**Summary of purpose of BSMS HTA licence and its use**

The main purpose of the HTA licence is to allow us to store human tissue. A licence is required in the following circumstances:

1. Once the Ethical approval from an NRES approved project has expired. *Material stored under valid NRES approval does not require an HTA licence.*
2. If you wish to store and use material from healthy volunteers (your project will require review and approval by an internal ethics committee (RGEC) only).
3. If material has been imported from elsewhere – another UK institute, a Biobank, international location

Notification to the BSMS Tissue Governance Manager (Natalie Chaplin) is required for 2 and 3 above and for 1 when the PI intends to store material after the completion of the NRES approved project ie – he/she wishes to store for future unspecified research (another project).

Requirements for storage under the BSMS HTA research licence

* All samples must be logged into FreezerPro (the dedicated, shared HTA sample database). Please contact Matthew.Pope@bsuh.nhs.uk or n.chaplin@bsms.ac.uk for guidance.
* Consent for the samples to be used in future projects (other than the current one) must include ‘Future unspecified research’ or similar.
* New project approval must be sought from the appropriate Ethics Committee prior to commencement of further work

**Biobanking**

BSMS does not currently have a dedicated Biobank where material is acquired specifically for this purpose. However, PI’s are welcome to build-up their own tissue collections through any of the routes described above (1, 2, and 3). This form of Biobanking is then essentially the storing of material acquired through a research study for a future project(s) and so PI’s need to ensure that the **correct consent (for future unspecified research)** is obtained **when the sample is collected.**

**FAQ’s**

* **Relevant material**

All material containing whole human cells (primary cells, not derived cell lines) is deemed relevant and so will fall under the HT Act; please see for full list: <https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004>

**Is blood relevant material?**

Yes, it contains cells and so is relevant.

**Is serum relevant material?**

No, serum and blood plasma contain no whole cells and so are not relevant.

**Are cell lines defined as relevant material?**

Primary human tissue and cells i.e tissues and cells removed directly from a person are defined as relevant material under the HT Act. Cell lines resulting from expansion of primary cell cultures are not relevant material, as all the original cells have divided and so have been created outside the human body. The storage of cell lines for research does not require an HTA licence.

**What do I do if I’m acquiring human cells to extract nucleic acids?**

You can store the human material for upto 7 days without needing an HTA licence, but then you must extract the nucleic acids. If you decide to store the material for longer than 7 days, you will be required to log it into the tissue tracking software, FreezerPro, and it will the treated the same as all other human tissue. in addition, you must, in either case, keep detailed records of the transport of tissue, its subsequent storage and dates of processing. **It is important to note that since the material is sourced from human subjects, data protection and data governance processes are still in force.**

**I plan to undertake some work using human tissue. The work is not diagnostic, but I’m not sure if I should classify it as research either. Can you help?**

 The HTA considers research to be a study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge. In addition, the HTA endorses the definition provided by the Department of Health and the Welsh Assembly Government, which is as follows: ‘‘Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.’’

* **Licensing**

**Does all research with human tissue need a licence under the HT Act?**

**No. Importantly, an HTA licence is for the storage for use in research, not the use itself. Specific research projects undertaken with approval from recognised Research Ethics Committee (REC) committees (or for which approval by such a committee is pending), do not require an HTA storage licence. In addition, researchers storing tissue samples received from a REC-approved tissue bank do not require a HTA storage licence. Finally, storage that is incidental to transportation or with the intent to render material acellular does not require an HTA licence. More information on the requirements for consent and ethical approval is included in flowcharts within the code of practice on Research.**

**BSMS does require that the Tissue Governance manager is alerted to the presence of the tissue on site and will require (in most circumstances) that the samples be logged into the sample tracking database, FreezerPro.**

**Do I need a licence to store tissue collected for diagnosis?**

 **Whether the storage of tissue requires a licence under the Human Tissue Act (HT Act) depends on the primary purpose for which the tissue is taken and stored. If the primary purpose for taking the tissue is for diagnostic purposes, then storage of that tissue is not licensable under the HT Act. If the primary purpose for taking and storing tissue is for research, then an HTA licence is required for storage of the tissue unless a licensing exemption applies. Tissue stored for research that does not have recognised Research Ethics Committee (REC) approval (see above) must be stored under a licence granted by the HTA.**

**Do I need a licence if extracting nucleic acids from human material?**

**No, providing the nucleic acids are extracted from the human material within 7 days of receipt of the tissue.**

* **Consent**

**Are there any circumstances when I can use tissue in research where consent is not present?**

Yes, if a researcher wishes to use material without asking their patients' consent, the research project can go ahead, but will need to be approved by a recognised Research Ethics Committee (NHS REC). In addition, the researcher must arrange the research so that they do not have access to information identifying the person from whom the tissue came. This does not mean that the records and tissue must be permanently unlinked.

As good practice, BSMS recommends that all material collected expressly for research has consent and, if stored for future unspecified projects (Tissue banking), will require consent for future, unspecified research. (See <http://www.hta.gov.uk/_db/_documents/Code_of_practice_9_-_Research.pdf> pg 10.)

**Do I need consent for imported material?**

The consent provisions of the HT Act do not apply if the material has been imported. Nonetheless, the HTA considers it good practice to ensure mechanisms are in place in the source country for obtaining consent. As good practice, importers should therefore satisfy themselves that, in the countries from which they seek to import tissue, the gaining of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained. This involves ensuring that procedures are in place giving the necessary assurances eg: obtaining copies of relevant consent forms or, at the very least, requesting a letter from the supplier assuring the importer that consent was taken along with an example consent form.

**Can consent from a patient be generic and enduring?**

Yes, consent can be generic and enduring. The HT Act sets the baseline that, for lawful storage and use of tissue for Scheduled Purposes, consent must be obtained from the appropriate person. The scope of that consent is not limited by the HT Act. Guidance for obtaining consent is provided in the HTA’s codes of practice and other documents. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking repeated consents – for example for research after the patient has had surgery or giving tissue which may be stored for use in a future, unspecified, project.

*BSMS require that the PI discuss their needs with the DI (Prof Davies) prior to applying for ethical approval of their projects.*

* **Material obtained from elsewhere – overseas, UK, blood bank, tissue bank**

**Will I need a licence to store material imported from overseas?**

Tissue may be imported for use in research projects under the same guidelines that apply to material collected in England; an HTA licence is required unless the project is approved by NRES. The HTA recommends that, wherever possible, the import and export of tissue is conducted via the HTA licensing regime, which involves a Designated Individual (DI) ensuring that premises are suitable for activities as authorised by the licence.

BSMS urges all PI’s to notify the Research licence DI if they intend to import human material from overseas.

**Will I need a licence to store material obtained from a UK licenced Tissue Bank?**

Yes, unless the material is completely non-identifiable to the researcher.

The HTA and National Research Ethics Service (NRES) have agreed a position whereby NHS Research Ethics Committees (RECs) can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. This approval can extend to specific projects receiving non-identifiable tissue from the bank. The tissue does not then need to be stored on HTA-licensed premises; nor does it need project specific ethical approval.

**What do I need to obtain if using material from a UK Bloodbank?**

Blood products can be purchased from UK bloodbanks, avoiding the need to acquire from healthy volunteers. Storage of these products beyond 7 days will require an HTA licence and so will be treated as any other human tissue – Ethics review (RGEC), logged into FreezerPro. If used up within 7 days then the HTA licence will not apply, however, Ethics approval for the project will still be required prior to purchase of the products.

* **Training**

**What training is required for work with human tissue?**

All staff working in studies using human tissue will require GCP training. This is available through BSUH (please contact Gemma Hamilton, G.Hamilton@bsms.ac.uk). In addition, an HTA induction will be provided by Natalie Chaplin. More specific training such as taking consent (provided through BSUH) and tissue culture techniques (contact Natalie Chaplin) may also be required. Work cannot commence until training has been completed.

**What other guidance is available?**

All documents (SOPs, Code of Practice) related to the acquisition, use and storage of human tissue at BSMS is available on Sharepoint under the ‘Research Admin’ tab- [https://mydepartment.brighton.ac.uk/bsms/RA/SitePages/Home.aspx?RootFolder=%2Fbsms%2FRA%2Fdocs%2FHuman%20Tissue%20Governance%20and%20Documents&FolderCTID=0x0120006E8780C4AA4C6C4786780B2D155934A9&View={825DE7CA-6218-4284-B2BC-2A71BE35AE86}](https://mydepartment.brighton.ac.uk/bsms/RA/SitePages/Home.aspx?RootFolder=%2Fbsms%2FRA%2Fdocs%2FHuman%20Tissue%20Governance%20and%20Documents&FolderCTID=0x0120006E8780C4AA4C6C4786780B2D155934A9&View=%7b825DE7CA-6218-4284-B2BC-2A71BE35AE86%7d)

The HTA website, Research sector, has FAQ’s, Codes of Practice and much more - <https://www.hta.gov.uk/regulated-sectors/research>