

CTI-BIOTECH SARL CONOFRANCE

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Dear Scientist,

RE : ETHICS POLICY AT CTIBIOTECH

CTIBiotech established a robust network of partner healthcare centres for sample collections in France, Europe and the Rest of the World.

CTIBiotech for the purpose of Biosourcing and scientific research, CTIBiotech collects human samples defined collections of biological samples taken from donors anonymously selected according to defined clinical or biological characteristics.

CTIBiotech has a double accreditation (reference AC-2018-3243 et DC-2018-3242) from the French Ministry in charge of research for the preparation and conservation of elements derived from the human body (CODECOH) with a view to their transfer for scientific purposes (pursuant to Article L. 1243-3 and L. 1243-4 of France Public Health Code which is a direct Transposition into French law of European Directive 2004/23/EC of 31 March 2004).

CTIBiotech was approved in 2013 as an organisation allowed to carry out conservation or preparation activities of elements of the human body for scientific purposes with the following procedures:

- i. Declaration of the activities of conservation or preparation of elements of the human body for scientific purposes to the Ministry of Higher Education and Research (MESR), the Regional Health Agency (ARS) and the Committee for the Protection of Persons (CPP) which is the French Ethics Regulatory Committee in charge of these matters in France.
- ii. Application for authorization for the transfer of elements of the human body for scientific purposes to the Ministry of Higher Education and Research (MESR), the Regional Health Agency (ARS) and the Personal Protection Committee (CPP) Committee for the Protection of Persons (CPP) which is the French Ethics Regulatory Committee in charge of these matters in France..

All biological samples collected by CTIBiotech are collected following informed consent of anonymized donor patients. Consenting and collecting procedures must be compliant with European standards and applicable local ethical guidelines (for example, Committee for the Protection of Persons (CPP) which is the French Ethics Regulatory Committee in charge of these matters in France).

France and EU legislations

CTIBiotech conforms to relevant France and EU legislations such as:

- The Charter of Fundamental Rights of the EU.
- Article L. 1243-3 and L. 1243-4 of France Public Health Code which is a direct Transposition into French law of European Directive 2004/23/EC of 31 March 2004.
- Directive 2004/23/EC of the European Parliament and of the Council on Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells", code number 2002/0128 (COD), Strasbourg, 31 March 2004.

International conventions and declarations.

CTIBiotech respects the following international conventions and declarations:

- Helsinki Declaration in its latest version.
- Universal Declaration on the human genome and human rights adopted by UNESCO.
- 1997/04/04, ES-Oviedo -Convention for the Protection of Human Rights and Dignity of the Human Being about the Application of Biology and Medicine.

Yours Truly,



Dr Nico FORRAZ
Chief Executive Officer, CTIBiotech