Human Tissue Research Activity

Checklist for reviewers during ethical application for research involving the storage of human tissue

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| Checklist criteria for HTA activity (checked by reviewers) | Yes/No |
| If section 12d is checked yes, then section 12l should only be checked yes if storing Human tissue (relevant material hereafter) |  |
| Training certificates (MRC consent & GDPR) are included/checked and up-to-date (within 3-4 yrs old) |  |
| Participant information sheet has clear information for subjects regarding the taking, storage and disposal of relevant material |  |
| Consent form contains clear information on taking, storage and disposal of relevant material |  |
| Risk assessment includes mitigating actions relating to withdrawal of consent, storage failures and disposal of relevant material upon completion of research |  |
| The lead researcher has read and understood the Human Tissue Usage Guidelines |  |
| The lead researcher understands their legal obligations working under the Human Tissue Act (2004) |  |
| Does the study involve collaboration with a 3rd party, 3rd parties licence no needed to support this. |  |
| Are relevant materials being transferred to another collaborator for analysis (if ‘yes’ provide a copy of the sample transfer sheet and destination details) |  |

Notes:

The Human Tissue Act (and therefore licence) only applies to the storage (stored longer than 24 hrs) of relevant material\* used for research activity. Common relevant material used at St Mary’s University consists of whole blood, plasma, saliva, urine, and occasionally faeces. Serum is generally not considered relevant material. DNA, RNA and other extracted material from cells is not relevant material (once extracted), however if relevant material is being stored for > 24 hrs before extraction then this counts as relevant material.

Please see John Pattison or James Simms for further guidance if required.