Participating in a clinical research study

Medical data or residual human body material (HBMr) collected from ambulatory or hospitalized patients are stored and can be used in clinical research studies. The objective of clinical research studies is to advance scientific knowledge, diagnostic methods and developing new therapy aiming at improving the life of patients. Clinical research studies are performed under the control of local ethics committees which role is to insure the protection of the rights, privacy and safety of the patient. Approval of the clinical protocol by the ehics committees is mandatory to the initiation of a clinical research study.

Belgium laws assume that patients consent to the use of stored medical data and HBMr[1] for scientific research purposes. Therefore, patients are not always informed of the use of their data and HBMr in a research project, yet they can proactively witdraw consent by filing an Opt-Out Form.

Patients that do not wish that their medical data or HBMr be used in in secondary research study need to file the following Opt-Out form with the hospital management directly or via the attending nurse

[1] Human body material are human biological samples, including human tissues and cells, gametes, embryos, fetuses, and substances extracted therefrom, regardless of their degree of transformation. Residual human body material are HBM remaining after primary use, that can be destroyed

Name :
Firs name :
Birthdate :
N° UMR :

Opt-out Form

Witdraw consent to the use of personal Medical data and residual human body materials

During your hospital visit (hospitalization or ambulatory), it is possible that human body material be collected and that medical data be stored. Once all the analyses necessary to your treatment are completed, this material can be used in clinical research studies without further agreement on your part.
In Belgium, the use of patients medical data and residual human body material, obtained during disease diagnostic or treatment, is fully covered under Belgium and EU legislations[2].

I, ……....(first and last name),

OR

I,…….(first and last name), legal representative of

……..(first and last name)

hereby declare that I oppose to :

☐ A: any use of my medical data
☐ A': any use of the medical data of …… (first and last name)

☐ B: the use of my human body material
☐ B': the use of the human body material of ……(first and last name)

☐ both A and B

Executed in ……, on ……

Signature :

Return the completed form to an attending nurse, or to the clerc at the consultation desk, alternately you can send a copy to the Clinical Trial Center at Service.Rech-biomed@erasme.ulb.ac.be

Attention to Hopital Erasme only :
Forward this document par email/fax, and send the original via internal mail.
Tel : 02 555 83 51 **Fax** : 02 555 82 60

[2] Law of 8 December 1992 on the protection of privacy in relation to the processing of personal data. Law of 22 August 2002 on patient rights. Law of 7 May 2004 on experimentation on humans. Law of 19 December 2008 on collection and use of human biological samples for medical applications or scientific researchLoi du 8 décembre 1992 relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel, Loi du 19 décembre 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique, Directive européenne 95/46/CE du 24 octobre 1995 relative à la protection des personnes physiques à l'égard du traitement des données à caractère personnel et à la libre circulation de ces données .