**Internal Audit Report (Human Tissue) Form A**

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| **CONSENT** |
| Date of audit |  | Location |  |
| Name of auditor  |  | Email address |  |
| Name of Principal Investigator (PI) |  | Email address |  |
| Name of study |  |
| UEC or NHS REC #  |  |
| Other persons present (name/email) |  |
| 1. **Checklist**
 |
|  | **All correct** | **Non-conformance** |
| Blank consent form(check version and location; matches version on RIGO records) |  |  |
| Blank PIS(check version and location; matches version on Assurance records) |  |  |
| Signed consent forms(Choose 5 random consent forms. Check secure access/ location /correctly completed/no ambiguities/ initials not ticks/ any donor withdrawal requests and if actioned etc) | 1.2.3.4.5. | 1.2.3.4.5. |
| Evidence/due diligence of consent for samples received from 3rd parties |  |  |
| Staff training records(Check training records for persons taking consent) |  |  |
| Study Protocol(Check consent procedure in protocol is being followed; no additional samples taken outside of approvals) |  |  |
| Other (please specify) |  |  |
| 1. **Corrective and preventative actions**

(actions may be delegated to a member of the research team, technical team, PD, RIGO or others as appropriate. They must be informed and agree to complete the action delegated to them). |
| Corrective actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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|  |  |  |  |
| Preventative actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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| 1. **Other actions/reporting**
 |
| Has any immediate corrective action been taken including any reporting or escalation – provide details: |  |
| Please provide any additional information relevant to the audit findings, including details of any meetings/discussions: |  |
| 1. **Date of Audit follow-up**

(to be entered by auditor) |  |
| 1. **Follow up**
 |
| Checked by (enter name): | Date: |
| All actions completed satisfactorily? | Y/NIf no, provide details of follow-up action: |
| 1. **Final sign off**

(to be signed once all actions have been satisfactorily completed) | Auditor Name: | Signature: |
| **Date:** | PI Name: | Signature: |

**Internal Audit Report (Human Tissue) Form B**

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| **GOVERNANCE AND QUALITY** |
| Date of audit |  | Location of audit |  |
| Name of auditor  |  | Email address |  |
| Name of Principal Investigator (PI) |  | Email address |  |
| Name of study |  |
| UEC or NHS REC #  |  |
| Other persons present (name/email) |  |
| 1. **Checklist**
 |
|  | **All correct** | **Non-conformance** |
| Study file/document check(check version and location of study documents; matches version on Assurance records; is HTA\_SOP\_011 for record management is being followed) |  |  |
| Ethics approvals in date |  |  |
| Where samples are sent to/ received from 3rd parties, check MTA in place. |  |  |
| Staff training records(Check training records for persons in research team are up to date including lab induction) |  |  |
| Check relevant SOPs have been read, understood and followed (SOPs 1-21) |  |  |
| Adverse Events/Incidents(Evidence that where such events have occurred, they have been reported, investigated, and corrective/preventative action taken in accordance with relevant SOP. |  |  |
| Other (please specify) |  |  |
| 1. **Corrective and preventative actions**

(actions may be delegated to a member of the research team, technical team, PD, RIGO or others as appropriate. They must be informed and agree to complete the action delegated to them). |
| Corrective actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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|  |  |  |  |
| Preventative actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
|  |  |  |  |
|  |  |  |  |
| 1. **Other actions/reporting**
 |
| Has any immediate corrective action been taken including any reporting or escalation – provide details: |  |
| Please provide any additional information relevant to the audit findings, including details of any meetings/discussions: |  |
| 1. **Date of Audit follow-up**

(to be entered by auditor) |  |
| 1. **Follow up**
 |
| Checked by (enter name): | Date: |
| All actions completed satisfactorily? | Y/NIf no, provide details of follow-up action: |
| 1. **Final sign off**

(to be signed once all actions have been satisfactorily completed) | Auditor Name: | Signature: |
| **Date:** | PI Name: | Signature: |

**Internal Audit Report (Human Tissue) Form C**

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| **TRACEABILITY** |
| Date of audit |  | Location of audit |  |
| Name of auditor  |  | Email address |  |
| Name of Principal Investigator (PI) |  | Email address |  |
| Name of study |  |
| UEC or NHS REC #  |  |
| Other persons present (name/email) |  |
| 1. **Checklist**
 |
|  | **All correct** | **Non-conformance** |
| Sample Tracker Records(check access and back-up of records; UOS\_HTA\_SOP\_012 for sample tracking being followed) |  |  |
| Check 10 samples(Choose 10 random samples from tracker including at least 2 disposed/used samples. Check secure access/actual location matches tracker/correctly labelled with unique identifiers at aliquot level/sample ID matches consent form ID/if disposed, check disposal tag number recorded/if used, usage logged in lab book) | 1.2.3.4.5.6.7.8.9.10. | 1.2.3.4.5.6.7.8.9.10. |
| Staff training records(Check training records for persons in research team are up to date including lab induction and disposal process) |  |  |
| Other (please specify) |  |  |
| 1. **Corrective and preventative actions**

(actions may be delegated to a member of the research team, technical team, PD, RIGO or others as appropriate. They must be informed and agree to complete the action delegated to them). |
| Corrective actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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|  |  |  |  |
| Preventative actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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| 1. **Other actions/reporting**
 |
| Has any immediate corrective action been taken including any reporting or escalation – provide details: |  |
| Please provide any additional information relevant to the audit findings, including details of any meetings/discussions: |  |
| 1. **Date of Audit follow-up**

(to be entered by auditor) |  |
| 1. **Follow up**
 |
| Checked by (enter name): | Date: |
| All actions completed satisfactorily? | Y/NIf no, provide details of follow-up action: |
| 1. **Final sign off**

(to be signed once all actions have been satisfactorily completed) | Auditor Name: | Signature: |
| **Date:** | PI Name: | Signature: |

**Internal Audit Report (Human Tissue) Form D**

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| **PREMISES, FACILITIES AND EQUIPMENT AND DISPOSAL** |
| Date of audit |  | Location of audit |  |
| Name of auditor  |  | Email address |  |
| Name of Principal Investigator (PI) |  | Email address |  |
| Name of study |  |
| UEC or NHS REC #  |  |
| Other persons present (name/email) |  |
| 1. **Checklist**
 |
|  | **All correct** | **Non-conformance** |
| Storage Facility Check(using the storage facility audit checklist on the Human Tissue Governance Site SharePoint site, assess the condition of storage area, door seals, servicing records, locks, monitoring systems, internal organisation, signage) |  |  |
| Risk Assessments(assessments available, findings communicated, reviewed as required and, at least, every 3 years) |  |  |
| Cleaning and Contamination(documented procedures, staff given induction training relating to HSE) |  |  |
| Contingency Plans(in place in case of failure of storage area) |  |  |
| Emergencies(documented process of what to do in an emergency, including contact list for each area) |  |  |
| TransportationDocumented policies, procedures and risk assessments, system for traceability during transport, records of transportation and delivery, records of agreements with recipients, records of agreements with couriers/transport companies) |  |  |
| Disposal(awareness of disposal SOP, documented procedure on disposal, disposal tracked detailing method and reason for disposal) |  |  |
| Other (please specify) |  |  |
| 1. **Corrective and preventative actions**

(actions may be delegated to a member of the research team, technical team, PD, RIGO or others as appropriate. They must be informed and agree to complete the action delegated to them). |
| Corrective actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
|  |  |  |  |
|  |  |  |  |
| Preventative actions(Enter each action on a separate line) | Delegated to | Expected completion date | Completion checked by (this should be completed by original auditor in follow up) |
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|  |  |  |  |
| 1. **Other actions/reporting**
 |
| Has any immediate corrective action been taken including any reporting or escalation – provide details: |  |
| Please provide any additional information relevant to the audit findings, including details of any meetings/discussions: |  |
| 1. **Date of Audit follow-up**

(to be entered by auditor) |  |
| 1. **Follow up**
 |
| Checked by (enter name): | Date: |
| All actions completed satisfactorily? | Y/NIf no, provide details of follow-up action: |
| 1. **Final sign off**

(to be signed once all actions have been satisfactorily completed) | Auditor Name: | Signature: |
| **Date:** | PI Name: | Signature: |