**Changes to the biobank information letter in connection with the General Data Protection Regulation**

The European privacy legislation, the General Data Protection Regulation (GDPR), which has been in effect since May 2018, also has consequences for the information provided to biobank participants. Below you can read what you need to do to amend the information letter based on the applicable legislation.

For what sub-biobanks does the information letter need to be amended?

For sub-biobanks which are still including new donors in order to collect data from them.

Why are the changes necessary?

The GDPR imposes more stringent requirements on the obligation to provide information and on data processing than the Dutch Personal Data Protection Act (Wbp) which previously applied. Because biobanks generally have long data storage periods, new donors must in any case receive information about this.

What are the main changes to the new template?

* In the new biobank information letter template (version dated November 2018), sections on data processing which previously appeared in different places in the letter have been brought together under point 3, item 7. All possible data sources to which the human biological material can be linked in the future are now described here.
* Under point 7, the section on the transfer of data to countries outside the EU is important when this is expected to be a possibility in the future.
* The information under point 11 (confidentiality of data and human biological material) has been rephrased and supplemented in order to comply with the GDPR.
* The structure of the letter has been somewhat amended, as a result of which old and new numbers may no longer correspond. See TCBio website for more information on the changes and a comparison between the new version and the version dated February 2015.

Which information has been removed?

To describe the processing of data as accurately as possible, the sentence stating that the Central Biobank itself collects and can release medical data has been amended. The same applies to the sentence stating that all data are subject to medical confidentiality. Both sentences did not accurately reflect the actual situation.

Can I change the template as I see fit?

The template letter has been designed to ensure that all components are internally consistent such that it meets the applicable statutory requirements. Changes to one component may affect other components. Therefore, it is important that you essentially follow the template and supplement it with biobank-specific information.

How should I amend existing biobank information letters to comply with the GDPR?

Based on the template you can check which text has been changed or removed or is missing from your version. A useful tool for this is the version of the template provided on the TCBio website which shows the changes compared to the version which applied before the GDPR entered into force. As we have explained above, the information letter is internally consistent. When an existing letter is changed, it is therefore important for the letter to remain consistent in terms of its substance as well as its legal aspects.

Is consent based on older versions of biobank information letters still valid?

At the moment we are assuming that consent for participation in biobanks given based on the older versions is still valid. It is important, however, to inform new donors included in biobanks and ask for their consent based on the legislation that is now applicable. For this reason the information letter must be amended as soon as possible and the new version must be used without delay for new donors to be included.

What will the review procedure for these amendments be like?

Amended information letters can be submitted to the TCBio as amendments in the usual way, and they will be dealt with in the normal review process. This means that amendments which merely concern changes to the information letter in connection with the GDPR and which follow the template can be dealt with by the secretariat in consultation with the chairperson. If the letter contains more changes than those which are required in connection with the GDPR, discussion during a Committee meeting may be necessary. The amendments can also be incorporated into a more extensive amendment. Depending on the nature of the full amendment, discussion during a Committee meeting may be necessary in this case.

How will biobanks be informed about the necessity of these changes?

A list of active biobanks will be made available to the Research Quality Coordinators. This list can be used to actively approach the coordinators who are responsible for these biobanks. In addition, information will be provided via the TCBio website, the Central Biobank, the Research Office, and via Research News. The biobanks themselves are responsible for amending the information letters in a timely manner and ensuring that they adhere to the applicable legislation.

Do information letters for sub-biobanks linked to a WMO study also need to be amended?

Yes, the same rules apply to these sub-biobanks. The amendments can be submitted to the MREC.