**Rules for use of human tissues at the Biomechanics Lab**

Mechanical Engineering Department, Room 639, for authorised personnel

With the introduction of the new Human Tissues Act 2004 into law, there will be severe penalties for anyone found in possession of human tissues and who is not complying fully with the law. Failure to comply with these rules may result in a CRIMINAL OFFENCE being committed, that is punishable by up to THREE YEARS IMPRISONMENT plus a FINE of up to £5,000. You must recognise that your activities in the Biomechanics Lab could be audited by H.M. Inspector of Anatomy at any time and without prior notice. Therefore, it is in your strong self-interest to follow these rules carefully! This applies particularly to Rules 1, 3 and 13.

1. As of the beginning of 2006, all **projects must have ethical committee approval for the use of human tissues** and a copy of that approval must be given to the Laboratory Chief (currently Professor Amis) before making any arrangements to bring human tissue to the lab. This ethical committee permit will include details of the procurement procedure, including informed consent. *The rule is a requirement of the Human tissues Act 2004.*
2. No human tissue may be brought to the Biomechanics lab without a prior written request from you and a written permission from the current Lab Chief (currently Professor Amis and in his asence, ask Dr U Hansen or Dr F Rodriguez y Baena). You/your supervisor must have completed the “Project notification and approval form” in order to comply with this. You must keep a copy of this permit with your specimen logbook (see below).
3. **No human tissue may ever be brought to the lab unless you have informed consent for the collection and specified use** of every specimen. For tissues of UK origin, you will be personally responsible for obtaining such consents and for ensuring that a file with all the consent documents is maintained, that could be produced for inspection by HM Anatomy Inspector at any time. That file will normally be kept on NHS premises, perhaps with the patent affairs officer. For tissues sourced from outside the UK, you must have evidence of informed consent at the place or origin. *This rule is a requirement of the Human Tissues Act 2004.*
4. If you have been authorised to bring human tissue to the lab, then the lab chief will assign you a freezer that will be for your personal use for storage of your tissue specimens. The freezer assignment will be recorded in the lab tissues logbook. You will be issued with a key to unlock the padlock on your freezer. You will also be issued with two copies of a personal tissue specimen logbook, in which you should keep details of every specimen. One copy must be kept in the pocket on the door of the freezer, as a working document in the lab; the other is your clean version for your office file.
5. The security and logging of the procurement, storage, use and disposal of human tissues used in your project will be your personal responsibility, so the logbook must always be kept up to date. *It may be required for inspection by HM Inspector of Anatomy without notice at any time*. There should **never** be a discrepancy between your logbook and what is held in the freezer!
6. You must keep your freezer locked at all times except when you are present in the lab. The freezer must never be left unlocked, even if you leave the lab for only a short time. You are personally responsible for whatever is in your freezer.
7. When you bring a new specimen to the lab, you must enter its details into both copies of your logbook and also give a copy to the lab chief for the main logbook. Each page of the book represents one specimen, and the layout of each page is shown in the appendix to this document. You must also enter a unique identification code of the form AA1, AA2, AA3, etc, i.e. you initials and number. That is now the number for identification of your specimen.
8. The lab has a supply of plastic key tags, marker pen and soft wire. You must attach a key tag securely to your specimen before it is placed into storage, with the identification number written on it. Secure fixation means that the wire will normally be passed through a drill hole in one of the bones or attached to the packing in a secure manner. The specimen tag must never be removed until the time of final disposal, except when it is interfering with an experiment in progress.
9. If the specimen will fit into one of the sealable plastic boxes, it should be kept in one during storage. This will help to keep pieces together if they are separated by dissection and not for immediate disposal. The box should also be marked clearly with the identification number.
10. If the specimen will not fit into a sealable box, it may be stored in a polyethylene bag that is tied shut and also labelled clearly as above, so that it may be identified easily even while frozen.
11. Every use of a specimen must be recorded in the logbook. You must make a habit of writing-up the work done before you leave the lab at the end of the day. This need only be brief, but it must detail the work done any tissue disposal process. When the last remaining part of the specimen has been disposed of, then you should state that clearly and add the date. You must also inform the lab chief of the disposal of each specimen, to keep the main logbook up to date.
12. If any specimen is to be cut into pieces, every piece must be labelled securely or otherwise kept so that its identification is always clear (e.g. by placing labels on each bone; by placing small pieces into labelled boxes or bags). *This applies strictly for even the smallest piece of tissue, even down to labelling a histology slide.*
13. **All specimens and parts thereof must be clearly identifiable at all times;** failure to maintain this is an offence under the Human Tissues Act 2004.
14. You must **never** mix together human and animal specimens. There is a dedicated freezer for storage of non-human material, and you must never keep human specimens in that freezer. Conversely, even if your work goes through a phase of studying non-human specimens, they must never be stored in your assigned human tissues freezer.
15. If you wish to thaw specimens overnight prior to use, this should be done by placing them in the refrigerator. Specimens must never be left out in the lab overnight, even if concealed. The refrigerator must be kept locked using the combination lock supplied. The lab chief will tell you the combination number. Other lab workers will also use this refrigerator, so you must keep it clean and tidy and remember that your specimen should still be easily identifiable via its number tag. Do not leave specimens in the refrigerator for a long time: If there is evidence of their deterioration, they will be disposed of without warning.
16. If there are any specimens in the open lab during the day, the lab door must be locked securely whenever there is no-one in the lab. This applies even for short absences. If there is any doubt about the length of time of absence, the specimen must be stored in the locked refrigerator or your freezer, as appropriate.
17. When you are dissecting pieces of tissue off, of your specimen, they must be placed in a polythene disposal bag. At the end of the session, this bag must be closed securely and placed in the waste disposal freezer compartment, that has a combination lock. You must never mix human and animal tissues together in the freezer, so keep animal tissue in the animal tissue freezer pending disposal.
18. You should inform the lab chief if the waste compartment is nearly full, so that it can be cleared in good time, before it becomes full.
19. When your project is coming to an end, you should ensure that you have obtained all necessary information from your specimens, including photography, and then arrange for their disposal and notify the lab chief that your freezer compartments are clear, returning your key. You should not assume that it is acceptable to leave specimens in storage in case you might need to look at them again, maybe when writing-up has prompted further thoughts!

**Do not forget that failure to follow these rules may have serious career-wrecking consequences. Therefore, any departure from these rules will be treated as a serious disciplinary offence.**

**Summary:**

1. No project using human tissue can start before ethical committee approval.
2. The specimens and adherence to the law regarding them are your personal responsibility.
3. Secure storage at all times is essential.
4. Specimens and parts of them must be clearly identifiable at all times.
5. Introduction of specimens into the lab, every stage of their use, and their disposal, must be documented in both your own logbooks and the lab logbook.

A final thought:

Please do not forget, ever, that you are handling the remains of what were recently fellow people. These are all precious gifts without which you could not do your work and are of immense sentimental significance, so treat them with great care and dignity while they are in your care.

Professor Andrew Amis

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