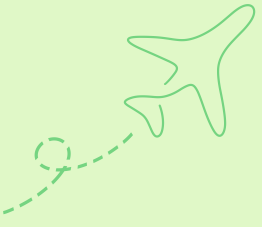
NEWSLETTER

Ethics Committee Research
UZ/KU Leuven

Number 30 - JUNE 2025





Dear all,

As an independent advisory body we are here to stand by your side throughout your research journey, ensuring every step is rooted in ethics, safety, and respect.

We are unwavering in our commitment to safeguarding the rights, dignity, and well-being of both patients and healthy volunteers. Participant welfare is our guiding principle.

We wish you all a restful, enjoyable, and sunny summer.

Warm regards,
The EC Research Team

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Francesca Bosisio, Guy Bosmans, Simon Brumagne, Catherine Cassiman, Valerie Christens, Ellen Deleus, Jean-Jacques Derèze, Erwin Dreesen, Lut De Groote, Theresia De Fraye, Jan de Hoon, Aernout De Raemaeker, Lia De Wilde, Dorien Fierens, Marie Gilliot, Rik Gosselink, Kelly Hoogeveen, Walter Janssens, André Loeckx, Koen Luyckx, Frederik Nevens, Marleen Renard, Miet Schetz, Peter Sinnaeve, Karin Sipido, Anne Smits, Mathijs Swaak, Anne Uyttebroeck, Marilien Vandeputte, Veerle Vanparys, Frank van Calenbergh, Ben Van Calster, Bart Van der Schueren, Laura Van Gerven, Kristel Van Landuyt, Katelijne Van Overwalle, Kristin Verbeke, Jan Verhaegen, Gregor Verhoef, Minne Casteels
Staff: Irene Borginon, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Kaat Van huyck, Indra Verhaeghe, Sofie Vervoort

- Nice memory of the team building of EC -
Abdij van Park

VIDEO RECORDING OF PARTICIPANTS IN NON-CLINICAL SETTINGS

A new guidance, prepared by EC Research with input from the legal services of UZ Leuven, outlines the principles and conditions for using video recordings of study participants in non-clinical (extramural) settings, primarily at home, in the context of clinical research. Although the focus is on video recordings, the same requirements apply to audio recordings.

The guidance emphasizes that recordings must be scientifically justified based on the "need-to-know" principle in line with GDPR standards — only recordings essential to the study may be collected. Detailed requirements for including this information in the ICF are provided, such as clear filming instructions and data protection safeguards.

Other key points include:

- Use of personal or study-provided devices (e.g. tablets or smartphones), with appropriate security measures.
- Restrictions on who may appear in recordings to protect third-party privacy.
- Guidelines for securely sharing recordings with external vendors, ensuring GDPR compliance through proper agreements.
- The need for pseudonymisation of recordings to safeguard participant identity whenever possible.

This guidance is intended to ensure that these decentralized elements do not increase risks for participants and that their privacy, dignity, and rights remain fully protected throughout the research process.

You can find the guidance on our website: https://www.uzleuven.be/nl/ethische-commissie-onderzoek/richtlijnen-notas-en-opleiding.

ANNUAL PROGRESS REPORT

For studies falling under the **Belgian Law of May 7, 2004**, we kindly remind you that it is **mandatory to submit an annual progress report** to the Ethics Committee, in line with **ICH-GCP guidelines**. This report functions as a continuation of the EC's ethical approval.
Failure to submit the report on time may result in the study being considered **legally expired** and potentially **subject to termination.**

Important: This obligation **does not apply** to studies **not** subject to the Law of May 7, 2004 — for example:

- Retrospective studies
- Studies involving only the **secondary use of human body material**
- Studies conducted under the **Medical Device Regulation (MDR) or Clinical Trial Regulation (CTR)**

This requirement was explicitly reaffirmed during the **2019 FAMHP inspection** of the Ethics Committee. The inspection report highlighted that **internal monitoring**, including the systematic follow-up of submitted progress reports, is a vital component of a strong and reliable **quality system**.

EC sends study teams a reminder when:

- A study was approved more than 12 months ago, or
- More than 12 months have passed since the last annual progress report was submitted.

In such cases, EC sends a reminder to request an update on the study status and to kindly ask that the annual progress report be submitted at your earliest convenience. This helps ensure that ethical approval remains valid and that studies remain compliant with applicable regulations.

STUDIES UNDER IVDR/MDR

We encourage all researchers **to carefully assess whether their study falls under the scope of the IVDR (In Vitro Diagnostic Regulation) or MDR (Medical Device Regulation).**
While opting to classify your study under these regulations may involve **additional administrative steps at the outset**, it can ultimately lead to **substantial long-term benefits** — including greater regulatory clarity, enhanced study credibility, and smoother pathways toward clinical implementation.

If you plan to use the study data in the future — whether for **regulatory submissions, validation purposes, or product development** — it is often crucial that the study is conducted in full compliance with the **IVDR or MDR**.

Failing to account for this from the outset may render the collected data **ineligible for these key applications**, potentially limiting its value and impact.

That's why this is not just a regulatory detail, but a **strategic decision** that should be made **early in the study planning process**.

For more information, we refer you to the MDR and IVDR regulations:

- Medical Device Regulation (MDR): https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32017R0745
- In Vitro Diagnostic Medical Devices Regulation (IVDR): https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32017R0746

NOTE ON ELECTRONIC INFORMATION AND DIGITAL CAMPAIGN ABOUT A SPECIFIC CLINICAL TRIAL USING WEBSITES AND SOCIAL MEDIA

We would like to inform you that a new document, **a note on electronic information and digital campaign about a specific clinical trial using websites and social media**, is available on the website of the CT-College. You can access it via the following link: https://consultativebodies.health.belgium.be/en/documents/note-electronic-information-and-digital-campaign-about-specific-clinical-trial-using.

This note, developed by Pharma.be, offers practical guidelines for creating and sharing digital information about authorized clinical trials through websites and social media. The goal is to support and improve patient recruitment in an ethical and transparent way.

The document was reviewed by the Belgian EC's recognized under the Law of 7 May 2017 and was formally approved by the Board of the CT-College on April 25, 2025.

USING AN F-NUMBER FOR FEASIBILITY SCREENING IN KWS

A feasibility screening refers to the preparatory phase before the start of a research project. At this stage, no official protocol exists yet — the goal is to evaluate the target population in order to draft a well-founded study protocol or to explore potential participation in a future study. Feasibility screenings thus serve to assess the availability of relevant data before the protocol is finalized, regardless of whether the study is academic or commercial, retrospective or prospective.

To document this process, a feasibility functionality in KWS is available via **an F-number.**

Feasibility screenings should ideally be carried out by a healthcare professional with an actual therapeutic relationship to the patient. This screening can be documented by registering an F-number.

1) **When an actual therapeutic relationship exists**, registering an F-number is not mandatory but strongly recommended, as it offers the advantage that, when a patient exercises their right of access to their medical record, the reason for access is immediately evident and it enables the continued use of the screening list. Even in the context of an actual therapeutic relationship, access to the file is, in principle, limited to those aspects and moments that are strictly necessary for medical care.

2) **If no actual therapeutic relationship** is in place and overrule access is required, F-number registration is mandatory.

3) In specific cases, other individuals who work in close collaboration with a (future) Principal Investigator (PI) with an actual therapeutic relationship may also carry out a feasibility screening. These individuals may be granted access to KWS **as privileged staff**, but only if:

- they have successfully completed the CTA training, including the GDPR module, and
- their access is explicitly justified with a valid F-number.

Access to patient records from other departments must always involve colleagues with an actual therapeutic relationship.

The manual for generating an F-number can be found in this procedure: https://wiki.uz.kuleuven.ac.be/display/KWShelp/Feasibility
Once a few fields are filled in in KWS, the F-number is automatically generated.
For more background information, please visit:
https://wiki.uz.kuleuven.ac.be/display/public/muzlidoc/Gezondheidsgegevens+en+onderzoek

HIGHLIGHTING CHANGES IN MODIFIED DOCUMENTS

When submitting **revised documents** — whether in response to EC feedback or as part of an amendment — we kindly request that **all changes be clearly marked within the updated documents**.

Ideally, revisions should be indicated using **track changes**, as this allows us to see not only the **newly added text**, but also, and more importantly, any **deleted content**.

Please note that simply highlighting changes with fluorescent colors is **less effective**, as it does not clearly reveal removed text. That said, if deletions are **explicitly indicated using color**, this is also acceptable.

The **essential requirement** is that **all modifications must be clearly visible**, ensuring a smooth and accurate **EC evaluation**.

ANSWERS TO EC-REMARKS

We would like to remind you that a response to the comments issued by EC is expected within 6 months.

If no response is received within this period, the study will be administratively closed. In that case, the research project must be resubmitted to the EC for a new opinion if you wish to proceed.

To help you stay on track, the EC will send reminder emails after 3 and 5 months of inactivity. If no reply is received within 6 months, you will receive a final notification confirming that the study has been administratively closed.

If it is not feasible to respond within the 6-month period, we kindly ask you to inform us in advance. In the context of monitoring our internal processes, we would also appreciate a brief explanation if the study is no longer being conducted. This helps us understand why certain projects are not continued and supports the improvement of our follow-up procedures.

If you do submit a response, please ensure it follows our guidelines as outlined in Newsletter No. 17 – April 2022.

We strongly encourage timely and complete follow-up to avoid delays in your research process.

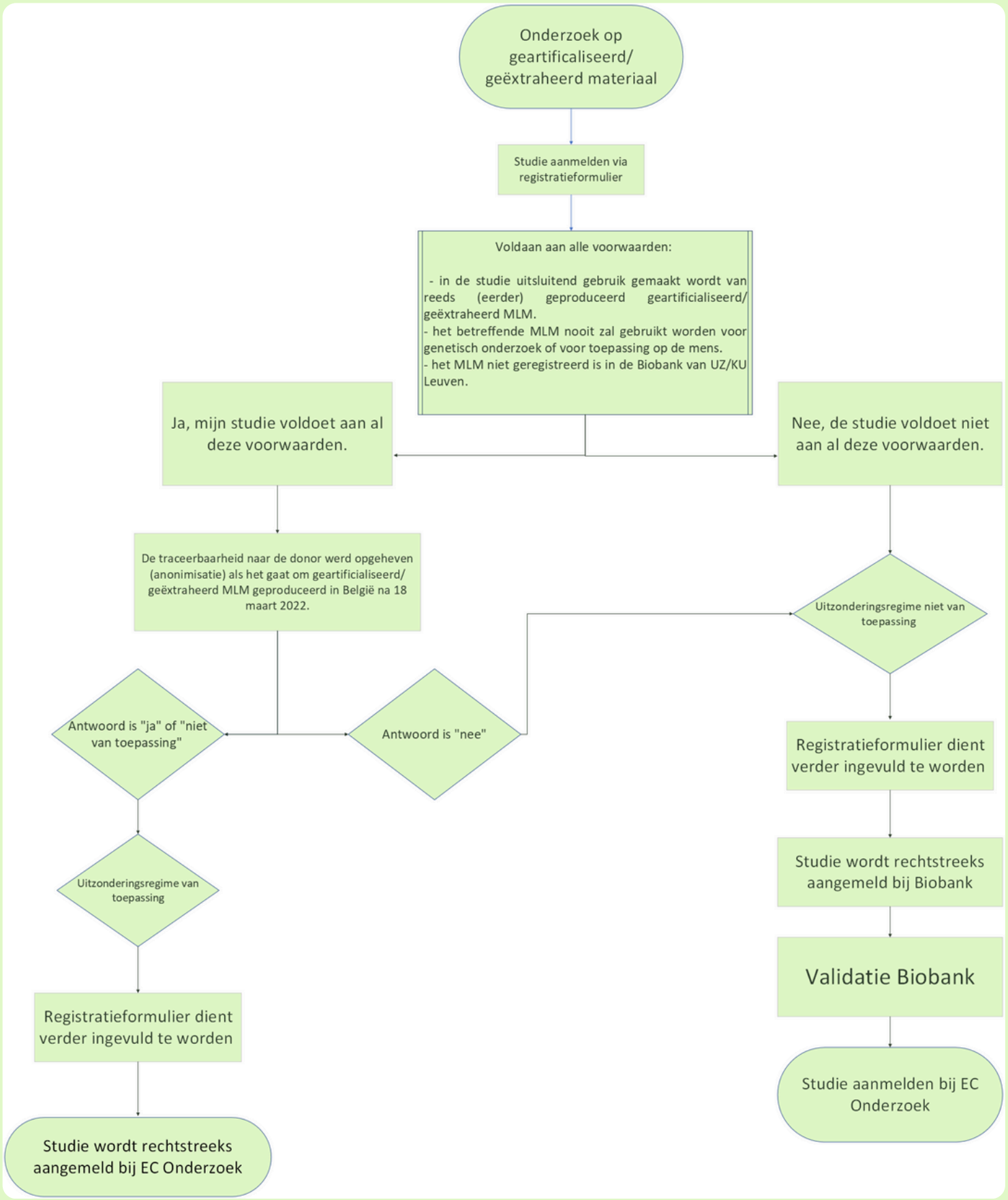
RESEARCH WITH ARTIFICIAL OR EXTRACTED HUMAN BODY MATERIAL

There is still some confusion about the administrative requirements for research using artificialized (e.g. cell lines, organoids, PDX models) or extracted (e.g. proteins, organelles) human body material without any therapeutic application on humans, whether under the general legal framework or under an exception regime and the administrative requirements that apply respectively.

To clarify this matter, UZ and KU Leuven now provide a clear context and practical guidance on how to submit such studies correctly, which allows for administrative simplification in specific cases.

Researchers can rely on structured processes, including the use of umbrella protocols and a streamlined submission flow. These measures aim to reduce administrative burden while remaining compliant with Belgian legislation. Especially for artificialized material obtain from official vendors such as ATCC, several simplifications have been introduced to ease working with this type of material. These have been summarized in the guidance document, which we recommend to consult prior to study submission. You can access the document here: https://www.uzleuven.be/nl/ethische-commissie-onderzoek/richtlijnen-notas-en-opleiding.

Below you can find a Dutch-language overview of what determines the application of the general or exception regime when submitting a study exclusively involving artificial/extracted human body material and whether the study needs to be evaluated by both the Ethics Committee and the Biobank or not:


Onderzoek op geartificaliseerd/ geëxtraheerd materiaal
Studie aanmelden via registratieformulier
Voldaan aan alle voorwaarden:
- in de studie uitsluitend gebruik gemaakt wordt van reeds (eerder) geproduceerd geartificialiseerd/ geëxtraheerd MLM.
- het betreffende MLM nooit zal gebruikt worden voor genetisch onderzoek of voor toepassing op de mens.
- het MLM niet geregistreerd is in de Biobank van UZ/KU Leuven.
Ja, mijn studie voldoet aan al deze voorwaarden.
Nee, de studie voldoet niet aan al deze voorwaarden.
De traceerbaarheid naar de donor werd opgeheven (anonimisatie) als het gaat om geartificialiseerd/ geëxtraheerd MLM geproduceerd in België na 18 maart 2022.
Uitzonderingsregime niet van toepassing
Antwoord is "ja" of "niet van toepassing"
Antwoord is "nee"
Registratieformulier dient verder ingevuld te worden
Uitzonderingsregime van toepassing
Studie wordt rechtstreeks aangemeld bij Biobank
Validatie Biobank
Registratieformulier dient verder ingevuld te worden
Studie aanmelden bij EC Onderzoek
Studie wordt rechtstreeks aangemeld bij EC Onderzoek

RETENTION PERIODS FOR STUDY DOCUMENTS IN CLINICAL RESEARCH

We hereby provide an overview of the retention periods applicable to study documents within research projects conducted at UZ Leuven, in accordance with relevant legal requirements and institutional policies.
Please note that retention durations may vary depending on the type of study, as different categories of research are subject to distinct regulatory and ethical guidelines.

STUDY TYPE OR APPLICABLE LAW	INFORMATION ABOUT RETENTION PERIOD
General Data Protection Regulation (GDPR)	No longer than is necessary for the purposes for which the personal data are processed.
Clinical Trials Regulation (CTR)	At least 25 years after the end of the clinical trial.
Medical Device Regulation (MDR)	- for a period of at least 10 years after the clinical investigation with the device in question has ended, or - for a period of at least 10 years after the last device has been placed on the market. - Implantable devices: at least 15 years.
In-vitro Diagnostic Regulation (IVDR)	- for a period of at least 10 years after the clinical investigation with the device in question has ended, or - for a period of at least 10 years after the last device has been placed on the market.
Belgian Act of 7 May 2004 on Experiments involving the human person	Although no legally defined retention period applies, UZ Leuven requests that study documents related to experiments be retained for 25 years, in line with the CTR.