East Midlands Academic Health Science Network
Igniting Innovation

How to guide

How to form a Consent to Approach Register: The Headlines

Updated 26/05/2018 *Download this from http://www.emahsn.org.uk/public-involvement*

Who wrote this document and why?

The Government wants people to be aware of health research and have the opportunity to serve as a participant when appropriate. One way to do this is to create a 'Consent to Approach' register. This kind of register allows public contributors[1] to register that they are willing to be approached with an invitation to participate in appropriate research.

This paper brings together what we have learnt across the East Midlands about Consent to Approach registers in health research. This will enable members of the public to encourage health staff to create a register; and health professionals and researchers to establish and maintain one. It increases democratic control.

The paper is structured as a series of *Frequently Asked Questions*, with a companion document offering technical background. Both papers were drafted by Peter Bates, Facilitator for Patient Leadership at the East Midlands Academic Health Science Network following a series of meetings[2]. As readers provide feedback, further insights will be used to update the paper.

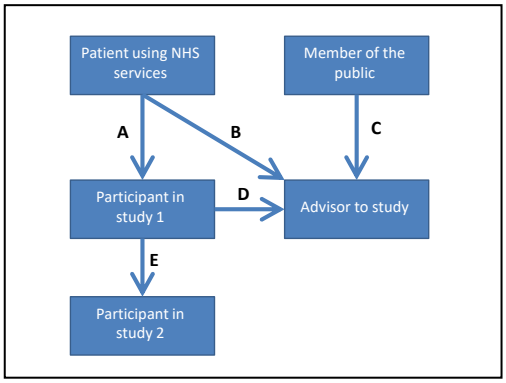
[1] In this document, the term 'public contributor' means patient, service user, carer, or member of the general public.

[2] A meeting was facilitated by Peter Bates at EMAHSN on 26/2/14 and attended by Julie Gosling, Caroline Fox, Sandra Smith, Jane Flewitt and Claire Ward. In addition, 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, Sue Slininger, Derek Stewart, Brian Thomson, Kirsty Widdowson and Nicola Wright. In early 2014, David Kelly and Ann Priddey were developing proposals on this topic for the Trent Hub of the Mental Health Research Network. Occasional amendments have been made to the document by adding single items rather than completing a wholesale review.

Please contact shahnaz.aziz@nottingham.ac.uk to suggest improvements or tell us how you have made use of this paper.

Who has created a Consent to Approach register?

These registers are generally created by small departments or charitable organisations that are particularly eager to recruit members of the public as research participants. They have a particular health condition in mind and a small enough team to create a shared enthusiasm to recruit people to the register. There are a few examples nationally of large organisations that create a single register spanning all departments, but these are rare and more difficult to maintain. Registers seem to work best when a single staff member has overall responsibility for the register's success.



The following organisations working in the East Midlands have a register[3]:

- The Nottingham Hearing Biomedical Research Unit has 900+ names on its register, which is managed by Sandra Smith, who also uses the register to send out newsletters about the work of the Unit.
- Hepatology at Queens Medical Centre, Nottingham run a register which is coordinated by Sue Slininger and has 700+ names.
- Gastroenterology at Queens Medical Centre, Nottingham run a register where people can register online and the database is overseen by a database manager.

Other parts of the country[4] have developed registers or added this function to their electronic health records system.

[3] Leicestershire Partnership Trust has registers on Dementia, Huntingdon's Disease, Eating Disorder, Drug and Alcohol, Learning Disability and possibly gypsy and travellers, where Dave Clarke is the key contact, according to Professor Susan Corr. Kathleen Holding at Derby Hospitals Trust is planning to establish a register. A number of other services may have registers. In 2016/17, Leicester Respiratory BRU had a register of 1700 names.

[4] For an example, see CRIS at SLAM, written up here - http://bmjopen.bmj.com/cgi/content/full/bmjopen-2014-005654?ijkey=YgtwghboEfv2i7l&keytype=ref. Also Robotham, D., Riches, S., Perdue, I., Callard, F., Craig, T., Rose, D. & Wykes, T. 14 May 2015 Consenting for contact? Linking electronic health records to a research register within psychosis services, a mixed method study In : BMC Health Services Research. 15, 1, 199. Also https://orioncloud.org.rhite.

Why are registers needed?

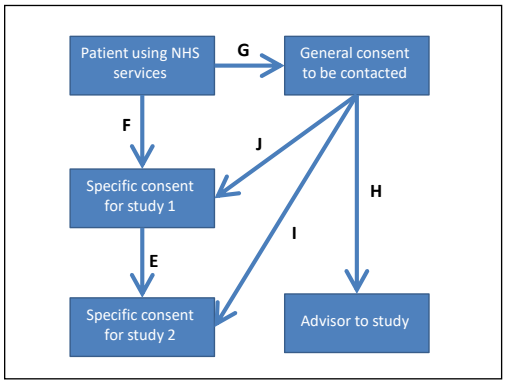
The Government wants all NHS patients to have the chance to participate in research, but mystery shopper audits have found that very few are afforded this opportunity. Involving patients and the public in advising studies normally increases both the quality of the research and the number of people who are recruited as study participants. At present, most health researchers obtain consent from the patient for participation in their own study, and anyone recruited in that way is lost to the research community at the end of the study.

There is a parallel expectation that research is co-designed and then co-produced by clinicians, researchers and the public all working together, but few patients are recruited as Advisors to studies. In the diagram on the previous page, few people follow arrow B and almost nobody follows arrow E.

It is not usually advisable to participate in more than one study at the same time and the chance of this happening can be reduced by maintaining a register. Similarly, if the same person is both a participant and an advisor in the same study at the same time, then care is needed to avoid a conflict of interest, and again a register can help to keep track of who is involved in each activity.

How should registers be advertised?

The most effective way to recruit people on to the Consent to Approach register seems to be to use a separate sign up leaflet that describes the register and provides an offline form for signature. This is then kept separately from any individual research study consent form or records of clinical intervention.



In addition, website information with online registration may be used, alongside social media.

Collecting Consent to Approach registrations at the earliest possible time means that consent is available in the future to contact the person again, even when involvement in a particular course of treatment or participation in a particular research study is over. Getting this right from the start and communicating with openness and transparency avoids all kinds of problems later on.

People can be recruited in the following ways:

- the Register Manager or others can approach people attending an outpatient clinic or GP practice, if appropriate permission has been given. A proportion of the people waiting for treatment will gladly register.
- a researcher who is seeking participants for a particular study can also invite the person to complete the Consent to Approach leaflet. This way, they are effectively 'cross-selling' and helping the overall research agenda, rather than restricting their impact to just their own study.
- Clinicians such as doctors and nurses or administration staff can offer a copy of the leaflet to patients during their usual contact[5].
- Leaflets can be left in waiting areas[6] as well as public libraries or community centres and other places where people may pick them up. Other marketing approaches have been tried too[7].

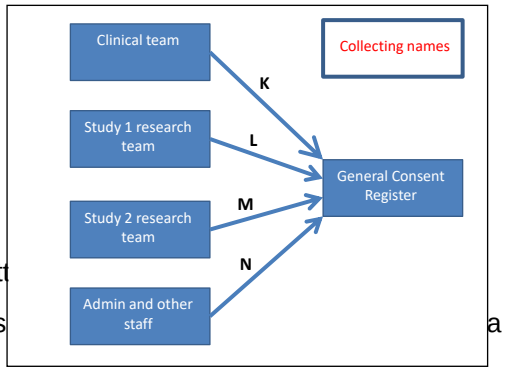
If I sign up, what will happen next?

The database manager will check the register and look for people who appear to fit the requirements of a particular study. You will then be contacted and sent the study information leaflet so you can decide if you would like to take part. If you agree, your contact details will then be passed to the researcher who leads the particular study and they will contact you to check that you meet the conditions that are being studied. If suitable, you will then be invited to become a research participant. At any stage, you can decline the invitation or withdraw your name from the register.

From time to time, there may also be an opportunity to join an advisory group to help shape future research. Again, you will be approached and invited to be involved, perhaps via a newsletter.

Who looks after the Consent to Approach register?

The registers we know about in the East Midlands are managed by one member of staff, who we call a Register Manager in this



[5] A GP practice in Northamptonshire recruited 500 people in a year.

[6] DenDroN placed a tear-off form in GP surgeries, according to Jane Flewitt

[7] A diabetes project in Leicester added texting details to advertising posters a year.

document. It is helpful to agree a specific allocation of staff time for establishing and maintaining the Register. One condition of success is that the Register Manager needs to offer continuity – they are most successful when they work on this project for a number of years. There is also a senior sponsor who offers broad support for the development of the register at a senior level in the organisation. The Register Manager[8] has specific responsibility for the following tasks:

- to advertise the register so that people have an opportunity to register if they wish.
- to add a personal touch, perhaps via initial telephone interviews to glean information for the register or to update on changes of circumstances, or capture information about the person's engagement in individual studies. Personal contact may be augmented by a newsletter or other way of keeping people in touch.
- to maintain information on a 'need to know' basis. This means that the Register Manager is the only person who sees all entries. When researchers ask for potential names and contact details for their research study, it is the Register Manager who trawls the whole database on their behalf and only supplies suitable names to the researchers.
- update information about registered persons who may have moved out of the area, changed their circumstances or died, so that people are not approached inappropriately.
- keep the information safe and confidential.

How much information is gathered?

Consent to Approach registers may collect some or all of the following information in order to make their task run smoothly:

- Contact details – email, phone and postal address for communications, and to know where people will be travelling from.
- Age and gender, as these are the commonest factors that affect whether people are suitable for a particular study. Sometimes additional demographic information is collected in order to find out whether the Register is reaching all sections of the community.

[8] It takes at least one day a week to set up and maintain a register, if you are well supported by your colleagues.

- The name of your GP, as it is often the case that researchers need the approval of the person's general practitioner before they can engage someone as a research participant.
- Headline information about your medical condition, so that suitable people can be invited to participate and so that others are not troubled without cause.
- Some indication of what you are willing to do – fill in a questionnaire, take medicines, be interviewed by a researcher, attend a meeting or sit on an advisory group.

What if I register and then I don't hear anything?

There may be quite a long delay after you register. This is because research studies are very specialist and take a long time to do well, and so only recruit from time to time. Secondly, they tend to need participants from a particular age group or who have particular circumstances, and so your situation may be different. The Register Manager will stay in touch via newsletters, but please be patient and we hope that any delay that occurs will not put you off.

Can I refuse or withdraw?

You can say no to the invitation to join the register if you wish. You can ask for your details to be removed from the Consent to Approach register at any time. Doing so will not affect the healthcare that you receive.

We know that some people are most highly motivated when they are in crisis and very aware of the seriousness of their health condition, while others prefer to be invited after they feel better. Many people, of course, have other things to do, and others are simply not interested in participating.

What happens when a particular study comes to an end?

If you have been taking medication or receiving a particular kind of treatment as part of the study, then you should take a rest before agreeing to participate in a second study. This is to keep you as healthy as possible and ensure that the new study is not affected by the previous one.

After a suitable rest, you may be invited to join another study. The Consent to Approach register will help you migrate from one research study to another, if that is what you wish to do.