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1. Informed Consent Form (ICF) templates

We are pleased to announce that new ICF templates are now available on the BAREC website. You can find:

- An adapted ICF for clinical investigations with a medical device on adult patients version 1.1 in Dutch, French, English.
- An adapted ICF for interventional clinical trials with IMP on adult patients in Dutch, French, English.
- A new ICF for interventional clinical trials with trial medicine in healthy adult participants in Dutch, French, English (prepared in consultation with Healixia).

These templates have been approved by the Board of CT-College and will soon become mandatory to use by the sponsors.

We hope that these new templates will support you in your work and contribute to a more efficient evaluation process.

We invite you to a Teams meeting on March 20, 2025, at 7 PM where we will provide more details about the changes that have been made. More information will follow.

2. Summary of the Joint Workshop on Harmonization of Recognized Ethics Committees

On November 23, 2024, BAREC and CT-College hosted a joint workshop focusing on the harmonization of recognized Ethics Committees (ECs) under the Law of May 7, 2017. Titled "*The Work of ECs Since the Implementation of the Clinical Trials Regulation (CTR) and the Way Forward,"* the event provided actionable insights into best practices, conditions, and tools for ECs to adapt effectively.

Participants discussed best practices, critical conditions, and practical tools to navigate the evolving landscape of clinical trial regulations and ensure alignment across all ECs.

The workshop opened with a plenary session that examined the types of considerations raised by ECs and evaluated their alignment with existing agreements from BAREC and CT College. The session focused on identifying considerations that could be universally applied across ECs while promoting improved knowledge-sharing practices among committees. It was recommended that subjective language or vague considerations should be avoided. Instead, ECs should strive to ensure their feedback is specific, actionable, and aligned with legal obligations.

When a consideration becomes a condition

One session addressed defining when a consideration becomes a condition. It was emphasized that conditions should only be applied in cases where issues are critical and where a favorable benefit-risk balance exists. As legally binding obligations, conditions must be carefully categorized based on when they need to be fulfilled—such as before recruitment begins or with the next substantial modification. The session also highlighted the importance of thoughtfully deciding whether amendments to fulfill specific conditions are necessary and stressed avoiding arbitrary deadlines.

Considerations on decentralization including the use of social media

The inclusion of decentralized elements and the use of social media in clinical trials were explored in detail. While such approaches can increase patient accessibility, they raise significant concerns regarding data privacy and patient safety. Third-party apps, for example, must comply with GDPR regulations, avoid advertising uses, and minimize the use of personal data. Social media use for recruitment was deemed permissible but must be carefully managed depending on the trial design and population. The workshop stressed that all decentralized elements, such as home visits or digital tools, must be justified for their inclusion, with priority given to patient safety and the risk-benefit profile.

Processing of personal data

During this workshop, attention was given to the use and processing of personal data. It was noted that determining and verifying the legal basis is not always straightforward. Some general rules were highlighted, such as the fact that public interest cannot serve as a legal basis for commercial studies and that legitimate interest is not applicable to studies involving children. However, uncertainties remain that need to be clarified. To address these, a working group will be established (see further details in the newsletter).
Additionally, it was emphasized that the GDPR does not apply to anonymous data, although truly anonymous data is exceedingly rare. It was also agreed that ECswill no longer need to request confirmation that the highest security standards are ensured during data transfer, as this is implicitly affirmed by the GDPR statement and is verified during audits.

Shaping the future: key actions ahead

There are still several action points planned for BAREC and CT College, and we hope to follow up on these as soon as possible. These include the creation of an advice on sample anonymization, an advice on retention periods for different types of studies, and a further review of the advice on compensation of participants in clinical research.

Additionally, the Assessment Report for Part II will need to be reviewed to implement necessary adjustments.

3. Overview of patient facing documents requirements for EC Review

The already available BAREC advice has been updated. The list of documents that do not need to be submitted in CTIS has been revised.

For the full advice, we refer you to the BAREC website: https://barec.be/advice-barec-patient-facing-documents/. This advice has been approved by the Board of CT-College.

Patient facing documents are materials provided to clinical trial participants during the trial that are not recruitment materials or subject information sheets.

According to the Q&A provided from the Clinical Trials Regulation (EU) No 536/2014, not all patient facing documents need to be submitted for Ethics Committee (EC) review.

Documents linked to trial endpoints must be submitted as part of **Part I** of the clinical trial application, alongside the protocol and in the same language as the Informed Consent Forms (ICFs). They will be assessed during the Part I review.

Other patient-facing documents not linked to trial endpoints should be submitted in **Part II**. Any document that might influence a participant's decision to join the trial must be reviewed by the EC to ensure compliance with ethical and transparency standards.

Examples of materials **not requiring** EC review:

- Insurance certificates in language of the patient
- Patient/trial ID cards
- Instructions for completing e-questionnaires
- Reimbursement tools (e.g., digital vouchers)
- Welcome or thank-you letters
- Dosing diaries and retention items like calendars or water bottles (unless considered compensation/incentives)

Sponsors are responsible for determining whether a document requires EC review and should carefully assess its purpose and impact on participants.

4. Join our new GDPR working group

To tackle key GDPR challenges, we are launching a new ad hoc working group. We are calling for members to join. Legal professionals are especially encouraged to participate and share their expertise.

The working group will focus on key action points, including:

- Developing advice on the legal grounds for processing personal data.
- Revising the confidentiality sections of the Informed Consent Form (ICF).

The working group will come to an end once the above action points are completed.

If you are interested in being part of this effort, please reach out to us at info@barec.be by 21feb2025. Your expertise can make a real difference to provide clear guidance on GDPR issues.

We look forward to your involvement!

5. BAREC Membership

We kindly invite you to join BAREC or renew your membership for 2025. The price for the ECs recognized under the law of 7 May 2017, is 450 euro and 300 euro for the other ECs.

Please make a payment to the following bank account number: BE35 0689 3066 7537
If you wish to receive an invoice, please let us know.

We look forward to having you all again on board in 2025!