

Research using human tissue samples

The following paper offers guidelines on the level of ethics approval required for research conducted by staff and students at London Metropolitan University involving the collection, storage and/or analysis of human tissue samples (including blood, tissues and excreta) at the University's various research facilities. These guidelines have been developed in consultation with the Human Tissue Authority,¹ in line with the provisions of the Human Tissue Act (2004).²

The guidelines recognise that the University has not been licensed by the Human Tissue Authority for the collection, storage and/or analysis of human tissue samples for research purposes, and that these guidelines would change were the University to successfully apply for such guidance. The guidance also recognises that the University has, in the past, engaged in research activities involving the collection, storage and/or analysis of human tissue samples and has a number of ongoing and prospective research projects which require the collection, storage and/or analysis of human tissue samples. With this in mind the guidelines provided below distinguish between previous (i.e. completed), present (i.e. ongoing) and future (i.e. prospective) research projects.

In general, the HTA Regulations require any research involving human tissues (including blood samples, biopsies, hair, cheek scrapes, sputum, urine or faeces) in which the tissue samples are not immediately analysed (i.e. where the samples are stored for any period of time prior to analysis) to be conducted in a licensed institution or to have received formal ethical approval from "an ethics committee recognised by the UK Ethics Committee Authority (UKECA) or the Secretary of State e.g. a REC Coordinated by COREC").

Research project status	Treatment of tissue samples	Level of ethics approval obtained	Immediate action required
Previous/completed	Collection, long term storage and analysis with samples that have been retained for use by future research projects	None	Suspend all research activity and refer to University Research Ethics Committee for consultation with Human Tissue Authority (see Note 1, below)

¹ See: <http://www.hta.gov.uk/>

² See: http://www.opsi.gov.uk/acts/acts2004/en/ukpgaen_20040030_en_1

Previous/completed	Collection, long term storage and analysis with samples that have been retained for use by future research projects	University Research Ethics Review Panel	Suspend all research activity and refer to University Research Ethics Committee for consultation with Human Tissue Authority (see Note 1, below)
Previous/completed	Collection, long term storage and analysis with samples retained for use by future projects	NHS Research Ethics Committee	Suspend all research activity and refer to University Research Ethics Committee for consultation with Human Tissue Authority (see Note 1, below)
Present/ongoing	Collection and immediate analysis with no temporary storage of samples prior to analysis or disposal	None	Suspend recruitment pending ethics application to University Research Ethics Review Panel or NHS Research Ethics Committee
Present/ongoing	Collection and immediate analysis with no temporary storage of samples prior to analysis or disposal	University Research Ethics Review Panel or NHS Research Ethics Committee	None – ethics approval sufficient
Present/ongoing	Collection, temporary storage and analysis with samples destroyed within existing project timeframe	University Research Ethics Review Panel	Suspend recruitment pending ethics application to NHS Research Ethics Committee
Present/ongoing	Collection, temporary storage and analysis with samples destroyed within existing project timeframe	NHS Research Ethics Committee	None – ethics approval sufficient

Present/ongoing	Collection, long term storage and analysis with samples retained for use by future projects	University Research Ethics Review Panel	Suspend recruitment pending ethics application to NHS Research Ethics Committee (see Note 1, below)
Present/ongoing	Collection, long term storage and analysis with samples retained for use by future projects	NHS Research Ethics Committee	Separate/additional ethics application for use of samples submitted to NHS Research Ethics Committee within project timeframe (see Note 1, below)
Research project status	Treatment of tissue samples	Level of ethics approval required	Immediate action required
Future/prospective	Collection and immediate analysis with no temporary storage of samples prior to analysis or disposal	University Research Ethics Review Panel or NHS Research Ethics Committee	None – future research
Future/prospective	Collection, temporary storage and analysis with samples destroyed within existing project timeframe	NHS Research Ethics Committee	None – future research
Future/prospective	Collection, long term storage and analysis with samples retained for use by future projects	NHS Research Ethics Committee (with separate/additional ethics applications for use of samples submitted to NHS Research Ethics Committee within project timeframe)	None – future research

Note 1. The retention and (re)analysis of tissue samples collected and stored from previous (i.e. completed) research projects will require immediate negotiation with the Human Tissue Authority to ascertain whether these samples: can be retained in current storage facilities at the University; must be transferred to a licensed authority pending an application for ethics approval submitted to NHS Research Ethics Committee (including a detailed description of original consent obtained and proposed efforts to obtain additional consent for the reanalysis of samples or equivalent additional measures proposed when additional consent is deemed impracticable).

Graduate School & Research Office
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