Newsletter
Ethics Committee Research UZ/KU Leuven
Number 26 – August 2024

Dear all,

As EC Research we have the task to protect study participants and to guide you through an increasingly complex regulatory landscape which does not (always) facilitate research or innovation, and can be very cumbersome to all of us.

Our ongoing mission is to contribute to safeguarding the general well-being, safety, dignity, rights, and privacy of patients/healthy volunteers participating in clinical research. EC ensures independent advisory services, always prioritizing the welfare of the participants.

Wishing you all the best in your endeavours and wishing you a nice Indian summer,

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1. New ICF templates

The ICF working group of BAREC (Belgian Association of Research Ethics Committees) has updated the ICF template for interventional clinical trials with an investigational medicinal product (IMP) on adult patients (CTR studies). Together with the workgroup on medical devices, we have introduced a **new** ICF template for adult patients participating in a clinical investigation involving a medical device reviewed by an independent Belgian Ethics Committee recognized under the Belgian legislation of May 7, 2017 (MDR).

Both ICFs are available now on the BAREC website and the EC website only in Dutch. The translations will follow later.

2. Statistics Seminar

EC Research invites you to a seminar by Prof. Ariel Alonso: "Mishandling of missing data". You can register via email at ec@uzleuven.be.

When: October 3, 2024, from 1:30 PM to 3:00 PM.
Where: ALO 07.200, Blue Street, Gate 5

3. Are you planning to conduct a clinical trial? Make sure to check whether or not you need biobank approval

All scientific research that includes the procurement and/or use of Human Bodily Material (HBM) is required to have biobank approval prior to the start of the research (see the website of the UZ/KU Leuven Biobank for more information).

However, an important **exception** to this rule applies to clinical trials with medicinal products and clinical trials comparing medicinal products to medical devices. In such cases, it is the scope of the **future use** of the HBM (and its derivatives) that determines whether biobank approval is required.

Clinical trial within scope

- Biobank approval is not required if the collected HBM (and its derivates) will in the future only be used for research on the same disease, the same treatment or the same medicinal products as those being investigated in the current trial. In this case, when you are submitting your study proposal via the CTC portal, you should **NOT indicate** the biobank as a supporting department.

Clinical trial out of scope

- If the HBM (or its derivatives) may in the future be used for a study dealing with other diseases, other treatments and other medicinal products than those being investigated in the current trial, then you still need to apply for biobank approval. Consequently, when submitting your study proposal, you should **indicate** the biobank as a supporting department.

4. Use of ICF and Protocol Templates for specific studies

Regarding the ICF templates, and also applicable to the protocol templates, we ask you to remove any paragraphs from the templates that do not apply to your specific study. The submitted documents must be study-specific. A template serves as a guide, implying not everything included may be relevant to your study.
Additionally, please ensure that all included sections are tailored to accurately reflect the unique aspects of your research. This approach helps maintain clarity and relevance, facilitating the review and approval process.

5. Flagging UZ Leuven patients in studies

Participants in studies (evaluated by EC Research or OBC) are informed about the research involving their data via Mynexuzhealth. For more information, we refer to our Newsletter of July 2020 and October 2022, which can all be found on our website. Through Mynexuzhealth, patients can view the studies for which their data are used. Flagging study participants with the corresponding S-number in KWS is therefore required.

You can find more information on how patients should be flagged in KWS through this Muzlidoc procedure:
https://wiki.uz.kuleuven.ac.be/display/KWShelp/Klinische+studies#Klinischestudies-Pati%C3%ABntincluderen.

6. Difference between Anonymous and Pseudonymous data

Understanding the distinction between anonymous and pseudonymous data is crucial for compliance with regulations such as the GDPR.

Anonymous Data: This refers to information that cannot be traced back to an individual by anyone, through any means. Once data is anonymized, it should be impossible to re-identify the person to whom the data originally pertained. True anonymization is a rigorous process that eliminates any potential for re-identification. However, for studies involving patient data from UZ Leuven, achieving true anonymization is nearly impossible. This is because the patient's medical records remain accessible and linked to the dataset, making complete anonymity nearly unattainable.

Pseudonymous Data: In contrast, pseudonymization involves separating personal identifiers from the data, so that the information cannot be directly linked to an individual without the use of additional information. In practice, pseudonymous data is encoded in such a way that the dataset remains identifiable only through a code, which is kept separately and securely. This means that while the data is not directly attributable to any specific person, it can still be traced back to individuals if necessary, using the associated code and additional information. This approach is often used when true anonymization is not feasible, as it allows for the secure handling of personal data while maintaining its usability for research purposes.

It is important to use the correct terminology consistently in your research protocols. If your study uses pseudonymous data, clearly specify this and avoid referring to the data as "anonymous" or "anonymized." While pseudonymous data is subject to the GDPR, anonymized data is considered out of scope, provided that it genuinely cannot be used to identify individuals in any way.

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Number 26 – August 2024

7. EFGCP eConsent Initiative

The EFGCP eConsent Initiative is a project focused on advancing electronic consent (eConsent) processes in clinical research. The initiative is led by the European Forum for Good Clinical Practice (EFGCP) and aims to create a standardized and effective approach to eConsent, which is crucial for ensuring ethical and transparent patient participation in clinical trials.

A key component of this initiative is the eConsent Fit-for-Purpose Study Framework. This framework is designed to evaluate and optimize eConsent solutions to ensure they are suitable for different types of clinical studies and diverse patient populations. The framework provides guidance on the development, implementation, and assessment of eConsent tools, ensuring they meet regulatory requirements, protect patient rights, and enhance the overall quality of clinical research. You can find the publication here: https://efgcp.eu/public/eConsent%20Fit%20For%20Purpose%20Framework.pdf

The EFGCP eConsent Initiative and its Fit-for-Purpose Study Framework represent a collaborative effort to make eConsent more accessible, user-friendly, and reliable, ultimately improving patient engagement and trust in the clinical trial process. These developments are crucial for the future of clinical research, particularly in an increasingly digital world.

This tool provides sponsors (and any stakeholder interested in eConsent) a guide on how to define and design the right eConsent for a particular study and how to generate effective and comparable study data on eConsent. Potential eConsent benefits and challenges of participants, sites and sponsors; or impact of various eConsent platform and operational aspects on targeted benefits, or potential eConsent Key Performance Indicators with qualitative and quantitative measurement approaches, are just some of the items that are detailed in the 5-process step framework.

8. Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials

In 2022, the ethics committee of the French medical research agency (INSERM) launched VolREthics, an international initiative to identify good practices to protect healthy volunteers in research. This initiative resulted in the recent launch of the Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials: https://www.inserm.fr/wp-content/uploads/Inserm_VolREthics_EthicsCharterFinalVersion_July24.pdf

This charter outlines key ethical principles and standards to ensure that volunteers are respected, informed, and protected throughout their participation in research. By adhering to these guidelines, the charter reinforces a commitment to ethical practices and ensures the safety of those who contribute to the advancement of medical science.

9. Fee commercial retrospective studies – initial submission and amendments

As mentioned in our May newsletter, a fee of €1000 is requested for the evaluation of commercial retrospective studies by EC Research (**initial submission**).
In addition, please note that a fee of €500 is requested for the evaluation of **amendments** on commercial retrospective studies by EC Research.
Therefore, please provide the following data to EC Research upon submission of an amendment to a commercial retrospective study:

- Invoicing address (preferably an address in Belgium)
- Name of contact
- PO number (Purchase Order), if applicable
- VAT number

The sponsor will receive an invoice from the Financial department of UZ Leuven (with payment reference). Payment is only possible upon receipt of an invoice from the Financial department.

10. Submission guidelines for study documents: important notice

When submitting a study and study documents to the Ethics Committee, we kindly request that you do not submit scanned documents. Only documents that allow for copying and searching should be submitted. For more information on how to submit documents, please visit our website.

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www.uzleuven.be/ethische-commissie/onderzoek