**ANNEX to the INFORMATION FOR ETHICS COMMITEES AND SPONSORS ON THE INFORMED CONSENT PROCEDURE IN TRIALS ONGOING AT OR COMPLETED BEFORE 25TH MAY 2018. Version 2.0 – publication date 05/12/2018**

*Note to the user:*

*Please remove all text in red, and remove text in blue (if not applicable) or replace text in blue by study specific information.*

**Accompanying letter**

Dear Participant,

As the investigator of the study [name of the study] in which you participate, I am pleased to transmit you the information below from the sponsor [name of the sponsor]. As I am responsible for processing your personal data, they/we [‘we’ in case the investigator is a *joint-controller*] would like to inform you how your personal data are being managed, saved and used. This information is complementary to the information you already received in the informed consent form (item [number]) at the beginning of your participation in the study.

You can always contact us for further questions.

Yours faithfully,

[name and signature of the investigator]

**Information on the treatment of your personal data.**

The new **European General Data Protection Regulation (GDPR)** 2016/679, in force since 25 May 2018, imposes additional requirements on how companies or organizations may use your personal data. One of these requirements is that the data controller provides the following information.

As already indicated in the informed consent form, **personal data** about you are being collected in the context of the study in which you participate. We, [name sponsor], are responsible for the proper processing and for the information duty this implies. That is why we again draw your attention to the fact that, in addition to common personal data such as your age and gender, also “**particular categories**” of personal data have to be collected. Examples are:

* Your ethnical background;
* your state of health and medical diseases, including your medical antecedents;
* your treatments and your response to them;
* your biological samples, e.g. blood samples, tissue, and the results of their analysis;
* your medical imagery material, e.g. scans, X-rays, as well as the results of their evaluation.

[Information on the legal base for data processing. ICFs signed before the 25th of May 2018, indicate as legal ground “with your consent”. Therefore, according to the GDPR, the following sentence has to be mentioned:]

As a matter of course, we may only use your personal data to the scientific research goals indicated in the informed consent form, which you signed at the beginning of your participation in the study.

It is possible that **your data are being consulted** by persons in countries that do not use the same norms as the EU regarding legal data protection. In those cases, we commit ourselves to enforce the conditions of the European and Belgian personal data protection legislation.

Besides, in compliance with the relevant legislation, the data that are collected as part of the study will be **retained[[1]](#footnote-2)** for at least 20 years, or 30 years if these data also make part of your medical file.

According to the GDPR, you have a number of **rights** concerning the processing of your data. If you have further questions about this, you can always contact your **investigator**.

In addition, the **data protection officer** of the trial site is at your disposal. Please find his/her contact information: [name and contact information of the research site’s DPO].

Finally, you also have the **right to file a complaint** on how your information is processed. You can do so with the Belgian regulatory body that is responsible for enforcing the data protection legislation:

*Gegevensbeschermingsautoriteit (GBA)*

*Drukpersstraat 35,*

*1000 Brussel*

*Tel. +32 2 274 48 00*

*e-mail:  contact@apd-gba.be*

*Website: www.gegevensbeschermingsautoriteit.be*

[This letter only needs to be signed by the participant in case of a change of the legal base or of his/her rights regarding the collection and processing of personal data.]

*I confirm to have read and understood this additional information on data protection, that I had the opportunity to ask questions, and that I received a copy of this letter.*

*Date:*

*Full name (in capital letters):*

*Signature:*

1. . The current legislation requires personal information that is part of this research to be retained for 20 years (and, if applicable, the European Regulation on clinical trials with medicinal products extends this retention period to 25 years). In the case of an investigational medicinal product for an innovative therapy involving the use of human body material, this storage period shall be a minimum of 30 years and a maximum of 50 years in accordance with the Belgian law of 19 December 2008 on the use of human body material and the applicable Royal Decrees. [↑](#footnote-ref-2)