East Midlands Academic Health Science Network
Igniting Innovation

How to guide

How to form a 'Consent to Approach' Register: The Technical Background

Updated 8/10/2014 *Download this from http://www.emahsn.org.uk/public-involvement*

Who wrote this document and why?

The Government wants people to know about health research and have the opportunity to serve as a participant when appropriate. This paper has been written to bring together what we have learnt across the East Midlands about some technical aspects of creating a Consent to Approach register in health research. This kind of register allows patients and the public to register that they are willing to be approached and invited to participate in research. It increases democratic control just a little.

This technical paper is structured as a series of *Frequently Asked Questions*, to accompany a companion paper that captures the headline messages. Both papers were drafted by Peter Bates, Facilitator for Patient Leadership at the East Midlands Academic Health Science Network following a series of meetings[1]. As readers provide feedback, further insights will be used to update the paper. Please contact shahnaz.aziz@nottingham.ac.uk to suggest improvements or tell us how you have made use of this paper.

Are there any issues with data protection?

Our experience in the East Midlands suggests that Consent to Approach registers are likely to be relatively small and held by individual teams that share

[1] Verbal or written comments have been gratefully received from Carl Edwards, Jane Flewitt, Fred Higton, Trevor Jones, David Kelly, Liz Lesquereux, Ann Priddey, Professor Steve Ryder, Dominick Shaw, Derek Stewart, Brian Thomson, Kirsty Widdowson and Nicola Wright. David Kelly is working with Ann Priddey to develop local proposals on this topic for the MHRN Trent Hub.

a commitment and enthusiasm to make them work[2]. Along with this model comes a need to ensure that each Register is managing its data governance effectively[3].

While some database managers maintain contact with registered people via newsletters and other contact, others prefer to keep the Consent to Approach database entirely separate from newsletter distribution or other involvement activities, as some people prefer to know exactly what they are 'signing up' to, and communications staff (who do the newsletter) and involvement staff (who recruit public representatives into advisory roles) should not have access to any of the medical information that might be on the Consent to Approach register.

It is commonly believed that all identifying details of each patient must be deleted at the end of each study and may not be used for another purpose, such as inviting people to participate in a subsequent piece of research. Others[4] have suggested that the data belongs to the funding body, not the individual research team, so people may be contacted and invited to participate in a second research study.

Whatever the detail here, a Consent to Approach register solves this problem, as the registered people have explicitly given their permission to be approached.

Dame Fiona Caldicott has recently led an independent review of the balance between data protection and data sharing in health and social care environments[5]. This work builds on the Data Protection Act and activities of Caldicott Guardians[6] and suggests some changes, particularly to manage the risk that several sources of 'de-identified data' can be combined to re-identify the individuals concerned. The role of the Information Governance lead in NHS Trusts continues under these proposals, and advice is also available from the

[2] As information management improves, larger registers will appear. See http://goo.gl/XFj4Of for an example of a national register for dementia research.

[3] Andrew Fearn, ICT Manager at Nottingham University Hospitals, has raised this question.

[4] Derek Stewart, Deputy Director of Involve, advises that NIHR consent documents indicate that the information is held by NIHR, not individual studies, and so, despite opinion to the contrary, it *can* be shared between studies. Advice from the Health Research Authority may be needed to resolve these differences of view.

[5] Caldicott F (March 2013) *Information: To share or not to share? The Information Governance Review March 2013.* London: Department of Health. Available here.

[6] A Caldicott guardian is a senior NHS manager who has responsibility for the protection of patient information.

Confidentiality Advisory Committee of the Health Research Authority who took over the National Information Governance Board's remit for s251 applications[7].

The Lancaster University Research Ethics Committee approved development of a Consent to Approach Register[8] and made it explicit that the University is the data sponsor and provides cover in terms of liability. They have learned some lessons about software and can offer advice[9] on this and on who has access to the data. Liverpool[10], SLAM, Sheffield Health and Social Care NHS Trust[11] have a General Consent Register, and MHRN West Midlands Hub[12] are building one. In 2013, Dendron developed a 'recruitment and feasibility tool'.

What kind of document is the Consent to Approach register?

All personal information is controlled by the Data Protection Act, including anything recorded in a Consent to Approach register, even if it is no more than names and contact details. Once details of the person's health condition or other circumstances are added to the Register so that researchers can decide whether the person is suitable for a particular research study, then additional safeguards may be required. Where staff employed by the NHS have access to the data, different rules may apply.

Consent to Approach registers should be maintained according to the usual Data Protection Act requirements. Normally, the Register Manager is specifically identified to work with the register and is the only person who routinely has access to the data, and sifts it for specific researchers, prior to

[7] Section 251 of the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001), allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practicable.

[8] Information about the Spectrum Connect database from Gerasimos Chatzidamianos, Senior Research Associate, Spectrum Centre for Mental Health Research, Lancaster University.

[9] Gerasimos (see footnote above) advises that http://www.limesurvey.org/en is free and has been more effective than survey monkey.

[10] The Liverpool approach is simpler and less technical than the approach used by SLAM. However, Liverpool's reference to "the healthcare team" is a little vague/non specific for good practice consent purposes (the patient might assume it means one thing when it means another, which is not very fair. It is important to ensure that patients are very clear about what they are agreeing to and who they are allowing to access their health records. Nottingham University Hospitals have assessed and rejected this approach.

[11] Information from Ann Priddey. The contact at Sheffield is Nick Bell on 0114 271 6310.

[12] The MHRN West Hub[12] have funded a 0.2 wte post to set up a scheme across their Trusts.

providing that researcher with suitable names. As a result, researchers only see details of potential participants and no one else.

What types of contact database are available in the NHS?

There are five kinds of register, as shown below. The broad principle is that the more information that is held about the person, the greater the obligation to confine communication to issues relating to the person's individual healthcare.

1. Membership Registers are a compulsory part of the structure of Foundation Trusts, and the membership officer may write to members and invite them to get involved in public activities or any other kind of activity related to the Trust. No clinical information is collected on this database.
2. A Consent to Approach Register simply records whether the patient is willing to be directly approached about current and future research with a view to participation, and this approach can be by any researcher and not just the person's individual healthcare team. Entry of the patient into any current or future study will then require separate and study-specific consent. The Register simply consists of a record of agreement to be approached and the person's contact details, and so it can be part of the routine patient experience.
3. Some clinics keep a Case Register database that includes clinical details. Such a Register is governed by many rules about how it can be used. It generally includes a screening process by which patients are selected for entry into specific research studies, and this requires assessment of patients against a range of study criteria to identify suitable cohorts. There are clear but surmountable information governance issues. If the process of cohort identification is done by a researcher, it must be done using de-identified data, as is the case with the Case Register at SLAM.
4. Biobanks provide an example of generic and enduring consent through which the patient permits researchers to use their stored biomaterials (actual blood, tissue and so on, or data about it) in current or future studies without any further information or further permission being required. The Government is currently proposing that any clinical data, and biomaterials gathered for routine care and excess to diagnostic purposes should be available for use in research without patient consent.

5. Casefiles record individual healthcare and may not be used for other purposes or by people outside the clinical team without special arrangements.

Is there evidence that Consent to Approach Registers are effective?

One might expect that, done well, a Consent to Approach register will be an effective way to improve recruitment of patients to research studies. We might expect that patients who are primed to be contacted are more likely to agree to participate, or people who have given their consent in principle wish to then be consistent to their initial aim by consenting to the specific invitation.

It would be interesting to know what proportion of people sign up to a Consent to Approach Register and what proportion of these subsequently become research participants or advisers. Dominick Shaw commented ‘our experience shows that at best only 10% of "cold-called" database patients get enlisted in a study. Most don't respond and the rest fail screening. The results are much better in face to face recruitment directly into a study such as through a clinic.

The Mental Health Research Network West Hub[13] have approached people with a history of depression for ‘pre-consent’. They agree in advance to participate in future studies when they are ill. Only a few people have withdrawn at the full consent interview.

How should family and friends be involved?

It has been suggested[14] that a culturally competent approach would move consent out from a one-on-one conversation into the family or personal network of the individual, creating a kind of ‘family consent’.

Is the whole community engaged?

A pro-active approach will be required to reach under-represented communities, and this may be most successful if done via community leaders in the target groups.

[13] Information from Chantal Sunter.

[14] Idea from Deb Wall, July 2013.

Can administrative staff help with recruiting people on to the Register?

In some projects administrative staff (such as GP receptionists) have been given the task of recruiting people to the Consent to Approach Database. In some cases this has been spectacularly unsuccessful and has actually reduced recruitment levels rather than increased them. This may be because the administrative staff have not been sufficiently briefed about the benefits of the Register. More details[15] are needed in order to be specific about what did not work and how to apply the lessons learnt into a local system.

Can we invite people who are already involved in one research study to sign up on the Consent to Approach register?

Sometimes the approval that has been given by the Research Ethics Committee makes it hard to approach research participants for any other purpose than the specific contacts specified in the research protocol. This is why it is important to invite people to join the Consent to Approach register at the very beginning of contact.

The commonsense principle is to offer information to people during informal contact and leave the initiative with them to make contact and pursue registration if they wish to do so. In this way, researchers balance their obligation to support the Government's agenda to allow everyone to participate in research with a proportionate appraisal of the risks to the individual and compliance with the terms on which each research study is established.

Consent forms which are currently study-specific may need to be amended so that they provide an opportunity for the patient to sign up to the Consent to Approach register.

Should your register operate on an Opt in or Opt out approach?

Advice may be available on whether to use an opt-in approach or the opt-out approach used by tissue banks[16]. The National Information Governance Board provides for circumstances in which the usual need for consent may be set aside.

[15] Information from Ann Priddey, July 2013.

[16] Section 251 of the NHS Act 2006 allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practical.

In Oxford they have been trying an opt-in policy for a Consent to Approach Register but it is producing a big burden of administration and may not be increasing recruitment. It is also upsetting care co-ordinators as they are getting multiple requests about studies with a tight response deadline. In contrast, the Mental Health Research Network West Hub[17] PPI groups preferred an opt-out rather than opt-in scheme. One or two Trusts have already changed their information leaflets to explain that all clients will be approached about participating in research unless they specifically opt-out.

Who can interrogate the Consent to Approach Register?

Some people have suggested that a 'super user' should have oversight of all data that is kept by the NHS organisation, following a simple consent process. The super user would then be able to manage the process of granting permission to individual researchers to approach individual patients.

The plan at Nottingham University Hospitals is to create a Consent to Approach Register where researchers may interrogate the Register at a future date to seek suitable participants for a new study. The researcher would not have to be a member of the patient's clinical team, or a member of the research team currently involved with the person. The patient would need a choice about what level of information was held about them.

South London and Maudsley NHS Foundation Trust (SLaM) have adopted a similar practice in the Case Register maintained in their Biomedical Research Centre. However, they separate 'Health Records' into two subgroups – records made at SLaM and other health records, only seeking consent for access to the records made at SLaM. Their patient information sheet is clear that consent to be included in the Case Register is only consent to be approached about future research, and there is no commitment to take part in any future research.

Adding detail, such as clinical information, converts the Consent to Approach Register into something more like a Case Register but allows marketing to be targeted and reduces the likelihood that people will ignore all messages or unsubscribe from the register. Alternatively, people identified through the Consent to Approach Register may then be screened for suitability prior to being invited to take part in a particular study, with or without consulting the person's medical notes.

[17] Information from Chantal Sunter.

Lancaster University interrogate their Consent to Approach Register to send out newsletters in addition to invitations to participate in research studies.

What might go wrong for patients?

The general principle is that the form of consent-taking should be proportionate to the risk involved, so there is a need to itemise the potential hazards to patients and the research community.

First, the invitation to join the Consent to Approach Register or individual studies may be perceived as an unwelcome nuisance by some patients, especially those who are very sick. This becomes more serious if the same patient is approached by several different researchers from different studies at the same time. A 'consent to approach' field on a patient database could record patient consent/refusal and make it available centrally, suspend the patient from the contact list when on a trial, as happens with a biobank, or provide for a 'rest time' in which patients are not approached a second time until 3-6 months have elapsed since their last approach or the end of their last study. On this last point, the TOPS database is used to prevent people over-volunteering for research studies.

Second, splitting the consent process into two steps may nudge some easily-led people into agreeing to participate in research who would have refused otherwise[18].

Third, the current informally held and poorly regulated databases may fail in their data protection responsibilities, leading to breaches of confidentiality.

Fourth, poor data quality would lead to some marketing messages being sent to people after they have died, causing distress to relatives.

What might go wrong for researchers?

First, clinicians may become 'register aware' through this process, but this is not the same as becoming 'research aware'. It is generally assumed that research aware clinicians provide better care, but register awareness may not have the same therapeutic impact. In the most successful teams, we would expect clinicians to be both research aware and register aware.

[18] Thaler & Sunstein promote 'nudge' politics as a way to encourage healthy behaviour. This may be contentious, as it may be perceived as either encouragement or coercive, depending on one's point of view.

Second, a poorly designed system could bombard patients with invitations to participate in numerous research studies, some of whom would then unsubscribe from the Register or explicitly refuse permission to be approached, thus shrinking the pool of potential research participants.

Third, the Consent to Approach Register may promote electronic marketing and recruitment activities in place of face to face invitations. Electronic marketing may be less effective in recruitment.

Fourth, data protection regulators may challenge the legality of current arrangements.

Fifth, failure to increase research participation will reduce income to research bodies.

What are the best words for a Consent to Approach form?

It would be helpful to obtain some examples from existing Consent to Approach registers. Researchers will need a degree of choice about how to word the general consent, to allow for community languages, age-appropriate communication and so on. For example, MHRN West Hub avoided the word 'consent' and instead emphasised 'permission to inform', and this has helped. The consent statement would be supported by an information leaflet. People who signed on to this Register would be free to decline an invitation to participate in an individual study, and those who declined to join the Register could nevertheless, participate in an individual study.

How do we spread innovation?

At present, some organisations (e.g. Nottingham Universities Hospitals) and some topic-specific research networks have made a start (e.g. Dendron or MHRN West Hub). EMAHSN could seek out issues that would benefit from a coordinated approach across the East Midlands, linking the Clinical Research Network with Research Ethics Committees and Research Departments. Centralised problem-solving will reduce duplication of effort, and a widespread support for the principles will reduce risk.