

List of standards for the transfer of human tissues samples from MRC unit premises (either to another organisation or to another MRC unit).

This is guidance for primary human tissue samples only, i.e. frozen tissues or samples containing whole cells (excluding cell lines), histology blocks and slides.

Any other manipulation of human tissue or samples may give rise to Intellectual Property, so for transfer of these materials please consult the MRC Technology contact for your unit (via the Unit Administrator).

Throughout this document, the terms human tissue samples or samples are used. This means all samples consisting of or containing human cells, which includes most biological fluids, but excludes cell lines in this context. If in doubt please see the Human Tissue Authority web page on Relevant Material.

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm>

Most of the standards below are considered best practice (i.e. should do), some must be done as there are legal implications or because a Unit has an HTA licence. On each standard this is indicated.

On transfer of human tissue samples, MRC research units should, or must do the following:

1. Check the terms of the consent given by the research participants, to see if they gave consent for their donated sample to be sent to collaborators or other researchers in the UK and/or abroad; and if appropriate, if they consented for use in future ethically approved projects.
2. If the recipient is to use the samples in another project (i.e. not the one that they were collected for), the recipient should (must if the Unit has an HTA Licence) give written assurance to the sender that NHS Research Ethics Committee approval is in place for the recipient's project¹.
3. If the appropriate consent for transfer is in place, the recipient should (must if the Unit has an HTA Licence) be informed in writing of this and the terms of that consent.
4. Samples must in all cases be sent in a coded form, so that no identifiable information is sent with them (unless there is explicit consent for transferring identifiable information from the research participant and this has been approved by an NHS Research Ethics Committee). If identifiable information is sent subject to these requirements, the recipient must confirm that these data will be treated in accordance with the Data Protection Act 1998.
5. In all cases, the sender must keep a record of when the samples were transferred and to whom.

¹ Ethical approval for future projects may be covered by a Research Tissue Bank if it has prospective generic ethical approval.

6. The sender should (must if the Unit has an HTA licence) agree in writing the terms of what the recipient is permitted to do with the samples, and stipulate in the agreement that only the agreed analyses should be performed on the samples.
7. The sender should (must if the Unit has an HTA licence) inform the recipient of what should happen to the samples following recipient use (disposal or return). If disposal, the agreement should stipulate how they should be disposed of (arrangements for disposal must also be outlined in the participant information sheet). If return, stipulate how they should do this and how costs will be met.
8. In all cases, stipulate that the recipient is not at liberty to use the samples for their own commercial gain, or to send the samples to any other third party.
9. In all cases, the sender should agree with the recipient how the donation of samples will be acknowledged in future publications – authorship if relevant, or acknowledgement.
10. If transferring samples that were taken post mortem from or to a licensed establishment, the statutory conditions set out in Annex C of the licensing conditions must be followed.
11. In all cases, the sender must inform the recipient how the sample is preserved and of any biological hazards associated with the sample, and the recipient takes responsibility for the appropriate management, appropriate preservation and handling of the sample. The MRC will not be liable for any harm caused to the recipient.
12. Where an agreement is required (see standards 6-11), the sending and receiving organisations must both sign the agreement before any samples are sent.