UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1017 UoL

DNA analysis

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

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.

Anyone holding bodily material intending to analyse its DNA and to use the results, without the consent of the person(s) concerned, could be breaking the law. It is an offence under section 45(1) of the Human Tissue Act (HT Act) to hold any bodily material without qualifying consent unless it is for an excepted purpose.

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.

2.0 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 HT Act regarding the DNA analysis of bodily material for research purposes.

This SOP also 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.

Definitions:

CI	Chief Investigator
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HRA	Health Research Authority
HT Act	Human Tissue Act
HTA	Human Tissue Authority
NHS	National Health Service
PD	Person Designated
PI	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

Any research project intending to analyse DNA as part of the research should have an explicit DNA analysis clause in the study consent form. Should 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 HTA-relevant material. Bodily material is defined as containing cells from the human body so includes hair and nails from the living as well as the deceased. In addition, gametes (human sperm and ova), and plasma samples that contain platelets count as bodily material.

DNA itself is not considered as relevant material under the HT Act, however it is an offence to analyse DNA without consent, and to store bodily material with the intent of analysing its DNA. This also applies to RNA analysis where it is to be used to provide information about DNA.

Research projects using human samples must be registered on the University's Research Management System to obtain any reviews or approvals. This would include undertaking DNA analysis on human samples.

3.1 When does the offence not apply? (Excepted purposes)

Excepted purposed are fully detailed in Schedule 4 of the HT Act. They include using the results for the following purposes relating to research;

1. Medical diagnosis or treatment of the person whose body the DNA is extracted from
2. Where the 'bodily material' is from a living person and used for: clinical audit, education or training relating to human health, performance assessment, public health monitoring, or quality assurance.
3. Where the 'bodily material' is an existing holding (pre-dates 1st Sept 2006)
4. Where the 'bodily material' is from the living, is non-identifiable to the researcher, **and** is to be used for research with/ or pending project-specific NHS REC ethical approval.
5. Where other legal frameworks apply, e.g., for research involving adults who lack capacity to consent in very specific circumstances. Please discuss with the HTA monitor (HTAenquiries@leicester.ac.uk) if you think your research falls into this purpose.

3.2 When is REC approval required for DNA Analysis?

Under the HT Act and HTA regulations, researchers are legally required to obtain NHS REC approval where bodily material is to be held from the living (e.g., Blood, Gametes etc.) with the intension of conducting DNA analysis without consent from the person whose body manufactured the DNA.

In these circumstances approval from an NHS REC is required under Schedule 4 Paragraph 1- of the HT Act, providing the researcher is unable to identify the tissue donor and not likely be able to do so in the future.

Under NHS governance systems, ethical approval is not required for research involving anonymised extracted DNA, as the research does not involve tissue (i.e., cellular material) or identifiable data of NHS patients. Ethical approval would be required where identifying data is held with the DNA sample.

Voluntary applications may be made for the review of DNA banks ('genetic databases') using the RTB IRAS application form. This could provide generic approval for future projects using identifiable or non-identifiable DNA.

3.3 Project-specific DNA analysis and DNA analysis as future research

Where consent is only given to analyse DNA for a specific study, further ethical approval would be required to analyse the DNA in further projects. It is possible that researchers may wish to analyse the DNA as part of future research, therefore it is recommended to seek broad consent at the outset. Please refer to our templates for NHS-approved studies.

3.3.1 DNA analysis from acellular material and primary cell lines

Section 45 applies to 'bodily material' which has come from a human body and consists of or includes human cells. Acellular material sits outside of this definition. In addition, the material is not regarded as bodily material if it is created outside of the body (Part 3(7)). Cell lines that no longer contain original primary cells are not bodily material and that the section 45 requirements do not apply. Cell lines containing primary cells are considered bodily material.

If unsure what constitutes bodily material in this context, please contact HTAenquiries@leicester.ac.uk for further advice.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensure the appropriate DNA analysis clause is added to consent forms as appropriate. Registering research in the research management system. Ensure guidance around this SOP is followed.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Give advice regarding the analysis of DNA to researchers.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place within the licenced establishment.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	V2.0	A Sutcliffe	• Administrative updates • Addition of Research Management System • Addition of when the offence does not apply • Removal of DNA analysis exemption • Addition of project specific and DNA analysis as future research (HRA update). • Further clarity around DNA analysis of acellular material