APPENDIX 3 – LEGAL REQUIREMENTS FOR REMOVAL OF ORGANS AND TISSUES FROM ORGAN DONORS

Removal of tissue/ organs for research purposes
Consent and removal of human tissue and organs for the primary purpose of research are regulated in the UK under the Human Tissue Act (2004) and the Human Tissue (Scotland) Act (2006).

Outside of Scotland, removal of tissue from deceased donors for the primary purpose of research must be carried out on Human Tissue Authority licensed premises.

Removal of tissues and organs from deceased donors for the purpose of transplantation is governed by a different legislation (Quality and Safety of Organs Intended for Transplantation Regulations). If organs or tissue are then deemed unsuitable for transplantation they may be used in a RINTAG approved study – as long as the appropriate consent or authorisation is in place.

The RINTAG approval process will confirm that appropriate consent and licensing requirements are in place for any study. NORS teams must not remove any material from organ donors for the primary purpose of research unless the research study has been approved by RINTAG and retrieval agreements and regulatory requirements are in place[1].

It is the responsibility of the researcher to ensure their study fulfils the requirements of the Human Tissue Act (2004) in England, Wales and Northern Ireland and the Human Tissue (Scotland) Act (2006). Researchers are therefore encouraged to take the time to familiarise themselves with the HTA guidance available on the HTA website and all local guidance.

The HTA has issued good practice guidance in its Codes of Practice, including the recently released Code of Practice for Research. Answers to Frequently Asked Questions are available. The HTA also licences a number of activities under the HT Act, one of which is the storage of tissue for "scheduled purposes" which includes research. The Research Project Manager can provide further advice on licensing issues.

Local Guidance
Local NHS Trusts/ Boards and Universities may have local policies on the handling of human tissue for research. Applicants must ensure that research involving human tissue, whether undertaken by University or NHS Trust/ Board employees, is subject to common governance procedures in line with local policies and current legislation.

Consenting/ authorising to use human tissue in research
The legislative framework for donation in England, Scotland and Northern Ireland is that of a hard 'opt-in' system of consent. The Human Transplantation (Wales) Act 2013 introduced '*deemed consent'* in Wales

The HTA Code of Practice on consent provides detailed guidance on all aspects of consent for the use of human tissue for a scheduled purpose.
It is routine for the families of organ donors to be asked to provide consent/ authorisation for the use of non-transplantable tissue to be used in research. Please consult with the Research Project Manager over issues around generic consent or if

[1] For more information, see Appendix 5

specific research consent is required. The equivalent Explanatory Notes are available for those following the Human Tissue (Scotland) Act 2006.

HRA approval will need to be sought. Please find further details, here. In order to ensure that the correct consent and legislative requirements are adhered to, all research studies that involved removal and use of organs and tissues from organ donors must be approved by RINTAG.