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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1017-UoL



Version Number: 1.0

Effective Date: January 2021

Supersedes: N/A

Last Review Date: N/A Next Review Date: Jan 2023

Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

DNA (Deoxyribonucleic Acid) is not considered to be relevant material under the HT Act. However, in all but exceptional cases (such as the prevention or the detection of crime), the law requires that consent is obtained from the person whose DNA is to be tested.

It is an offence under section 45(1) of the HT Act to hold any bodily material (any material that has come from the human body and which consists of or contains human cells) intending to analyse the DNA in it without qualifying consent.

The offence can attract a fine, a term of imprisonment of up to three years, or both. The offence of non-consensual analysis of DNA applies to the whole of the UK, including Scotland.

Purpose and Scope

The purpose of this Standard operating procedure (SOP) is to ensure that all UoL staff students and external visitors understand the requirements of the Human Tissue Act (HT Act) regarding the DNA analysis of bodily material for research purposes.

This SOP applies to the human materials that fall outside of the HT Act (Gametes and other cells) that come under the remit of the Human Embryology and Fertilisation Authority (HEFA).

Definitions:

DI	Designated Individual
DNA	Deoxyribonucleic Acid
HEFA	Human Embryology and Fertilisation Authority
HRA	Health Research Authority
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Persons Designated
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RNA	Ribonucleic Acid

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SOP Standard Operating Procedure

UoL University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA codes of practice.

It is the responsibility of the HTA Monitoring officer for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and changes to the HTA Codes of Practice for research.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes.

All researchers involved in DNA analysis have the responsibility of ensuring the appropriate consent for DNA analysis has been given by the donor. Where appropriate consent for DNA analysis has not been obtained, this can be undertaken on anonymised samples where appropriate ethical approval is in place. This does not apply to the study of RNA unless the RNA is being used to obtain information on the patient's DNA.

Procedure to follow

Any research project intending to analyse DNA as part of the research project should have a clause in the consent form regarding the analysis of the DNA. Should later down the line, samples from a historic research project be required for DNA analysis, the researcher should obtain the appropriate NHS REC approvals for the body of work to be undertaken on anonymised samples before undertaking the work.

Bodily material in this circumstance differs from relevant material as it also includes hair and nails from the living as well as the deceased. In addition, to gametes (human sperm and ova).

DNA itself is not considered as relevant material under the HT Act, and is therefore not subject to licencing. This also applies to RNA analysis where it is to be used to provide information about DNA.

When consent is legally required for DNA analysis?

Consent is required to analyse the DNA or use the results of the analysis for research purposes where:



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- The tissue is obtained on or after 1st September 2006 from a living individual in the UK and the researcher knows, or is likely to know, the identity of the donor.
- The tissue is obtained on or after the 1st September 2006 from a living individual in the UK and the research is not ethically approved.
- The tissue is obtained on or after 1st September 2006 from a deceased individual who died before 1st September and less than 100 years has elapsed since their death.
- Tissue is obtained from a deceased individual who died on or after 1st September 2006.

DNA Analysis Exemption

According to the HTA Codes of Practice for Research: The results from DNA analysis can be used for research without consent, providing the bodily material from which the DNA is extracted:

1. Is from a living person; and
2. The researcher is not in possession, and not likely to come into possession of information that identifies that person from whom it has come; and
3. The material is used for a specific research project which has received ethical approval from a recognised REC.

When is REC approval required for DNA Analysis?

Under the HT Act and HTA regulations, researchers are legally required to obtain ethical approval in order to carry out analysing human DNA in materials from the body of a living person (or using the results of DNA analysis) without consent, providing they are unable to identify the tissue donor and not likely be able to do so in the future. This can be either by project specific approval or by generic approval for an RTB providing the tissue.

Analysis of DNA from acellular material

The DNA analysis offence in the HT Act only applies to bodily material. However, it is possible to extract human DNA from acellular material, such as serum, for analysis. Although the offence does not extend to acellular material, the HRA expects researchers intending to extract DNA from acellular material for research analysis



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should submit their proposal for ethical review to a recognised REC. Please refer to SOP *HTA-A1015*.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N