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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision as to the definition of ethical approval for the purposes of certain provisions of the Human Tissue Act 2004 (c. 30) (“the Act”). They also specify circumstances in which licensing by the Human Tissue Authority is not required for the storage of relevant material and sets out the information that must be provided to NHS Blood and Transplant in connection with transplants using certain material from a human body.

Regulation 2 defines ethical approval for research for the purposes of section 1(9)(a) of, and paragraph 10(b) of Schedule 4 to, the Act as approval by a research ethics authority.

Regulation 3 provides the following exceptions to the requirement under section 16(2)(e)(ii) of the Act to hold a license for storage of relevant material which has come from a human body:—

where the relevant material has come from a living person unless storage is for the purpose of transplantation (other than transplantation of an organ or part-organ or where the storage is for less than 48 hours) or for the purpose of research for which ethical approval has been given or sought

where the relevant material has come from a living person where storage is for the purpose of research for which ethical approval has been given or sought”; and

where the relevant material has come from a human body where storage is for the purpose of transplantation and either the material is an organ or part of an organ, or the storage period is for less than 48 hours

where the relevant material has come from a deceased person and storage is for the purpose of research for which ethical approval has been given or sought, or the material has been sent from licensed premises for analysis for a scheduled purpose other than research.

The information that must be provided to NHS Blood and Transplant in connection with the transplant of such material is specified in regulations 4 and 5 and in Schedules 1 and 2.

Regulation 4 and Schedule 1 prescribe the information to be supplied by a person who has removed transplantable material from a human body that is proposed to be transplanted to another person, to NHS Blood and Transplant.

Regulation 5 and Schedule 2 prescribe the information to be supplied by a person who has received transplantable material which is proposed to be transplanted, to NHS Blood and Transplant.

A Regulatory Impact Assessment was prepared for the Human Tissue Act 2004 and a copy has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment are published on the Department of Health’s website ([www.dh.gov.uk](http://www.dh.gov.uk)) and can be obtained from room 611, 6<sup>th</sup> Floor North, Wellington House, Waterloo Road, London SE1 8UG.