BAREC ADVICE FOR HOSPITALS REGARDING THE GREEN LIGHT PROCEDURE

This opinion was approved by the College in plenary session on 10/10/2025.

BAREC has taken note of the College's letter dated December 1, 2023, concerning the internal "green light" procedures that some hospital institutions apply through their local ethics committee (EC). With this opinion, BAREC wishes to present its vision and recommendations on this matter.

We refer to Article 70 of the Law of July 10, 2008, relating to the coordinated law on hospitals and other healthcare institutions:

> *Art. 70 – To be accredited, each hospital must have a local ethics committee, it being understood that the King may define the conditions under which this committee may operate within the framework of a collaboration agreement between hospitals.*
> *The committee performs the following tasks when requested:*
> *1°) A role of support and advice concerning the ethical aspects of hospital care practices;*
> ***2°) A consultative function on all protocols involving experimentation on humans and human reproductive material.***
> *The tasks mentioned above may be specified by the King, after consultation with the National Council of Hospital Establishments.*
> *The King may, after consultation with the National Council of Hospital Establishments, set the conditions, rules, and procedures under which the task referred to in 2° must be carried out jointly by the ethics committees of several hospitals.*
> *The King shall determine, after consultation with the National Council of Hospital Establishments, the composition and functioning of the local ethics committee.*

BAREC understands that institutions wish to comply with the obligation mentioned in the above article and acknowledges their intention to inform their local ethics committee of ongoing or planned clinical studies. At the same time, BAREC emphasizes that the current legal framework — notably the Clinical Trials Regulation (CTR, EU No. 536/2014) and the Law of May 7, 2017, on clinical trials of medicinal products for human use — stipulates that in Belgium, the evaluation of clinical trials falls exclusively under an independent ethics committee.

BAREC also shares the College's concern that internal procedures within institutions must not result in delaying the effective evaluation or the start of a clinical trial.

Our recommendation to Belgian ethics committees and hospital institutions is therefore as follows:

- If an institution chooses to maintain or introduce an internal procedure, it must ensure that this procedure has **no delaying effect** on the implementation of a clinical trial.
- Local information or consultation meetings may be useful, but they must take place **in parallel with or prior to the legal submission**, and not as an additional condition after a favorable opinion and approval.

Through this opinion, BAREC aims to help establish a balance between transparency and efficiency.