAG will be responsible for approving and registering projects on the BAPAM research register. The protocol in Section 4 outlines the registration process.

Any empirical research involving invasive or experimental clinical procedures, biomedical interventions, randomised controlled trials, or psychiatric assessment and treatment would require REC approval and external management responsibility. This would not necessarily preclude some BAPAM involvement², 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

² SERAG will seek research partnerships to develop BAPAM's role as a PAM knowledge hub

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 approved and registered by SERAG

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

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). Research applicants intending to conduct this type of research with BAPAM patients and service users will need to provide the following information to SERAG:

- a rationale which demonstrates that these data and the use of such techniques/questions for data collection are relevant to the research project
- full details of the questions to be asked, how, where and by whom
- details of 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 drop-out and onward referral)
- the conduct of the research is in accordance with British Psychological Society guidelines, particularly relating to informed consent and issues of discomfort and distress (www.bps.org.uk)

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

4. SERAG Research Protocol

4.1 SERAG Principles

This protocol outlines the procedures for ensuring that all research involving BAPAM and its patients meets the highest standards and is recorded by the organisation.

SERAG will be responsible for approving and registering all proposed research involving BAPAM, its patients and service users. SERAG will consider a research proposal at a scheduled SERAG meeting and will make decisions according to the following guiding principles:

- 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

A summary of the key underlying principles and resources is provided in Appendix C.

A standardised submission form is under development and will be available on the BAPAM website. The form will provide guidance on how to incorporate these principles and other requirements within a research proposal.

4.2 Process for submitting research proposals to SERAG for approval and registration on the BAPAM Research Register

- 4.2.1. Details of a proposed research project must be presented in writing to BAPAM for consideration at a SERAG meeting.
- 4.2.2. BAPAM office staff will acknowledge receipt of the proposal and will confirm the date of the SERAG meeting when it will be considered and when a decision will be expected. Applicants will have the option of attending the meeting to present their proposal.
- 4.2.3 Applicants may be asked to clarify details of the proposal or to respond to questions from SERAG members before a final decision is made. SERAG

members will decide at the time of this request whether, on receipt of this information, responsibility for a final decision will be delegated to the Chair or whether it requires further SERAG consultation.

- 4.2.4 SERAG's decision will be confirmed in writing by the SERAG chair. Unsuccessful applicants will receive constructive feedback and, where appropriate, will be encouraged to re-apply. There is currently no limit on the number of times a proposal can be re-worked and re-submitted
- 4.2.5 SERAG will make recommendations for proposals that are beyond its remit, are not suitable for BAPAM involvement, or would require REC approval in addition to SERAG approval
- 4.2.6 Where additional REC approval is required, researchers will still be able to submit proposals to SERAG prior to or in parallel with their REC application, but SERAG approval will remain provisional and cannot proceed until written evidence of REC approval is provided.
- 4.2.7 Members of SERAG who have a conflict of interest in connection with a tabled research proposal may be asked to abstain from decisions about the proposal.
- 4.2.8 Details of all research projects approved and registered by SERAG will be listed in an annual report to the Medical Committee and BAPAM Board.
- 4.2.9 SERAG members are entitled to request additional information if they have concerns about any research proposal involving BAPAM, its patients and service users, and may refuse or halt research 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.

Appendix A

BAPAM Service Evaluation & Research Advisory Group (SERAG)

Revised Terms of Reference

Context and Role

BAPAM's mission is to achieve a healthy performance environment for all full and part-time professional and student performing artists, via effective health promotion strategies, performance-related health care services, and accredited postgraduate training in Performing Arts Medicine for health care practitioners.³

BAPAM's Service Evaluation and Research Advisory Group (SERAG) will be responsible for overseeing a research programme to support these aims. BAPAM SERAG is a subgroup of the BAPAM Medical Committee and is serviced by the CEO. The main aims of the group are:

- a) to assess the quality, efficacy and accessibility of BAPAM's clinical, advisory and health promotion services
- b) to develop BAPAM's role as a Knowledge Management Centre for Performing Arts Medicine in the UK
- c) to develop BAPAM's roles as sponsor, partner, co-ordinator and funder of Performing Arts Medicine research both in the UK and internationally

To achieve these aims, SERAG will be responsible for BAPAM's Research Strategy and Work Programme, which includes the development, implementation and monitoring of BAPAM's Research Policy (and the BAPAM Research Register).

Business and Priorities

The core business of SERAG will be (a) above, which will be managed strategically by SERAG and undertaken by the CEO and secretariat to be reported as standing items at each SERAG meeting.

SERAG will also oversee work under (b) and (c) as development projects. SERAG Members will prioritise and review these projects at each meeting.

³ within the extent permitted by the Trust Deed

Membership

Membership will be open to all BAPAM Trustees and BAPAM Medical Committee members. The following members must attend each meeting:

- ❖ a BAPAM Trustee nominated by the Board as lead for research issues, who will chair the SERAG.
- ❖ the Medical Director or a nominated representative from the BAPAM Medical Committee

The following personnel would also be able to attend meetings or become regular members (at the discretion of the Chair):

- ❖ BAPAM service users
- ❖ colleagues from independent UK institutions involved in PAM practice and research

Meetings and Reports

SERAG will meet at least twice yearly. The Group will review the Terms of Reference, Research Policy and research activity annually. Issues arising between meetings which require SERAG consultation will be dealt with as decided by the Chair - wherever possible, consultation will be through “virtual” meetings.

Minutes will be recorded by the SERAG Chair and presented to the BAPAM Medical Committee, and an annual report will be provided to the BAPAM Board.

Appendix B

BAPAM Research Register: Relevant Legislation

SERAG is responsible for maintaining a register of all research involving BAPAM patients in order to meet the following legislative requirements:

Healthcare Commission Standard C32.

All organisations providing health or social care in England must be aware of all research being undertaken in their organisation or drawing on patients or clients (or their data or tissue) from their organisation... The registered person remains responsible for the quality of all aspects of the care of their patients or users, whether or not they are involved in research and whoever that research may be conducted or funded by.

Private and Voluntary Health Care Regulations 2001:

I.9 (1) j

where research is carried out in an establishment, it is carried out with the consent of any patient or patients involved, is appropriate for the establishment concerned and is conducted in accordance with up-to-date and authoritative published guidance on the conduct of research projects.

III. 24:

- (a) Before any research involving patients, information about patients, or bodily material and organs is undertaken in or for the purposes of an establishment, or for the purposes of an agency, a research proposal is prepared and approval is obtained from the appropriate REC; and*
- (b) All such research project include adequate safeguards for patients and employees*

Appendix C

Summary of key points from Department of Health Research Governance Framework for Health and Social Care.

2.7.2. Key elements of a quality research culture

- valuing the diversity within society
- personal and scientific integrity
- leadership
- honesty
- accountability
- openness
- clear and supportive management
- respect for participants dignity, rights, safety and well-being

2.1.3 Research Standards and Requirements

Health and social care research must take consideration of legislation, standards and good practice requirements in 5 key domains:

- ethics
- science
- information
- health, safety and employment
- finance and intellectual property

The framework document outlines the requirements and principles for each of these domains and is available via Department of Health Website:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

British Psychological Society (BPS)

Ethical Principles for conducting Research with Human Participants

1. Introduction

1. The principles given below are intended to apply to research with human participants. Principles of conduct in professional practice are to be found in the Society's Code of Conduct and in the advisory documents prepared by the Divisions, Sections and Special Groups of the Society.
2. Participants in psychological research should have confidence in the investigators. Good psychological research is possible only if there is mutual respect and confidence between investigators and participants. Psychological investigators are potentially interested in all aspects of human behaviour and conscious experience. However, for ethical reasons, some areas of human experience and behaviour may be beyond the reach of experiment, observation or other form of psychological investigation. Ethical guidelines are necessary to clarify the conditions under which psychological research is acceptable.
3. The principles given below supplement for researchers with human participants the general ethical principles of members of the Society as stated in The British Psychological Society's Code of Conduct (q.v.). Members of The British Psychological Society are expected to abide by both the Code of Conduct and the fuller principles expressed here. Members should also draw the principles to the attention of research colleagues who are not members of the Society. Members should encourage colleagues to adopt them and ensure that they are followed by all researchers whom they supervise (e.g. research assistants, postgraduate, undergraduate, A-Level and GCSE students).
4. In recent years, there has been an increase in legal actions by members of the general public against professionals for alleged misconduct. Researchers must recognise the possibility of such legal action if they infringe the rights and dignity of participants in their research.

2. General

1. In all circumstances, investigators must consider the ethical implications and psychological consequences for the participants in their research. The essential principle is that the investigation should be considered from the standpoint of all participants; foreseeable threats to their psychological well-being, health, values or dignity should be eliminated. Investigators should recognise that, in our multi-cultural and multi-ethnic society and where investigations involve individuals of different ages, gender and social background, the investigators may not have sufficient knowledge of the implications of any investigation for the participants. It should be borne in mind that the best judge of whether an investigation will cause offence may be members of the population from which the participants in the research are to be drawn.

3. Consent

1. Whenever possible, the investigator should inform all participants of the objectives of the investigation. The investigator should inform the participants of all aspects of the research or intervention that might reasonably be expected to influence willingness to participate. The investigator should, normally, explain all other aspects of the research or intervention about which the participants enquire. Failure to make full disclosure prior to obtaining informed consent requires

- additional safeguards to protect the welfare and dignity of the participants (see Section 4).
2. Research with children or with participants who have impairments that will limit understanding and/or communication such that they are unable to give their real consent requires special safeguarding procedures.
 3. Where possible, the real consent of children and of adults with impairments in understanding or communication should be obtained. In addition, where research involves any persons under 16 years of age, consent should be obtained from parents or from those in loco parentis. If the nature of the research precludes consent being obtained from parents or permission being obtained from teachers, before proceeding with the research, the investigator must obtain approval from an Ethics Committee.
 4. Where real consent cannot be obtained from adults with impairments in understanding or communication, wherever possible the investigator should consult a person well-placed to appreciate the participant's reaction, such as a member of the person's family, and must obtain the disinterested approval of the research from independent advisors.
 5. When research is being conducted with detained persons, particular care should be taken over informed consent, paying attention to the special circumstances which may affect the person's ability to give free informed consent.
 6. Investigators should realise that they are often in a position of authority or influence over participants who may be their students, employees or clients. This relationship must not be allowed to pressurise the participants to take part in, or remain in, an investigation.
 7. The payment of participants must not be used to induce them to risk harm beyond that which they risk without payment in their normal lifestyle.
 8. If harm, unusual discomfort, or other negative consequences for the individual's future life might occur, the investigator must obtain the disinterested approval of independent advisors, inform the participants, and obtain informed, real consent from each of them.
 9. In longitudinal research, consent may need to be obtained on more than one occasion.

4. Deception

1. The withholding of information or the misleading of participants is unacceptable if the participants are typically likely to object or show unease once debriefed. Where this is in any doubt, appropriate consultation must precede the investigation. Consultation is best carried out with individuals who share the social and cultural background of the participants in the research, but the advice of ethics committees or experienced and disinterested colleagues may be sufficient.
2. Intentional deception of the participants over the purpose and general nature of the investigation should be avoided whenever possible. Participants should never be deliberately misled without extremely strong scientific or medical justification. Even then there should be strict controls and the disinterested approval of independent advisors.
3. It may be impossible to study some psychological processes without withholding information about the true object of the study or deliberately misleading the participants. Before conducting such a study, the investigator has a special responsibility to
 - (a) determine that alternative procedures avoiding concealment or deception are not available;
 - (b) ensure that the participants are provided with sufficient information at the earliest stage; and
 - (c) consult appropriately upon the way that the withholding of information or deliberate deception will be received.

5. Debriefing

1. In studies where the participants are aware that they have taken part in an investigation, when the data have been collected, the investigator should provide the participants with any necessary information to complete their understanding of the nature of the research. The investigator should discuss with the participants their experience of the research in order to monitor any unforeseen negative effects or misconceptions.
2. Debriefing does not provide a justification for unethical aspects of any investigation.
3. Some effects which may be produced by an experiment will not be negated by a verbal description following the research. Investigators have a responsibility to ensure that participants receive any necessary debriefing in the form of active intervention before they leave the research setting.

6. Withdrawal from the investigation

1. At the onset of the investigation investigators should make plain to participants their right to withdraw from the research at any time, irrespective of whether or not payment or other inducement has been offered. It is recognised that this may be difficult in certain observational or organisational settings, but nevertheless the investigator must attempt to ensure that participants (including children) know of their right to withdraw. When testing children, avoidance of the testing situation may be taken as evidence of failure to consent to the procedure and should be acknowledged.
2. In the light of experience of the investigation, or as a result of debriefing, the participant has the right to withdraw retrospectively any consent given, and to require that their own data, including recordings, be destroyed.

7. Confidentiality

1. Subject to the requirements of legislation, including the Data Protection Act, information obtained about a participant during an investigation is confidential unless otherwise agreed in advance. Investigators who are put under pressure to disclose confidential information should draw this point to the attention of those exerting such pressure. Participants in psychological research have a right to expect that information they provide will be treated confidentially and, if published, will not be identifiable as theirs. In the event that confidentiality and/or anonymity cannot be guaranteed, the participant must be warned of this in advance of agreeing to participate.

8. Protection of participants

1. Investigators have a primary responsibility to protect participants from physical and mental harm during the investigation. Normally, the risk of harm must be no greater than in ordinary life, i.e. participants should not be exposed to risks greater than or additional to those encountered in their normal lifestyles. Where the risk of harm is greater than in ordinary life the provisions of 3.8 should apply. Participants must be asked about any factors in the procedure that might create a risk, such as pre-existing medical conditions, and must be advised of any special action they should take to avoid risk.
2. Participants should be informed of procedures for contacting the investigator within a reasonable time period following participation should stress, potential harm, or related questions or concern arise despite the precautions required by the Principles. Where research procedures might result in undesirable consequences for participants, the investigator has the responsibility to detect and remove or correct these consequences.
3. Where research may involve behaviour or experiences that participants may regard as personal

and private the participants must be protected from stress by all appropriate measures, including the assurance that answers to personal questions need not be given. There should be no concealment or deception when seeking information that might encroach on privacy.

4. In research involving children, great caution should be exercised when discussing the results with parents, teachers or others acting in *loco parentis*, since evaluative statements may carry unintended weight.

9. Observational research

1. Studies based upon observation must respect the privacy and psychological well-being of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in situations where those observed would expect to be observed by strangers. Additionally, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

10. Giving advice

1. During research, an investigator may obtain evidence of psychological or physical problems of which a participant is, apparently, unaware. In such a case, the investigator has a responsibility to inform the participant if the investigator believes that by not doing so the participant's future well-being may be endangered.
2. If, in the normal course of psychological research, or as a result of problems detected as in 10.1, a participant solicits advice concerning educational, personality, behavioural or health issues, caution should be exercised. If the issue is serious and the investigator is not qualified to offer assistance, the appropriate source of professional advice should be recommended. Further details on the giving of advice will be found in the Society's Code of Conduct.
3. In some kinds of investigation the giving of advice is appropriate if this forms an intrinsic part of the research and has been agreed in advance.

11. Colleagues

1. Investigators share responsibility for the ethical treatment of research participants with their collaborators, assistants, students and employees. A psychologist who believes that another psychologist or investigator may be conducting research that is not in accordance with the principles above should encourage that investigator to re-evaluate the research.

The principles are available online at:

www.bps.org.uk/the-society/code-of-conduct/ethical-principles-for-conducting-research-with-human-participants.cfm