Guidelines for the use of psychological tests in healthcare research
Acknowledgement

These guidelines have been reviewed and updated by Christina Buxton, Dr Jerry Burgess and Dr Stephen Mullin who are members of the Committee on Test Standards (CTS). The guidelines have been approved by the BPS Ethics Committee.
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1 Introduction

1.1 Historical context of this guidance update and for whom it now applies

This guidance offers wider interpretations of the *Principles for the use of Published psychological tests in research* produced by the British Psychological Society (BPS) in 2016, and extends the previous version of *The use of psychological tests in healthcare research* published in 2011. Whilst the earlier version focused on research conducted in the NHS it is now recognised that psychological assessments conducted as part of healthcare research encompass a much wider remit than primarily conducted under the auspices of the NHS. This updated version therefore expands the previous remit to include:

- The NHS
- Third sector and independent health and social care services
- Occupational health
- Other specialist healthcare settings
- Academic settings
- Any service audit or service evaluation

It is envisaged therefore that the revised guidelines will be applicable in a range of occupations working within these settings, and relate particularly to psychologists working within clinical, counselling, health, forensic and neuropsychology arenas. It is also envisaged that these guidelines will apply where individuals are involved in either the design and/or conduct of such research.

1.2 Why this update was needed

Whilst the Society’s *Principles for the use of Published psychological tests* (2016) provide a necessary basis for best practice in the use of psychological tests in testing research they do not explicitly address the welfare of research participants who, as part of engaging in the research process, are those whom psychological tests are administered to. Rather, these principles have a focus on addressing issues of test choice, test administration, informed consent and feedback. Although research testing in healthcare settings undoubtedly also requires such considerations, the *Principles* assumed that typically the psychological testing of research participants is not used to inform decisions affecting those individuals, such as making a diagnosis of a psychological disorder. Rather, it is presumed that test use in research is limited primarily to ‘the collection of data for the development and evaluation of new tests, theories and models’ (BPS, 2016, p.2).

Use of tests in healthcare research is known to have an impact. For example, the testing process itself can have a strong impact on test participants, and test results can influence conclusions made about the nature of clinical conditions. There also may be the potential for test results to play a role in influencing the process of clinical decision-making, or for gaining access to treatment in clinical trials. Notwithstanding these instances, the testing process itself is likely to directly affect those taking a
test, raising awareness of symptoms and severity which, where their healthcare needs place individuals in a position of vulnerability, warrant careful consideration. More widely, research test data can also influence decisions made about service provision generally, thereby impacting directly on the service provision for other service users.

Whilst the *Principles for the use of published psychological tests in research* remain fundamental and relevant in all research, and whilst the previous version of the guidelines for the *Use of tests in healthcare research* did acknowledge the potential effects on the individual test taker, this version expands upon aspects of these effects and sets the context in which testing in healthcare takes place in a much wider arena. It is recognised that these revisions will offer new and particular challenges for researchers, and, in significantly broadening the types of environments in which testing in healthcare research is considered to take place, and the types of activities that are now considered under the umbrella of healthcare research, it offers new challenges for organisations in subsuming these into their policy and practice.

1.3 How these guidelines are intended to be used

These guidelines are intended to foster best practice when using psychological tests in healthcare research. They are designed, where relevant, to complement but not override other healthcare research ethics processes or requirements, and to provide a useful adjunct to the relevant legislation that has a bearing on practice in this area. This document is not all encompassing nor is it intended to be prescriptive. Each project will have its own characteristics to which some of the guidance discussed here may not apply. It may be the case that this guidance does apply and researchers are advised to consider all aspects of the research from within them. However, there may be instances where there are justifiable reasons why this may not be practicable. In the latter case, and before embarking upon the research itself, researchers are advised to pay particular attention to:

- Implications of this guidance for the design and implementation of their projects
- Impact their research may have on participants and others
- Precisely what healthcare participants may or may not receive as a consequence
- Any other risks that may be entailed
- How your research enterprise is perceived
- Perceptions of the researchers themselves and their profession
- Ethical and professional practice of psychological testing more generally

A final note of caution when considering these guidelines is that essentially, they represent a static account of a living process. The Society’s policies and documents referred to, as well as the external processes and procedures detailed, are organic in nature and evolve with changes in legislation, practice and the advancement of knowledge. Whilst the authors can testify to the accuracy of the content at the time of publication it is advised that any referenced material should be separately assessed for its currency at the point in time at which these guidelines are being utilised.
2 The use of psychological tests in healthcare research

2.1 Ethics and research governance in healthcare research

Best practice in research involving human participants should include some form of ethical governance or oversight, even for the most experienced researchers. This governance should involve an external assessment of the intrinsic worth of the research, its social value, ensuring it complies with the relevant legislative frameworks, and that it is culturally sensitive to the population in which the research is planned to take place. Research in healthcare settings commonly requires ethical clearance which may also include aspects of governance in its process of due diligence. Ethical clearance is given through appropriately constituted ethical committees usually, but not always, situated in the organisation through which the research is being conducted and/or is taking place.

The *BPS Code of human research ethics* (2014, p.5) defines research ethics as: ‘the moral principles guiding research from its inception through to completion and publication of results’, and a research ethics committee (REC) as: ‘a multidisciplinary, independent body responsible for reviewing research proposals involving human participants to ensure that their dignity, rights and welfare are protected’. These definitions underline the importance of not only having an independent ethical review of the research but that ethics must be seen as a fundamental and ongoing part of the research process from its design to inception to dissemination. In healthcare research both aspects are vitally important to safeguard the welfare of the human research participants, and the researchers themselves.

Much of the ethical best practice in healthcare research is devolved from the World Medical Association (WMA) Declaration of Helsinki. This represents an international collaboration to produce a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. For medical research in the UK these principles are embedded in the Health Research Authority *UK Policy Framework for Health and Social Care Research* (2017). This framework supersedes the earlier Department of Health (DoH) *Research Governance Framework for Health and Social Care* (DoH, 2005). All research taking place in the NHS must be ethically reviewed and approved by the Health Research Authority (HRA), prior to commencement.

Outside of the domain of the NHS however the importance of ethical governance and sound ethical conduct throughout any research in healthcare setting is not diminished. Whilst the ethical orientation of the HRA reflects the overarching position that research involving NHS service users will be dealing with a group who may be particularly vulnerable because of their health status, the position of these guidelines is that the same applies to any research involving service users, patients, clients or other individuals engaged in healthcare seeking endeavours. There remains the real potential for power imbalances, both implicit and explicit, in healthcare relationships, to act as a compelling force for compliance with any requests made for research participation. These inequalities can arise from the
physical and psychological dependence of patients and carers on the specialist knowledge, skills and access to resources controlled by healthcare professionals. For these and other reasons, ethical oversight is essential.

If ethical issues are overlooked in the design/planning of research, participants may be harmed, their time wasted, or the research findings or conclusions invalid or useless. In these senses, poorly designed and executed research can be unethical. In a similar vein, improper or incompetent management and use of psychological tests and test data in healthcare research can constitute unethical practice. Responsible test use goes beyond the selection of instruments with appropriate psychometric properties. Among other things, it encompasses robust informed consent procedures, standardised administration and scoring, competent interpretation and feedback, secure data storage, proper management of confidentiality, and procedures for managing associated risks. While such considerations may apply in other research contexts, all have a particular and significant salience in healthcare research. As noted above, this derives at least partly from the particular status such participants’ may hold in their healthcare situation, as well as the ways in which their test data may be used.

2.2 Definition of ‘psychological test’

In order to understand the scope of this document, it is necessary to clarify what is considered to be encompassed by the term ‘test’ in relation to these guidelines.

The term ‘psychological test’ tends to be most closely associated with questions and tasks intended to measure a psychological construct, that are administered, scored and interpreted in a standardised manner using numerical scoring systems. However, many procedures may be considered as constituting a psychological test. These can range from normative questionnaires (including paper and pencil tests, online versions or standalone computer administration) and performance-based tasks (which may also be computerised), to observational methods, clinical and other structured interviews, and psychophysiological monitoring devices.

A psychological test is traditionally viewed as consisting of ‘standardised or reproducible tasks (e.g. questions, stimuli or indeed tasks), standardised or reproducible methods of observation, and standardised or reproducible methods of scoring these tasks and/or observations, which are deemed psychological in providing measures or examinations of a person’s abilities, skills, interests, preferences, disposition, attitudes, emotions or wellbeing’ (Cronbach, 1990). However, as the International Test Commission (ITC) guidelines on test use (2013) note, any attempt to precisely define a psychological test is likely to exclude aspects that should be included or include other aspects that should excluded.

Following the ITC guidelines in outline, and for the purposes of psychological tests used in research, testing involves a wide range of procedures that may measure ‘normal’, ‘abnormal’ and ‘dysfunctional’ behaviours, and gather data using standardised conditions and involve systematic scoring protocols, that draw inferences from the data collected, either about individuals’ behaviours, or in
terms of classification or ordering of people. Most commonly, the psychological mechanisms and processes of interest are higher-level constructs assumed to be sampled and then quantified through the use of the test. Any procedure that involves the above, regardless of publisher, source, or mode of administration (self-report, online, face to face etc) should be regarded as a psychological test.

2.3 Test use in healthcare
The following instances illustrate potential different uses of tests in healthcare research, and support the need for special arrangements for psychological testing in healthcare settings:

■ Where test data may contribute to diagnosis and other forms of participant.
■ Characterisation and selection, for instance in epidemiological and intervention studies.
■ Where test data may be used to allocate or exclude individuals from experimental or other treatments that may have significant consequences for those taking the test.
■ Where test data may form the basis of decision-making about treatment or contribute to clinical decision-making more generally. The quality of testing can therefore have a profound impact on treatment options both for the research participant and for others requiring health services concurrently and in the future.
■ Where test results are shared or fed back to test takers potentially raising awareness of symptoms and severity, or existence of conditions, and as such may influence their perception of themselves and/or how they are perceived by society more generally (for general guidance on communicating test results see the Society's guidance, Communicating test results: Guidance for test users (2016).

2.4 Process considerations
In undertaking research in healthcare settings, a number of special features also need to be taken into account. These include:

■ The healthcare context requires particular attention to informed consent for all participants who, as a consequence of their healthcare status, may be in a permanent or transient state of increased vulnerability. Such issues are discussed by special guidance arising from the Mental Capacity Act 2005 (2007), see also Society's leaflet Mental Capacity Act 2005 – A Short Reference Guide for Psychologists and Psychiatrists, and any other relevant legislation and legal precedents.
■ Particular groups may require additional, special, consideration where their group status may place them in particular positions of vulnerability. These groups include children and young people, some older people, those whose lack mental capacity, those with visual, hearing, speech or other sensory disabilities, and people with learning difficulties. For Society's guidance see, Hearing loss, deafness and psychometric testing (2016), Visual impairment and psychometric testing (2016), and Dyslexia and occupational testing (2005).
Where there is necessity and justification for research data being included in clinical or healthcare records, and may therefore be seen or shared with others, including team members, other healthcare services and external agencies, robust and ethical data sharing protocols should be in place. It should be pointed out to participants prior to participation that third parties will have access to the results and where such data may be used in future research, audit and service evaluation, that this will be maintained anonymously.

The use of all research data collected in a healthcare setting should be covered by formal guidance on ethics, confidentiality, security and record retention. Where appropriate the use of the data should be subject to the scrutiny of an ethics committee or carried out under the governance of the sponsoring healthcare organisation.

Psychological research can involve working with individuals who are in atypical situations or experiencing distressing mental states. Test taking has the potential to be aversive and potentially to exacerbate psychological distress, particularly if used inappropriately or without due care and consideration. The use of psychological tests in healthcare contexts in particular therefore necessitates that appropriate consideration be given to such eventualities and appropriate management of risk and appropriate safeguards be put in place.

The process of testing or test findings themselves may indicate the need for further, sometimes urgent, clinical action. Those undertaking tests should be informed in advance of the reasonably foreseeable or possible immediate outcomes or consequences of taking a test in this respect.

Psychological tests may be designed or intended for use only by appropriately qualified psychologists or those under the supervision of an appropriately qualified person. In such situations it is incumbent upon the supervisor to ensure the appropriate training and monitoring of any such ‘assistants’. Failure to ensure that tests are administered by appropriately qualified individuals and/or by individuals receiving appropriate supervision in this matter may increase the potential of risk to those taking tests and/or the quality of the research being undertaken.

With regard to ethical approval, a distinction is drawn between audit, service evaluation, and research activities in healthcare settings. Whereas the latter requires formal ethical approval, audit and service evaluation do not. Nevertheless, the position adopted here is that all applications of testing should ensure best practice, irrespective of the type of application and where carried out in an institutional context that the institution shall provide ethical governance as the sponsoring healthcare organisation.
3 Guidance specific to the use of psychological tests in healthcare research

The following is offered as broad guidance and, where appropriate, more specific considerations relating to the use of psychological tests in healthcare research:

3.1 Follow available BPS guidance on ethical practice

Members of the Society are required at all times to act in conformance with all the various Society codes of conduct. Currently this would include, but not be limited to, the Society’s Code of ethics and conduct’ (2018), the Code of human research ethics’ (2014) and the current Practice guidelines (2017). Members and other individuals who are involved in the design, implementation and conduct of research using psychological tests in a healthcare setting are advised to consult the Society’s Principles for the use of published psychological tests in research’ (2016) and the Code of good practice for psychological testing (2016). It is also recommended that those using psychological tests in research in healthcare settings avail themselves of the relevant accompanying society documents and guidelines pertaining to each aspect of the research, as appropriate.

3.2 Have any research reviewed, approved, and monitored by a local Research Ethics Committee (REC)

Best practice for any research involving individuals located in a healthcare setting should involve some form of ethical governance or oversight. For any research conducted within the NHS, or using NHS patients or staff, such research must be ethically reviewed and approved by the HRA prior to commencement. For research conducted in healthcare settings outside of this remit it is recommended that the sponsoring organisation, in, or through, which the research is being conducted (e.g. university, professional or charitable association, research laboratory), should provide ethical oversight through an appropriately constituted REC. In the absence of a formally constituted REC the organisation should undertake to provide ethical governance that should involve an external assessment of the intrinsic worth of the research, its ethical and social value, ensuring it complies with the relevant legislative frameworks, and is ethically and culturally sensitive to the population in which the research is planned to take place.

3.3 Provide justification for use of particular tests in the research

It should be recognised that in any sponsoring organisation where ethical approval is given by an REC, or where the organisation provides ethical governance and oversight, these procedures may not have input from individuals with the expertise to evaluate the use of the psychological tests proposed for the project, and the use and management of test data as covered in 3.7 below. Hence, clear statements should be provided when describing any proposed research as to why the particular tests chosen are appropriate for the research aims, and for the population they are
intended to be used in. Evidence relating to the psychometric properties of the chosen tests should be documented and their ‘fitness for purpose’ justified.

3.4 Establish specific test administrative requirements in advance of testing

The administration requirements for the testing should be made explicit in advance of the research taking place. This will include any use of standardised instructions, test apparatus and any additional materials needed (e.g. computers, pens, additional paper). Specific consideration needs to be made for the secure housing of the test materials both before during and after the test administration.

3.5 Consider the particular implications of the test medium and testing environment

The nature of the environment required to effectively carry out the testing should be detailed and the medium through which the test is to be conducted should be specified (computer based, face-to-face, remote self-report etc). Consideration should be given to the specific environmental challenges that the medium may present for security and confidentiality of test materials, and of individuals’ results. The principle researcher and others carrying out the testing on their behalf should be familiar with the test providers’ data storage policy and security arrangements. The medium of the testing may give rise to particular needs to be considered under relevant legislation where individual’s electronic details, such as email address and IP address, are collected as part of the testing process. Where the psychological testing takes place using an Internet mediated host, researchers are advised to consult the Society’s Ethics Guidelines for Internet-Mediated Research (2017).

3.6 Seek guidance and provide justification for any adaptations to tests or materials used in the research

Tests and performance records (paper or electronic form) should only be used in the format provided (e.g. test publishers may provide a research copy of the test or refer the researcher to an online version), or in the form of adaptations approved by the test publisher and/or copyright owner in advance of the research taking place. Researchers are advised to seek assurance that any adaptations would not violate test reliability and validity through changes to administration or test content.

3.7 Protect participant confidentiality and test copyright and security

Confidentiality, copyright and security of test materials need to be considered at all times (e.g. test materials should not be photocopied or downloaded from a website without authorisation). This should include attention to the following:

a. Copies should only be made available to individuals appropriately qualified in test use, or to individuals acting under the close supervision of competent practitioners.

b. Details should be provided regarding the arrangements for the secure storage of test records and data. This should cover the content of both paper and
electronic research records, and their processing. For instance, the data may be anonymised, i.e. participant identity not discoverable from record form or electronic store; or pseudonymised, i.e. participant identity recoverable from the record itself but only with secure, confidential separately stored knowledge. In all cases individuals must have been made aware of how their data will be held, and for what purpose, and have consented to this as part of the informed consent process.

c. Encryption of electronic versions stored on local hard drives or individual computers should be considered, with arrangements for access to the encryption key specified. This key should be available to at least two responsible individuals.

d. Back-up copies of test data should be made and stored securely, preferably in a different location to the original data set. It is recommended that where any electronic data are stored in online repositories that the researchers consult the Society’s *Ethics guidelines for internet-mediated research* (2017).

e. Details should be provided about the management of test records and data when the project is completed, including duration of retention and security arrangements. For instance, the proposals for the disposal of completed test record sheets need to be clearly documented.

### 3.8 Specify and assure researchers are competent in test use

Researchers should detail the competence requirements for use of the research tests. These should take into account the competence levels expected of test users, details of which are available from the Society’s Psychological Testing Centre (PTC). In particular, details should be provided in advance of testing to cover the following:

a. Knowledge and skills required to administer the tests (i.e. who is competent to administer the tests).

b. Knowledge and skills required for scoring and interpretation of the tests (i.e. who is competent to score and who to interpret the tests).

c. Supervision and monitoring of test administration, scoring, interpretation (i.e. who has supervisory responsibility for the use of the tests).

### 3.9 Consider the relationship between test scores and clinical records

Where individual test scores and records also form a part of individuals’ clinical records particular attention should be paid to the current legislative requirements regarding the storage and retention of that material. Currently where the research takes place in the NHS these requirements can be found on the NHS website, or more specifically in *Records management: Code of practice for health and social care*. Other legislative requirements include the Data Protection Act (1988), and the EU General Data Protection Regulation (GDPR). Any data collected and held for any purpose in any public organisation, including these records, will also be subject to provisions under freedom of information legislation. Public organisations include any local or central government authorities, state schools and universities,
police authorities or any other organisation or body receiving public funding. It is recommended that consideration is given to the following:

a. How test-related information is included in the participant’s clinical paper record or, electronic record, and to whom and how it is to be communicated (see 3.13 below).

b. Apart from confidentiality provisions, entitlements to access, and requirements of relevant application legislative frameworks, what record access and disclosure protocols may also apply to the data collected, and through whom this should be processed.

3.10 Seek informed consent in relation to test use in the research

The administration of tests for the purposes of research should abide by the principles of informed consent. Participants in the research should be told in advance:

a. Exactly what will be required of them when participating in the test/s.

b. What will happen to the information collected through completing the test/s and what the test scores will be used for.

c. Who will have access to their test data, and how the information will be used in the future.

d. What, if any, impact it may have on their care or access to services, now or in the future.

e. Their rights of refusal to participate and the implications of such refusal, which will be withoutreprisal.

f. Their rights to withdraw their data from the research, any time there may be limitations on doing this, and what procedure they should follow in order request their test data are removed.

g. The procedures to follow should they wish to lodge a complaint specifically about the testing interaction and outcome/s.

h. How their test data will be stored including the extent to which it is anonymised, and/or held in pooled or aggregated data sets.

i. What feedback, if any, they will be entitled to receive after the testing, and the nature of that feedback, i.e. one-to-one communication of test scores, or written generic feedback on the collective research outcomes.

3.11 If research requires participants who may lack mental capacity, follow national/BPS guidance

In special cases (for instance, minors, or of those who demonstrably lack capacity permanently or transiently), specific guidance regarding consent is detailed in various sources, including provisions arising from the Mental Capacity Act 2005 (Department for Constitutional Affairs, 2007) and other relevant legislation. If applicable, the research should explicitly detail how consent under the Mental Capacity Act will be sought, and how this meets the legislative requirements. Where necessary proportional consent to participate and be tested should be
obtained from the individual or someone with recognised authority in accordance with relevant legislation. The agreement should note the key points in 3.10 above.

3.12 Consider how the dual researcher/clinician role is managed in the research process

In healthcare research, it is important that consideration be given to how the clinicians responsible for the research participant are to be involved in the research process. Best practice in this regard will facilitate participant collaboration in further projects by the team/clinicians. Particular attention should be paid to the following:

a. Ensuring that individuals and/or teams responsible for the clinical care of the participant are informed in advance of the desire to recruit and test one of their clients.

b. Providing information about the project, its aims, and the nature of the test to all service staff immediately involved – commonly those with a need and a right to know.

c. Obtaining agreement in advance from clinicians, carers and/or participants to approach specific participants who are under active care or, if relevant, who were previously involved with the service.

d. If appropriate, seek views regarding the suitability of potential participants for the specific research project.

3.13 Give consideration to whether, and how, to give test results feedback to research participants

Feedback following psychological testing as part of the research process in healthcare settings also requires particular attention:

a. Even if the test data do not lead to any decision, the informed consent process should identify the type of feedback expected and to whom it can be given.

b. It is recommended that, in the case of in vivo assessment leading to a decision regarding a test taker, written or oral feedback is provided as part of normal practice.

c. Where it is the case that owing to the numbers of participants involved, the developmental nature of the tests being used, or for confidentiality issues inherent in the research design, the provision of feedback may create practical difficulties (e.g. staffing and costs) or conflict with research objectives (e.g. criterion contamination). In such cases, participants taking tests should be told in advance that feedback will not be provided and why, with the option for the participant to pull out from the study clearly stated or re-stated at that point.

d. Where feedback is to be provided, this should be in accordance with the Society’s Standards for competence in test use. It is recommended that the Society’s document, Communicating test results: Guidance for test users (2016) is used as a guide to best practice.
e. Where the participant is also a clinical service user a note that the participant has been tested should be recorded as part the clinical notes. Where it is in the best interests of the participant’s healthcare a suitable interpretation of the test data, given by a competent practitioner, should also be noted in the clinical record.

f. Consideration should also be given to feedback about the outcome and implications of the project, such as providing a copy of the report or a paper arising from the study, both to the participant and the clinicians or team who supported recruitment.

3.14 Give consideration to when testing may need to be abandoned and the specific procedures for this

The research protocol should make clear what is to happen in the event of a crisis, or distress during testing or, in the event of test results that give rise to concern. This is particularly important if the tests are being administered by an assistant. Such protocols should include emergency contact information for the responsible researcher and should include the following:

a. A requirement that testing is only undertaken when other colleagues are onsite – out of hours and off-site testing and lone working should be avoided if possible.

b. Clear and ethical guidance about the limits of pressure to exert for continuation of testing; how to abandon testing if the circumstances point to such a decision; and where and how to record this, in addition to making a note in the test log (see 3.15 below). Suitable debriefing procedures should also be in place to support any participant who becomes unduly upset during the testing process.

c. Advance protocols to cover certain contingencies. These should include a section on dealing, if necessary immediately, with test results that may have implications for the welfare and clinical management of participants; the people to be informed, such as the responsible clinician/team; and if relevant, the participant’s GP. A record should be made in the research log if one is being kept (see 3.15 below) about the event and action taken, signed, with date and time of entry.

d. If the lead researcher is not carrying out the testing, clear arrangements need to be put in place to inform assistants of these protocols and to ensure they have been understood and are implementable. This remains the lead researchers’ responsibility.

3.15 Make use of logs for all testing sessions

Good practice should include a written, signed, timed and dated log of all testing. The place of testing should also be noted. The main purpose of the log is to record incidents that may impact on the quality of the test data and to provide a detailed description of events should any untoward incidents arise in the course of testing or subsequently.

a. This should be done if possible in a bound notebook or, if electronically, in a system that allows tracking of modifications to the record.
b. Any alterations to the log should be signed and dated.
c. The log is to be used as a reference point if there are concerns later about unusual test data.
References


Further information

Records management: Code of practice for health and social care

Data Protection Act (1988)
www.gov.uk/data-protection

EU General Data Protection Regulation (GDPR)

UK Policy Framework for Health and Social Care Research
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