

Guidance for staff asked to volunteer blood and/or other samples for research

Introduction

Your colleagues may ask you to provide blood and/or other samples to be used as control material for their research. This guidance has been developed to provide you with the information that you need in order to make an informed choice when approached to donate samples. Within this guidance we have outlined what you should expect if you do decide to volunteer and some of the questions that you may wish to consider before making your decision.

Do I have to take part?

It is important that you feel free to say no as well as yes when asked to provide blood or other samples by your colleagues. You should not be approached directly by your supervisor or boss and asked to donate; you should never be put in a position where saying no does not feel like an option. You should be provided with all the information that you need in order to make an informed choice. Information about the study should be available to take away with you to read in your own time. You should be given enough time to think about your participation, given the opportunity to ask any questions that you may have and above all should not feel rushed into making a decision. If you do decide to provide blood or other samples to your colleagues, then you should be asked to sign a consent form just as any other volunteer would be.

How will my confidentiality be maintained?

Your privacy is an important issue to consider before making a decision to provide blood or other samples to your colleagues. This may present you with specific issues of sensitivity or concern and you should therefore think through the full implications of volunteering before deciding to donate samples. It can often be impossible to ensure complete anonymity even when samples are anonymised by coding. There will usually be a small number of individuals within your unit who may be able to link donated samples back to donors: for example, the person who actually collects the sample, or the person who holds the key to the code used to identify samples within the unit. Again, you should be given detailed information on how your samples will be collected, coded, by whom and how the cipher or code will be kept. If you feel uneasy about the arrangements, you should feel free to decline the invitation to participate.

Coding will limit who can identify you from your sample, whilst enabling a possible link to be maintained back to you. However, even when your name is not used on samples, you should be aware that in some circumstances colleagues may still be able to identify you from other information associated with your sample, for example if you have a particularly distinctive date of birth. Again, if you are concerned, you should ask how samples will be coded and what other information will be made accessible to investigators using any donated samples, before deciding if you would like to donate.

Finally you should also consider the types of information that your colleagues may find out about you from their analysis of your sample if you decide to volunteer. They could identify an underlying medical condition or other unexpected clinical finding. You should ask how likely this is, and how such information would be handled.

What about re-sampling?

If you do consent to provide blood or other samples to your colleagues, you should be aware that this does not automatically extend to any future donations. If your colleagues intend to approach donors for re-sampling in the future, then this should be made clear to you at the outset. Consent for re-sampling must not be assumed, but sought specifically for each subsequent donation (again you should feel free to say no as well as yes to any subsequent donations). If successive re-sampling is planned, you may wish to find out if:

- re-sampling will be dependent on specific findings of analyses; and
- how your anonymised samples will be re-identified, and to whom, in order to re-contact you for re-sampling.

Who can use my samples?

It's not uncommon to share samples with others: within the research group, within the unit, with other MRC units, with NHS and/or university collaborators, or more widely, including with commercial organisations. You should be informed of how widely your colleagues intend to share your samples, and any transfer of your samples must only occur in line with the terms of consent that you provide. If you would rather the use of your samples were restricted, then feel free to say so.

What assurances should be in place?

First and foremost, the unit and all those involved in the collection and use of your samples must comply with the law and MRC best practice (e.g. Human Tissue Act, Data Protection Act, Health and Safety legislation, the conditions of Human Tissue Authority (HTA) licences, MRC Good Research Practice etc).

Ethical review: An appropriate independent research ethics committee may have reviewed and approved the collection of your samples. In particular a committee should review the measures in place to protect confidentiality and how any unexpected clinical findings are to be handled.

Management/Director's approval: Management within the unit must approve all research activity before it starts. Routes available within units vary, but will include Director's approval, which may be delegated to either a research governance committee or other management structure. The Health and Safety co-ordinators should be aware of and approve all arrangements made for the collection of samples and subsequent handling. If your unit holds a Human Tissue Authority licence, the unit Designated Individual should always be made aware of the collection and use of blood or other samples from colleagues, and should ensure that those involved have adequate training and that all activity is compliant with the conditions of the unit's licence. Your unit's Designated Individual may also periodically monitor research activity involving the collection, use and storage of human tissue samples, to ensure that all such activity is being conducted in line with the law, local policy and licence conditions.

Where should my sample be collected and who should collect it?

Your sample should be collected in a place that feels appropriate and comfortable to you, preferably on neutral ground, in a private room with appropriate facilities. Health and Safety should already be aware of where sample collection will take place and they will have assessed any risks involved.

Ideally, all research samples should be collected by someone who is:

- Trained in taking research consent (including generic consent if appropriate);
- Aware of the issues posed by the specific study or studies for which the samples are being collected;
- Trained in phlebotomy and needle-stick injury (in addition their hepatitis B status should be managed within the NHS as appropriate); and
- Ideally, independent of the study/laboratory.

Remember, this is the one person who will know that you have donated a sample for research.

What if my cells are to be cultured?

It is vital that you do not work with cultures derived from your own cells (see Health and Safety Policy). If donated samples are to be grown in culture you must ensure that appropriate measures are in place to ensure that you do not end up working with your own cells in the future. If you think this may be an issue, or may become an issue in the future, you must raise it during the consent procedure, so that an appropriate mechanism to mitigate risk can be put into operation. One possible mechanism is for all donors to be provided with a code, enabling you to identify your own samples. If you are given a donor code, you must remember it, even if your job changes within the unit. You should also keep your code confidential, thereby ensuring that no one else can identify your samples or the data associated with them.

Should I expect to receive payment for any samples I provide?

If you agree to donate samples for research conducted by your colleagues, within your unit, you should not normally expect to receive reimbursement of expenses or other payment. In exceptional circumstances, if excess travel is required, repayment for the costs of additional travel may be offered. Anyone offering their colleagues payment for sample donation must be able to justify such payment, in light of any perceived inducement such payment may present. If you feel undue pressure to donate samples, including financial incentives, you should be aware that donation is still voluntary and you are free to refuse.

Can I ask my colleagues to provide blood or other samples for my research?

Finally, you may want to collect blood or other samples from your colleagues for your own research. There is nothing in the Human Tissue Act to say that this practice should not happen but previous HTA inspection findings have highlighted the potential issues posed by the collection and use of colleagues' samples (i.e. freedom to say no; maintaining confidentiality etc).

You should consider the use of alternative sources of control samples (National Blood Service, hospital excess, existing collections) before embarking upon the collection of samples from colleagues. It is acknowledged that for many reasons, practical and scientific, that the use of colleagues' samples may in some cases be the only option available.

Always talk to your Designated Individual before you embark upon the collection of samples from colleagues and ensure that they are happy with the arrangements that you plan to put in place.

Reporting and complaints

If you are asked to donate samples to your colleagues for their research you should be aware that your decision to take part or not must be: voluntary and appropriately informed. If you ever feel that this has not been the case or if you have any other concerns around how you were approached, how samples were collected, and how they were stored and used, you should inform the:

1. Designated Individual (If your unit has an HTA licence, or works under a licence held by another organisation);
2. Person responsible for Research Governance (if your unit holds human tissue under NHS Research Ethics Committee approval and not under a HTA licence).

Your complaint will be handled in confidence, and you should be assured that all issues will be pursued as appropriate.

The unit values the contribution colleagues can, and do make to the science by donating samples and will protect the rights, dignity and wellbeing of all staff involved.