Recruitment and informed consent procedure

How to use this document

This template should be used for specifying recruitment and informed consent procedures to fulfil the requirements of the CTR (Chapter V, Annex I K and L). The content of the template is mandatory for all clinical trials and it is therefore highly recommended to complete the template for all Member States concerned. If any of the items are also addressed in the protocol, reference may be made to the relevant section in the protocol (including the protocol version number).

National language requirements shall be taken into account when using the template.

This template has been developed and endorsed by the MedEthicsEU and the EU Clinical Trials Coordination and Advisory Group (CTAG) to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use.

EU clinical trial number	**Click or tap here to enter text.**
Full title of the clinical trial	**Click or tap here to enter text.**
Sponsor version/date of the document	**Click or tap here to enter text.**

1. Recruitment procedure *(Complete this section for all trials)*

1.1 **Specify how potential participants will be identified and if it involves access to identifiable information.** *(e.g. at the clinic/trial site, via referrals, publicising of the trial/advertisement, via access to identifiable information such as existing patient lists and medical records, or a combination of several methods)*

Click or tap here to enter text.

1.2 **Specify what the first act of recruitment is.** *(e.g. approaching potential participants at the clinic, recruitment letter, posting of advertisement. CTR, Annex I, K59)*

Click or tap here to enter text.

1.3 **If communication material (such as advertisement) is used for recruitment purposes, specify how the material will be used and why the material is necessary for recruiting the intended number of participants in this Member State.** *(Specify the format of the material, e.g. paper or electronic (digital form, AI tools, video and audio files), and how the*

material will be presented to potential participants e.g. via the post, in the clinic, through social media)

Click or tap here to enter text.

1.4 In case communication material (such as advertisement) is used for recruitment purposes, specify the procedures in place for handling responses to the advertisements, including arrangements for information or advice to respondents found not to be suitable for inclusion in the clinical trial. *(CTR, Annex I, K60)*

Click or tap here to enter text.

1.5 Specify who initially will be approaching potential participants regarding participation in the trial. *(Specify the professional role and whether there is a prior clinical relationship with potential participants and/or if there is an external service provider for pre-screening of potential participants in place)*

Click or tap here to enter text.

1.6 Specify any additional information that is of relevance to the Member State applicable rules on recruitment procedure, e.g. specific national requirements and legislation. *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.

2. Informed consent procedure *(Complete this section for all trials)*

2.1 Specify the procedure for providing potential participants (or their legally designated representative, if applicable) with sufficient details on the trial to ensure that they have understood the information and can provide an informed consent. *(Specify the various formats of information e.g. written, oral, video and if any information is given using decentralised methods. Specify who will provide the participant with the information (professional role, prior clinical relationship) and in what setting it is done. Specify how the interests and rights of the potential participants are safeguarded (e.g. right to withdraw, right to bring companion, privacy rights, time to consider participation))*

Click or tap here to enter text.

2.2 Specify the procedure for obtaining informed consent. *(Specify when and where informed consent will be obtained, how privacy will be ensured, the professional role of the person obtaining*

the informed consent, whether there is a prior clinical relationship with the potential participant, and if there are any decentralised elements)

Click or tap here to enter text.

2.3 Specify any additional information that is of relevance to the Member State applicable rules on informed consent procedure, e.g. specific national requirements and legislation. *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.

3. Recruitment and informed consent procedure for incapacitated adults

Does the clinical trial involve inclusion of incapacitated adults in the Member State? *(See article 31 in CTR for all conditions)*

☐ **Yes, please fill in the requested information in section 3.**

☐ **No, not applicable. Please continue with section 4.**

3.1 Specify how the potential participant will be involved in the decision to participate in the trial in a way that is adequate in view of their capacity. *(This should include how information will be tailored to ensure participants are able to understand the information.)*

Click or tap here to enter text.

3.2 Specify any additional information that is of relevance to the Member State applicable rules on the procedure for inclusion of incapacitated adults e.g. designation of the legal representative or other specific national requirements and legislation. *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.

4. Recruitment and informed consent procedure for minors

Does the clinical trial involve inclusion of minors in the Member State? *(See article 32 in CTR for all conditions)*

☐ **Yes, please fill in the requested information in section 4.**

☐ **No, not applicable. Please continue with section 5.**

4.1 **Specify how the potential minor participant will be involved in the informed consent and/or assent procedure.** *(Specify appropriate arrangements for obtaining and recording assent)*

Click or tap here to enter text.

4.2 **Specify who will obtain consent/assent from a minor participant.** *(Specify what kind of training and experience the members of the investigating team have in working with children)*

Click or tap here to enter text.

4.3 **Specify the procedure for obtaining informed consent when the participant reach the age of legal competence.** (*See Question 9.4 in CTR Q&A*)

Click or tap here to enter text.

4.4 **Specify any additional information that is of relevance to the Member State applicable rules on the procedure for inclusion of minors e.g. designation of the legal representative or other specific national requirements and legislation.** *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.

5. Recruitment and informed consent procedure where consent is witnessed by an impartial witness

Does the clinical trial involve a study population that might need consent witnessed by an impartial witness in the Member State? *(See article 29 in CTR and section 2.8.9. in ICH E6(R3) for all conditions)*

☐ **Yes, please fill in the requested information in section 5.**

☐ **No, not applicable. Please continue with section 6.**

5.1 **Specify why is it expected that an impartial witness might be required.**

Click or tap here to enter text.

5.2 **Specify how an impartial witness will be selected and the procedure for involving the impartial witness in the informed consent situation.**

Click or tap here to enter text.

5.3 **Specify any additional information that is of relevance to the Member State applicable rules on the procedure for clinical trials where consent witnessed by an impartial witness will occur e.g. specific national requirements and legislation.** *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.

6. Recruitment and informed consent procedure in an emergency situation

Does the clinical trial involve inclusion of participants in an emergency situation in the Member State? *(See article 34 in CTR for all conditions)*

☐ **Yes, please fill in the requested information in section 6.**

☐ **No, not applicable.**

6.1 **Specify why it would not be possible to obtain informed consent from potential participants or a legal representative prior to enrolment into the clinical trial.**

Click or tap here to enter text.

6.2 **Specify the arrangements in place for obtaining informed consent from the participant or from a legal representative, whichever can be obtained soonest.** *(Where a legal representative is expected to be required due to the participant not having capacity to consent, please also complete section 3 and 4 (if relevant) of this document)*

Click or tap here to enter text.

6.3 **If the participant regains capacity, specify how the informed consent will be obtained from the participant in situations where the legally designated representative initially provided the informed consent.**

Click or tap here to enter text.

6.4 **Specify any additional information that is of relevance to the Member State applicable rules on the procedure for inclusion of participants in emergency situations e.g. designation of the legal representative or other specific national requirements and legislation.** *(It is recommended that you refer to national law and/or legal guidance to ensure that all required information has been provided)*

Click or tap here to enter text.