

Criteria for the use of human residual tissues for scientific research.

Permitted use

The Residual Tissues¹, parts thereof or derivatives² thereof may be used for:

- fundamental scientific and biomedical research (without obligation to publish data generated with the Residual Tissues);
- toxicological research or research required by law;
- forensic research;
- educational purposes;
- unprocessed ex vivo application, the isolation of cells and cellular parts (microsomes, proteins, membranes, DNA, RNA) and their further application or analysis;
- the isolation of (primary) cells;
- the production of immortalised cell lines, induced pluripotent stem cells and stem-cell derived organoids for use within the research project, for a period of up to 10 years after donation, provided this is described in the application and the patient/donor has given informed consent.

Derivatives of Residual Tissues may furthermore be used by third parties involved in the research project mentioned in the application³, provided that: (1) the supply to these third parties is made without consideration; (2) this use is specified in the application; and (3) the research institution submitting the application (the "End User") remains responsible for ensuring compliance with all agreements with VitalTissue. This use will hereafter be referred to as: "Non-commercial use by third parties."

Prohibited use

In any event, the Residual Tissue, parts thereof or derivatives thereof may NOT:

- be redistributed to third parties (in whole or in part), unless it concerns non-commercial use by third parties (as defined above)⁴;
- be used for research projects other than those mentioned in the application;
- be used for human or animal (medical) application;
- be used for full genome sequencing / identifying patient/donor;
- be patented or otherwise marketed⁵.

¹"Residual Tissues" are tissues released after the medical treatment of patients in hospitals or independent treatment centres which would normally be destroyed as waste.

²Derivatives of Residual Tissues include, for example, cell components (microsomes, proteins, membranes, DNA, RNA), immortalised cell lines, induced pluripotent stem cells and stem-cell derived organoids.

³"Third parties" refers to the *"the research institutes involved"* or the parties involved in the *"contract research,"* as mentioned above.

⁴Non-commercial use of derivatives of Residual Tissues by certain third parties and under specific conditions is in fact permitted.

⁵Research with Residual Tissues, parts thereof or derivatives thereof may, however, lead to the development of patentable or marketable results or methods.

Criteria set for research institutions for the use of human residual tissues in scientific research.

The following legal and natural persons may purchase human Residual Tissue as End Users:

- (i) all legal and natural persons;
- (ii) with a branch in the Netherlands where biomedical research is conducted that meets the legal and regulatory safety requirements;
- (iii) who further have access to the necessary infrastructure for conducting research;
- (iv) who in addition can plausibly demonstrate that they have the people (expertise), resources, facilities and money to conduct research with Residual Tissue; and
- (v) about which, moreover, public information is available that bears witness to a good reputation.

These include, in particular:

- academic institutes and university medical research centres;
- Applied research institutions -TO2 institutions in the Netherlands- (Deltares, NLR, TNO, WUR or MARIN);
- research institutes;
- (commercial) companies in the pharmaceutical industry, food and nutrition industry, cosmetics industry, chemical industry, as well as (commercial) companies focused on medical devices and/or other medical equipment;
- educational institutions (MBO, HBO, WO) with a focus on biomedical and applied research, including (scientific) research.

The following legal and natural persons may not purchase Residual Tissue as End Users in any event:

- legal and natural persons working in or affiliated with the tobacco industry, including legal and natural persons engaged in research into alternatives to smoking;
- Legal and natural persons working in or affiliated with the arms industry;
- Legal and natural persons employed in or associated with the production of alcoholic beverages or production of other addictive substances, including legal and natural persons engaged in research into alternatives thereto;
- Legal and natural persons of questionable reputation;
- Legal and natural persons maintaining an import business without a research programme;
- primary and secondary schools;
- senior secondary vocational education (mbo) or higher professional education (hbo) educational institutions without research facilities;
- private individuals.