

Recommendation of the College Board regarding pre-recruitment for phase I clinical trials

This advice was endorsed by the College Board during the meeting of 11/10/2024.

To keep the remarkable position of Belgium in high-quality early phase clinical research, **prerecruitment** is extremely important for Phase I studies as defined in art 3, 8° of the law of 7 May 2017 (including vaccine trials).

This prerecruitment is **not part** of the clinical trial under CTR¹. Therefore, the College considers that this can be evaluated under the law of 7 May 2004 by one of the ethics committees (ECs) recognized under the law of 7 May 2017. All documents used would be approved by the latter EC. All these documents should mention "*approved by the ethics committee of XXX (name EC) dd/mm/yyyy*". If new items are added to an approved document/template, this document must be re-approved.

For transparency reasons, the approval of that document by the EC should be added to the dossier submitted under CTR. This may help to assure the evaluating EC, assigned by the College, of the careful prerecruitment procedure: (1) does the prerecruitment take place before the study start under CTR as defined by the protocol and (2) have prerecruitment documents been evaluated under the law of 7 May 2004 .

As the prerecruitment documents are not part of the clinical trial under CTR, they should not be re-evaluated under CTR by the EC assigned by the College.

¹CTR: Clinical Trial Regulation, Regulation (EU) No 536/2014