Gaining approvals for mental health research in the NHS

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SUMMARY

When embarking on mental health research it is often necessary to apply for approvals from one or more review bodies to ensure that the research is ethical and that the safety and well-being of participants are safeguarded. This can be complicated and time consuming, particularly to those unfamiliar with the process. In this article we describe the approvals commonly required for National Health Service-based research involving patients and endeavour to clearly explain what is involved at each stage. We then highlight some of the main considerations, including ethical aspects, which are particularly pertinent to conducting research in the field of mental health, and finish with general advice and considerations for future developments in the area.

LEARNING OBJECTIVES

- Gain understanding of the processes involved in applying for approvals in NHS research
- Gain awareness of particular issues in mental health research, including capacity, consent, stigma and confidentiality
- Consider factors such as the time it can take to obtain research permissions and the importance of building good working relationships with the relevant committees from the start

DECLARATION OF INTEREST

None

The term 'ethics' is defined in the *New Oxford Dictionary of English* as the 'moral principles that govern a person's behaviour or the conducting of an activity'. Clinicians will be very familiar with the four principles of medical ethics in relation to clinical practice (Beauchamp 1979): beneficence (to act in the patient's best interest), non-maleficence (to do no harm), autonomy (the patient's right to choice in their treatment) and justice (fairness in the distribution of resources). 'Research ethics' refers to fundamental ethical principles which should be followed when carrying out scientific research. It is hard to believe some of the atrocities carried out by doctors across the world in the name of medical research in the 20th century (e.g. the wide-ranging medical experimentation in Nazi Germany and the Tuskegee syphilis experiments

in the USA, reviewed in Gaw (2006)). Although it seems unthinkable that such crimes would or could occur today, it is nonetheless imperative that all proposed research is reviewed objectively according to a standard framework to ensure transparency and accountability, and to protect participants and researchers alike.

The principles of research ethics are in accordance with the Declaration of Helsinki, a set of articles first developed in 1964 to mandate physicians to act ethically in the conduct of research on humans and thereby 'promote and safeguard the health, well-being and rights of patients' (World Medical Association 2013). These principles apply to research in any specialty, but mental health research may more prominently raise ethical issues such as capacity and consent (Saks 2006), owing to the nature of the conditions under investigation. A large number of review bodies exist (Table 1), some of which may be particularly pertinent to aspects of mental health research.

Any research involving National Health Service (NHS) patients in the UK requires the approval of an NHS research ethics committee (REC); also, depending on the exact nature of the research, local NHS management permissions, also known as research and development (R&D) approvals, are often needed. However, the process of obtaining these approvals is not always straightforward, especially for investigators unfamiliar with the regulatory system. It can also be time consuming, potentially taking many months for a new project to gain all the approvals needed to commence the research.

In this article, we will focus on RECs and R&D departments and their procedures, as they are the most frequently encountered bodies when undertaking research in the NHS.

The roles of RECs and R&D departments

RECs

All research conducted in the NHS should undergo review by the REC. They are:

- part of the Health Research Authority's (HRA) National Research Ethics Service (NRES) in England (www.hra.nhs.uk)

- managed by the Health and Care Research Wales Ethics Service in Wales (www.healthandcareresearch.gov.wales/gaining-ethical-approval) (before 2015, Health and Care Research Wales was named the National Institute for Health and Social Care Research, NISCHR)
- supported by the Chief Scientists Office (CSO) and NRES in Scotland (www.nhsresearchscotland.org.uk/226_Research+Ethics.html)
- supported by the Office for Research Ethics Committees in Northern Ireland (ORECNI) (www.hscbusiness.hscni.net/orecni.htm).

These overseeing organisations broadly aim to promote and support high-quality ethical research in the NHS and maintain patient safety and well-being. The specific role of RECs is to review research proposals and give opinions on whether the proposed research is ethical. RECs are composed of members of the public as well as healthcare professionals with specialist knowledge who can help clarify particular aspects of research proposals. RECs are independent of research sponsors, funders and investigators. There are currently more than 80 RECs across the UK, and each year they review around 6000 research applications. On average, they give an opinion in less than 40 days.

R&D departments

If research is to be carried out on the premises of an NHS organisation, with NHS patients or with NHS staff, then NHS R&D approval is likely to be necessary. The overall purpose of NHS R&D departments is to support the promotion and delivery of research within NHS organisations, providing a 'supportive and safe environment for research activity' and 'specifically support individual studies' (National Institute for Social Care and Health Research, undated).

Coordinated systems for NHS R&D review are now in place across the UK (www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review), allowing one R&D application to be made centrally in the first instance. Each country's coordinating unit is a central organisation (e.g the Health and Care Research Wales) which conducts 'global' checks, ensuring that all necessary information and documentation has been submitted. These checks include ensuring a project has a favourable (or pending) REC opinion, appropriate sponsorship and indemnity, as well as broadly reviewing potential risks that the project may pose to participants and staff.

An NHS organisation is a legal entity responsible for its own local governance checks, therefore the application will be passed on from the central service to each local NHS R&D office at the sites in which it is proposed that the research is carried out. Local governance checks consider the aspects of the research study that are specific to each participating NHS research site. They establish whether there are suitable resources, equipment and facilities locally and make sure that appropriate arrangements are in place to allow the research to be undertaken.

Locally, R&D departments need to be satisfied that it is feasible to carry out the research within their organisation and that the well-being of their patients is being promoted.

The processes involved in applying for approvals

The processes involved in applying for approvals are summarised in Fig. 1 and are explained in detail in this section. Before applying for the necessary approvals, a research idea should be developed and the study carefully designed (see 'Study design'). Funding should have been agreed and a sponsor identified.

Sponsorship

Prior to obtaining REC and R&D permissions, a project needs to be approved by the research 'sponsor'. The sponsor is the institution or organisation responsible for the management and financing of the research (e.g. a health board/authority or an educational institution). The sponsor needs to approve all aspects of the proposed research before submission to the review bodies, including the protocol, information sheets and consent forms. They also provide indemnity for the research.

TABLE 1 Examples of review bodies whose permission may be required to carry out research

Research permission body	Purpose
Research ethics committee (REC)	To give an overall opinion on whether the proposed research is ethical
Research and development (R&D) department	To support and promote the delivery of research in the National Health Service, particularly in the relevant health board/authority
Medicines and Healthcare products Regulatory Agency (MHRA)	Review of clinical trials of investigational medicinal products or medical devices
National Offender Management Service (NOMS)	Review of projects involving prisons or probation trusts
Administration of Radioactive Substances Advisory Committee (ARSAC)	Review of research involving administration of radioactive medicinal products
Human Fertilisation and Embryology Authority (HFEA)	Review of research involving human embryos and gametes
Human Tissue Authority (HTA)	Review of research involving storage of material from a human body

Electronic submission process

Research permissions, including REC and R&D approvals, are then applied for in parallel through the Integrated Research Application System (IRAS, www.myresearchproject.org.uk), a single online portal for health and social care/community care research in the UK. IRAS enables information about the project to be entered just once for all review bodies, including both REC and R&D, using filters to ensure that the data collected are appropriate to the type of study and the bodies being applied to. All documents, including the protocol, information sheets, consent forms, and evidence of sponsorship, funding and peer review are submitted to the review bodies electronically via the IRAS website. A representative of the sponsor, in addition to the chief investigator, needs to approve the whole submission electronically via IRAS.

RECs

Researchers will usually apply to their local REC. Some REC panels will have specific interests and expertise (e.g. in reviewing clinical trials of medicinal products), and researchers should check which panel would be the most suitable to review their study. Researchers submitting a full application to a REC are invited to attend the committee meeting(s) at which a decision is made about the suitability of their proposed research. It is in the best interests of the research team for at least one representative to attend these meetings to
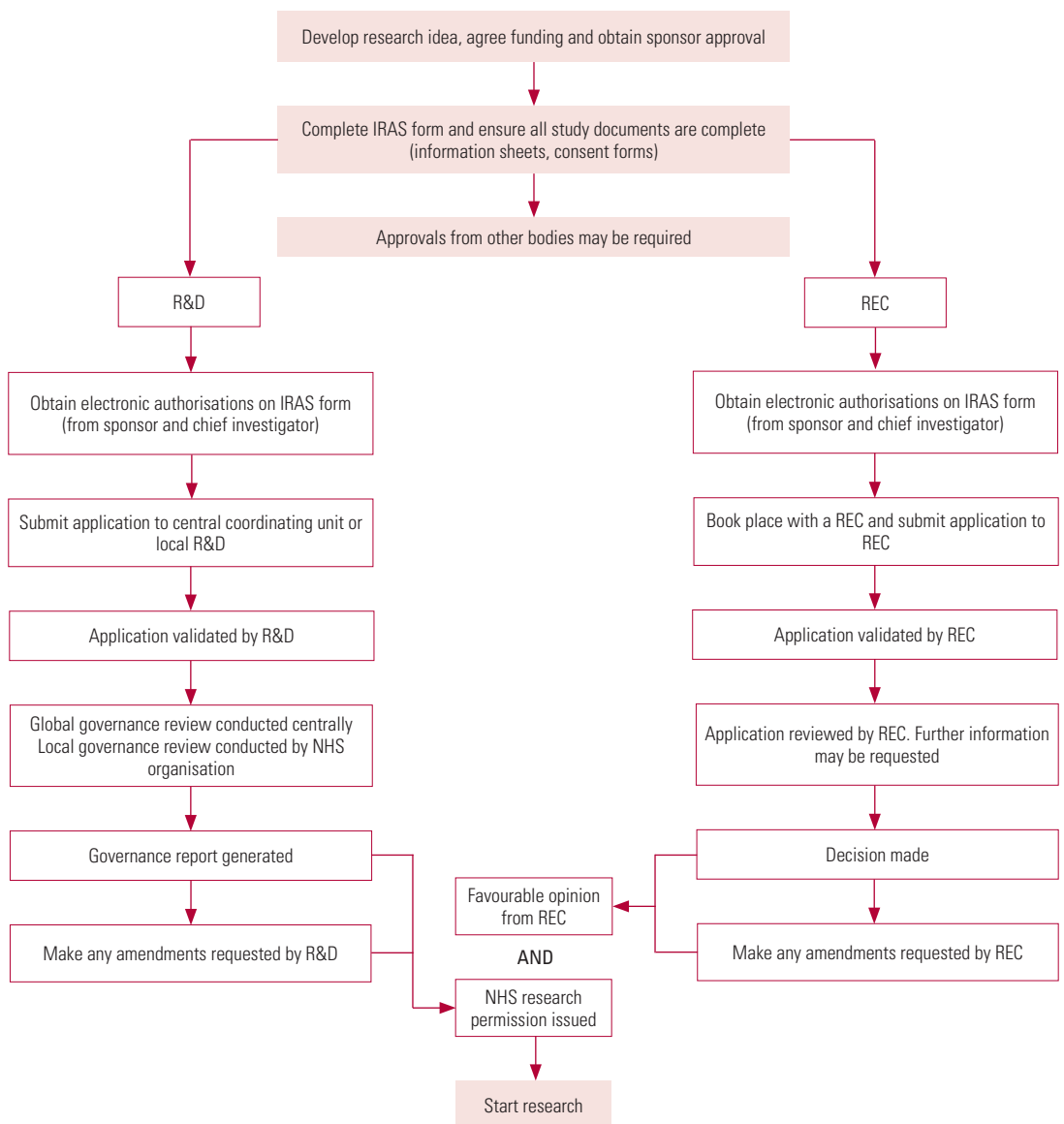

FIG 1 The research approval process. IRAS, Integrated Research Application System; NHS, National Health Service; R&D, research and development; REC, research ethics committee.

provide any clarifications needed. The researcher must satisfy the REC that their research will be ethical and worthwhile, and that any risks to participants are minimised and justified. The REC may approve the proposed research immediately, but will probably require amendments which will need to be resubmitted, either for further scrutiny by the committee if major or for approval by the committee's chair if minor. Once approved, a formal letter is issued in confirmation.

R&D

Once the R&D application is made via IRAS, the central body then passes it on to the local R&D department involved for approval of the details of the research. If the proposed study involves more than one site (e.g. a number of hospitals/clinics), with protocol differences at each, a Site Specific Information form (via IRAS) will be needed for each site to explain these differences. However, there will normally be a lead NHS R&D office for the project (usually the NHS organisation that employs the chief investigator of the study). If applying to more than one R&D department, each office may require their own amendments to be made. These may be different to each other and to those required by the REC. Any changes required by the R&D departments should be notified to the REC and *vice versa*. Once approved, an NHS permissions letter must be provided by each NHS organisation before the research is started. This R&D approval is required prior to starting the research, even if a favourable ethical opinion has already been obtained.

In addition to obtaining R&D approvals for the research, it is necessary to clarify the organisation of local governance procedures to identify which further paperwork needs to be completed in relation to the project. For example, a Disclosure and Barring Service (DBS) (formerly Criminal Records Bureau, CRB) check is likely to be required if the research is being carried out at an organisation which is not the researcher's employing organisation and there are inconsistencies as to which trusts/health boards accept the research passport. It would be useful to clarify these procedures early on in the process to avoid delays in starting the research.

R&D departments have a target to ensure that the first participant is recruited into a study within a set time after approvals have been granted. The duration of this interval is currently changing from 60 days to 30 days, with some offices aiming for 15 days. It is therefore important that researchers do not gain approvals before they are able to start recruiting or they may miss this target.

Considerations when planning mental health research

There are a multitude of ethical and other issues which need to be considered when carrying out all research, including mental health research. This section does not aim to be exhaustive; rather, it gives an overview of the main issues involved at each stage of the research process that may be relevant to approval bodies. Case studies from our own experiences in child and adolescent mental health research (Boxes 1–3) illustrate various issues that we have encountered in different research areas.

Study design

As with all other health research, a study should be designed appropriately so that it is able to answer the research question and test the postulated hypotheses; equally, any data gathered should be pertinent to the study question. This will ensure the best use of resources and participants' time. Both the research sponsor and the REC are likely to require evidence that a proposal has been externally peer reviewed, and this will help ensure that a study is well designed prior to the approval process.

Depending on the question being posed, recruitment of a control group is often an important aspect of study design. This raises the issue of

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BOX 1 Developing and evaluating an online mental health intervention for young people

E-mental health (the use of digital technologies to help with mental health issues and difficulties) is a growing area of research. One of the authors is involved in the development and evaluation of an online package to help prevent and manage mental health difficulties in young people. Some of the considerations for the design of this project included how best to consult potential users of the package during its development and evaluation, and interviews and focus groups with young people, parents/carers and professionals were arranged. It was important to facilitate engaging, non-judgemental and friendly discussions without disclosing personal experiences or psychiatric histories of vulnerable participants, especially in the young person focus groups. Other considerations included the use of non-stigmatising, age-appropriate language for the package and project documents (information sheets, consent forms), so that individuals were not identified according to their mental health difficulties. The intervention will include mood-monitoring components and links to social media and forums, and a secure database and regulated site is paramount, ensuring users are not identified or cyberbullied.

BOX 2 Neuroimaging in adolescents with neurodevelopmental disorders

Rapid advances in technology mean that the utility of magnetic resonance imaging (MRI) in mental health research has increased greatly over the past few years. Two of the authors are involved in studies investigating the aetiology of neurodevelopmental disorders using structural and functional MRI scanning in adolescents. Considerations pertinent to these projects have included the development of group- and age-specific information sheets (including those for younger and older adolescents), the length the sheets had to be to include all the information about the scanning procedure, and the delivery of this complex information in appropriate language. One of the projects has also included participants with intellectual disabilities, necessitating particular consideration of the issue of capacity to consent. Careful thought has been given to the acceptability of the scanning process to young people by age-appropriate explanations and the use of a 'mock' scanner first to acclimatise participants to the scanning environment. Both studies have formed part of larger longitudinal studies and the effort involved for individuals to participate repeatedly has been gratefully acknowledged by the researchers.

who are suitable controls? Controls should be as similar to cases as possible and this may involve, for example, matching on characteristics such as age, gender or IQ. However, in certain instances, when a variable on which matching is proposed is associated with case status, matching may remove the variance associated with the characteristic under study so this needs to be carefully considered. Individuals volunteering as controls for scientific studies are likely to be highly motivated, but may have particular reasons for taking part, such as an affected family member, which could act as a genetic confound for heritable disorders. Such issues need careful attention and the decision on who to recruit as controls will depend both on the research questions posed and pragmatism with regard to what is achievable.

Consultation at each stage of research

It is recommended that a range of individuals and groups are consulted when planning each stage of the research. In fact, consultation is an expectation of the ethical review process. Potential consultants could include patient groups as well as individuals, families, carers, professionals and charities who are associated with the area of interest. Consultations could range from informal communication and meetings, to the use of questionnaires, semi-structured interviews and

focus groups. Themes to discuss could include the method of recruitment, the design of information sheets and the acceptability of the study protocol – particularly in view of the potential difficulties in identifying and engaging participants (e.g. due to the symptoms and stigma associated with mental illness, as will be described below).

In the UK there is a strong tradition of encouraging service user involvement in the planning and undertaking of mental health research. This approach has been shown to benefit both the service users and researchers (see NHS National Institute for Health Research's (2013) guidance on involving people with experience of mental health problems in research).

Recruitment methods

Recruitment methods need careful thought. There are many possible avenues for recruitment, but broadly these would fall under (a) direct identification of potential participants through previous studies, population studies, clinics and charities, and (b) study adverts (e.g. websites, posters, newspapers), depending on the group being targeted.

Once potential participants have either been identified or have volunteered, there are several methods of communicating with them about a study. This could involve individuals and families being invited directly, for example when they attend

BOX 3 Longitudinal clinical research in adolescents with developmental disorders

Understanding the clinical course of neurodevelopmental disorders is important in order to be able to make predictions about an individual's prognosis and identify potentially modifiable factors which may improve outcomes. One of the authors is involved in a study using questionnaire and structured interview-based assessments of adolescents with attention-deficit hyperactivity disorder (ADHD) to examine the relationship between childhood ADHD and later depression. Development of information leaflets for different age groups has been an important aspect of this project. It has been imperative to be clear that a research interview is not a clinical contact and may not provide any direct benefit to participants. As young people are undertaking research diagnostic interviews and answering detailed questions on their emotions and behaviours, it has been important to have a clear protocol in place to deal with distress, worrying disclosures, or disclosure of significant symptoms of mental illness during an interview. In view of the likelihood of these occurrences during interviews with a clinical population, an explanation of confidentiality has been particularly relevant.

a clinic, or having a letter sent out by the local study lead. Over recent years, however, electronic methods of communicating such as email or SMS/text messaging have been used increasingly. There are particular issues and risks pertinent to all modes of invitation, for example that an invitation will be received by someone other than the person targeted. The postal address, email or telephone number of the individual should be confirmed before the communication is sent out. If possible, invitation documents should not suggest that the person is being invited because of a particular diagnosis or difficulty – this is especially important in relation to the sensitivity of psychiatric diagnoses.

Challenges in engaging potential participants

Participant recruitment can pose a major challenge in mental health research. In studies where potential participants are recruited from clinics, medical staff may express their support to help with recruitment but may not actually have the time to be able to do so in the context of a busy clinic setting. Close liaison with clinicians about the nature of the project and having project staff sit in on clinics to help with recruitment can facilitate clinicians' involvement in the process. Also, although in our experience people with psychiatric disorders tend to be broadly supportive of being involved in research, the nature of psychiatric symptoms may affect an individual's interest in and their ability to participate. For example, patients with depression may not feel motivated to take part during episodes of low mood, patients with psychosis may lack insight into how their condition affects their ability to engage, and those with attention-deficit hyperactivity disorder may lack the organisational skills to liaise with researchers about participating. This may result in inherent biases in recruited patient samples, with those with less severe symptoms, higher IQ and socioeconomic status, and those in remission being more likely to participate. Furthermore, for vulnerable groups such as children and adults lacking capacity participation is likely to also involve a carer. Therefore the decision about whether or not to participate will be influenced by their carers' ideas, concerns and expectations about research, and indeed their psychopathology.

Confidentiality and data protection

Although many people with mental health problems are enthusiastic about research, mental health problems continue to be associated with stigma (Corrigan 2005), which may prevent patients from wanting to be recruited into research. There may

be instances where an individual would wish to conceal their diagnosis from their doctor, employer and family members. Ensuring confidentiality about mental health problems is paramount when undertaking research in this area.

The collection and storage of study data must be operationalised such that participants are not identifiable to those outside the research team, and researchers must adhere to the Data Protection Act 1998 in how they record, anonymise/pseudoanonymise and securely store the data, and must specify in the approval documents how this adherence will be achieved. However, there may be times when confidentiality needs to be breached, for example if a patient makes a clinically significant, risky disclosure during the course of a study. Clear procedures must be in place to deal with such instances.

Reasons for participating

Potential participants should be made aware of opportunities to take part in research without feeling pressurised or coerced. The possible advantages and disadvantages of participating must be clear from the outset. It must be made explicit that individuals are free to take part and withdraw from the study without any negative impact on their clinical care.

As is the case for research in all medical specialties, mental health research relies heavily on the goodwill of participants, as studies (e.g. epidemiological, genetic and neuroimaging studies, and even trials) may not provide them with any direct, tangible or immediate benefit. In such instances, it must be made clear that participating in the study is only to help better understand the aetiology of a disorder or the mechanism of an intervention, and to help others who might be affected in the future. Gift vouchers are often used (especially for young people as a substitute for cash payments) as a reward or recognition for involvement in research (Mental Health Research Network 2013), and this should be made clear to ensure that a legitimate reward does not act as an incentive in itself.

Capacity and consent

An individual's capacity to consent to participate in research is distinct from their capacity to consent to treatment. The HRA's guidance on the Mental Capacity Act 2005 states that 'a core principle of the Act is that capacity should be assumed unless established otherwise. If a participant has consented to take part, it may generally be assumed that capacity remains in place but the researcher should be alert to any changes suggesting that

capacity has been lost' (NHS Health Research Authority 2013). However, gaining informed consent to participate in research may be difficult in some patient groups. For some disorders, an individual's capacity to consent to participate may be persistently affected or may fluctuate (e.g. intellectual disabilities, schizophrenia, dementia). It is therefore imperative that all members of the research team have adequate training in this area.

Different information sheets (see below) may be needed so that material is clear and understandable to participants of different ages and with different levels of cognitive functioning, to allow them to provide properly informed consent. Participants must be given sufficient time (usually at least 48 h) to read the information sheets, digest their contents and obtain any answers to questions they might have before agreeing to take part. Children under 16 years old are not allowed to provide consent to take part in research and so will need to sign an 'assent' form in tandem with a parental consent form. It is also good practice to obtain parental consent for those aged 16–18 years old to participate in research. Consent forms need to be designed so that consent to each facet of the research process is signed for separately, such that a participant could agree to some parts of the research but not others.

Information sheets

Both the content and design of the information sheet are important in determining whether it is effective in engaging and informing potential participants and their families and carers. The language needs to be targeted to a lay audience, with the avoidance of stigmatising language and medical jargon. For example, it is preferable to describe someone as an individual with a particular disorder, such as 'a person with schizophrenia' rather than as 'a schizophrenic'. It is particularly important to consider the age group under study, and it is best practice for leaflets for children to be presented differently according to whether they are under 16 years old or 16–18 years old (National Patient Safety Agency, National Research Ethics Service 2011).

The choice of overall visual design and imagery can affect the way in which an information sheet is read, and an unhelpful image next to the text can detract from the message. There is a tradition of overusing certain imagery in relation to mental health, especially negative ones, for example photographs of people in the 'fetal' position holding their head in the corner of a room. Organisations such as the Samaritans have published guidelines regarding reporting and the

use of images, particularly in relation to suicide (Samaritans 2013). Time to Change also launched the Get the Picture campaign in 2015, with a wide range of images suitable to be published in relation to mental health issues (www.time-to-change.org. uk/getthepicture).

A balance needs to be struck between making information sheets short enough to be accessible, especially for children, and including all the necessary detail about the research process. This can be difficult to achieve.

Newsletters and feedback

It is good practice to provide feedback to research participants on the progress and outcomes of the study, which could be in the form of newsletters, presentations or meetings. This is particularly important because mental health research often provides no contemporaneous direct benefit to participants as previously discussed. Feedback not only helps inform those involved of the results of their important contribution, but could help make them feel engaged in the process and increase the likelihood of them wishing to participate in future studies.

General advice and considerations for the future

Consulting REC and R&D guidelines and departments

It is advisable to consult electronic resources as well as relevant individuals and organisations in the initial stages of planning mental health research. This will help in adhering to guidelines as closely as possible and avoiding unnecessary delays in the review process, which may affect the project start date. There are freely available guidelines for various aspects of commencing a new research project (e.g. for designing information sheets and consent forms: www.hra.nhs.uk/resources/before-you-apply), which are updated regularly. Although parallel applications for all R&D departments are recommended, it is advisable to engage in discussion with the R&D department most closely affiliated with your centre and the REC office at the initial stages of writing the research plan. This can help pre-empt difficulties and challenges, save time and paperwork, and build good working relationships with individuals who can help facilitate current and future research projects.

Streamlining and centralisation

In a multicentre study, the process of completing the initial documentation, responding to each department's queries and making the necessary

amendments can be time consuming. Therefore, it is important to factor in the time required accordingly. However, plans are afoot to further streamline the governance processes – there will be changes, for example, to the approvals system in Wales in line with those proposed by the HRA in England (Health and Care Research Wales 2015). This is a positive development as it will potentially avoid duplication and will expedite the review process, without affecting its rigour or standards.

Online and other electronic approaches

Over recent years, the process of applying for REC or R&D reviews has become increasingly reliant on electronic means, with all documents now submitted online via the IRAS. It is likely that it will become more 'electronic' in future, with greater emphasis on user interface design and streamlining the process. Other aspects are also likely to become more electronic, for example research participant recruitment, information sheets and consent forms, mental health research assessments and recording of responses to interventions. This will require more dialogue with local information services and consideration of the benefits (e.g. time saving, ease of access to information, ease of participant response) as well as risks (e.g. storage failure, safe storage of and access to identifiable data, confidentiality) of using digital technologies. These issues are also pertinent to the growing area of e-mental health (Box 1), including the development and evaluation of electronic clinical assessment tools and interventions.

Collaborations with other groups in academia and other sectors

Research teams are becoming increasingly multi-disciplinary (e.g. health and education, laboratory and clinical teams). There are also collaborations between public, private and third-sector organisations. In additional, multicentre research projects – which seek to analyse large quantities of data to improve the power of studies – involve collaborative efforts between various research and clinical centres at local, national and international levels. Researchers should have an appreciation of the ethical, legal and research processes of each participating discipline, organisation and country. They should ensure that they understand their site-specific responsibilities and allow sufficient time for approvals to be gained locally. Given that there will be shared, but also possibly varying interests across involved parties, it is important to be aware of any competing interests from the outset.

Greater consultation with potential research participants

As described previously, there is an expectation that potential research participants are consulted from an early stage with regard to the research plan. This is likely to become more formalised over coming years, with groups set up with interests in different aspects of mental health (e.g. parents of children with mental health disorders). Such groups might also approach researchers with ideas and plans for projects of their own. Public engagement training is important in this regard. Evidence of consultation with potential participants is especially helpful to inform the acceptability of research protocols, as there is evidence that RECs can overestimate the distress that they think research will cause participants (Petrie 2013).

Conclusions

Research permissions have become an integral part of research preparation in all areas of medicine. However, individuals with mental health difficulties are a vulnerable population, and aspects that need special consideration include recruitment methods, stigma and confidentiality, and capacity and consent. Feedback obtained from both RECs and R&D departments provides a useful external perspective and can highlight ethical and organisational issues which may not have been considered. It is important to make contact with the relevant REC and R&D department early in the development of a research proposal. Although their roles may seem duplicative, they are in fact quite different, with RECs providing an independent opinion on ethical aspects of the proposed research, and R&D departments considering issues pertinent to the environment in which the research is going to be carried out and the risks which the NHS organisations might incur in hosting the research. It is important to consider that even with a favourable decision on the project's ethics, research cannot commence unless the R&D department is satisfied that all issues that have been raised have been addressed satisfactorily.

The process of filling out the required paperwork can be very time consuming and thus it is essential to be familiar at the outset which forms need to be completed and which agencies need to be involved at each stage of the application, and factor in time accordingly. In future, it would be ideal if the processes involved could become more streamlined, while ensuring there is no compromise to the integrity of the review process and thus to participant and researcher safety.

MCQ answers
1 b   2 d   3 b   4 d   5 a

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MCQs

Select the single best option for each question stem

1 All research involving NHS patients requires the approval of which regulatory body?

a Medicines and Healthcare products Regulatory Agency (MHRA)
b Research ethics committee (REC)
c Research and development (R&D) department
d Human Tissue Authority (HTA)
e Human Fertilisation and Embryology Authority (HFEA) .

2 Who provides indemnity for research activity?

a the chief investigator
b the REC
c the R&D department
d the research sponsor
e the research funder.

3 What is the Integrated Research Application System (IRAS)?

a the body which provides approvals for research
b the system by which applications for REC and R&D approvals are made
c the body which reviews clinical trials of investigational medicinal products
d the system through which research funding is applied for
e the body which reviews research involving storage of material from a human body.

4 On average, within how many days does a REC give their decision?

a 10
b 20
c 30
d 40
e 60.

5 The HRA manages the research ethics service of which country or region?

a England
b Northern Ireland
c Scotland
d Wales
e the UK as a whole.

Correction

CORRECTION

Foreman D (2015) The psychiatry of children aged 0–4: advances in assessment, diagnosis and treatment. *BJPsych Advances,* **21**: 377–86.

The last row and footnote of Table 2, on p. 380, should read:

ADBB	Structured, scored interpretation of clinician attempts to interact with children aged 2–24 months	Clinical cut-off has been replicated internationally; has 2 dimensions (temperamental and interpersonal) and is predictive of relationship and behavioural problems at 3 and 5 years respectively

a. The M-CHAT was preferred to the Social Communication Questionnaire (SCQ) as there was evidence that the latter works less well in younger age ranges, requiring cut-off adjustment (Wiggins 2007).
3Di, Developmental, Dimensional and Diagnostic Interview; ADBB, Alarm Distress Baby scale; ADI-R, Autism Diagnostic Interview – Revised; ADOS, Autism Diagnostic Observation Schedule; ASEBA, Achenbach System of Empirically Based Assessment; Attachment Q-Sort; CHAT/M-CHAT, (Modified) Checklist for Autism in Toddlers; DAWBA, Development and Well-Being Assessment; DISCO, Diagnostic Interview for Social and Communication Disorders; ECI-4, Early Childhood Inventory for DSM-IV diagnoses; K-SADS-PL, Schedule for Affective Disorders and Schizophrenia for school-age children (Kiddie-), Present and Lifetime; NBAS, Neonatal Behavioral Assessment Scale; PAPA, Preschool Age Psychiatric Assessment; PAS-R, Preschool Anxiety Scale – Revised; PFC, Preschool Feelings Checklist; SDQ, Strengths and Difficulties Questionnaire.

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