

Recruitment and Informed consent procedure template

How to use this document

It is not mandatory to use this template for describing recruitment arrangements (Annex I K.59) and/or informed consent procedure (Annex I. L) but where this template is not used for this purpose, all the relevant information below should be included in the protocol as a minimum, according to Annex I (D.17.z). This is notwithstanding additional appropriate information also being included in the protocol.

Sections which are not appropriate should either be deleted or marked as Not Appropriate / NA.

This template has been developed and endorsed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use. However, this template is also relevant under Directive 2001/20/EC and may be used in advance of the Regulation applying.

1. All clinical trials (This section should be completed for all trials)

1.1	How will potential participants be identified? <i>(e.g. publicising the trial or via existing patient lists)</i>
The patients will be identified among the ones followed up by the site	
1.2	What resources will be used for recruitment? <i>(Describe the format of the resources, e.g. paper or electronic and how these will be presented to potential participants e.g. via the post, in the clinic, through social media or on the radio)</i>
No resources will be used, the study will be proposed during the visits at the site	
1.3	Will identification of potential participants involve access to identifiable information? If yes, describe what measures will be in place to confirm that access to this information will be lawful <i>(in accordance with Member State requirements)</i> .
The identifiable information will not be displayed outside the site-	
1.4	Who will be approaching potential participants and who will be obtaining informed consent? <i>(Describe the professional role and whether there is a prior clinical relationship with potential participants)</i>
The principal investigator and the other delegated physicians members of his staff will approach potential participant and obtain the informed consent	
1.5	When will free and informed consent be obtained? <i>(Describe when and where informed consent will be obtained and how privacy will be ensured)</i>

	Free and informed consent will be obtained in a study dedicated room, with the presence of PI or his delegate only at the site.
1.6	How long will potential participants (or their legal representative) be given to decide whether to participate?
	All the time they need.
1.7	How will it be assured that potential participants (or their legal representative) have understood the information and that consent is informed? <i>(This should include how the informational needs of individuals will be identified and addressed)</i>
	The potential participant can ask all the questions they want and obtain all the clarifications they need, moreover they can bring with them the study information and ask the opinion of their GP
1.8	What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak the national language?
	The presence of someone able to translate and explain the study to participant will be warranted.
1.9	How will it be ensured that participants can withdraw their consent at any point? <i>(This should include how any potential consequences of consent withdrawal will be dealt with)</i>
	Each patient will be informed that participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical treatment or relationship with the physician. In case of patient consent withdrawal, no further data will be collected. However, any previously collected data will be used for study analyses
1.10	Please provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere in this document. <i>(It is recommended that you refer to national guidance to ensure that all required information has been provided)</i>
	NA
1.11	In case this form is used also to describe recruitment arrangements (Annex I K59), please provide a clear indication of what the first act of recruitment is
	NA

2. Clinical trials which will recruit incapacitated adults

Incapacitated adults may be recruited into clinical trials only where consent has been obtained from a legally designated representative and data of a comparable validity cannot be obtained in clinical trials involving participants who are competent to give informed consent. Where potential participants do lack capacity to consent, arrangements should be in place to involve them as much as possible in the decision to participate in the clinical trial.

2.1	Provide justification for recruiting incapacitated adults <i>(This should include details of the nature of the condition which has caused the person to be incapacitated and the relevance of this condition to the clinical trial)</i>
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NA	
2.2	Who will assess and confirm whether a potential participant has the capacity to consent?
NA	
2.3	Where capacity to consent will fluctuate or will be borderline, how will potential participants be involved in the decision to participate in the trial? <i>(This should include how information will be tailored to ensure participants (potential and existing) are able to understand the information and also how participants who regain capacity will be consented to continue in the trial)</i>
NA	
2.4	How will a legal representative be identified? <i>(This should include which roles could act as legal representative for this trial)</i>
NA	

3. For clinical trials which will involve minors

Minors may be recruited into clinical trials only where consent has been obtained from a legally designated representative and where the clinical trial is such that it can only be carried out on minors. The minor should take part in the informed consent procedure as much as would be appropriate based on age and mental maturity. Where it would be appropriate, please specify any different arrangements for different age ranges.

3.1	Provide justification for recruiting minors
	<p>The onset of FDA occurs usually when patients are in their teenage and causes patients to be wheelchair bound approximately 10 years after diagnosis. The result is that the social costs for such disability are both direct, for the costs of physiotherapy and symptomatic drug management, but also indirect for their loss in productivity.</p> <p>The availability of an effective treatment able to halt or slow disease progression may be of immense value as it may help cut both healthcare and social costs of the disease. no approved therapy for FRDA exists</p>
3.2	How will potential participants be involved in the decision to participate in the trial? <i>(Describe arrangements for obtaining and recording assent, including who will be obtaining consent and details of their training and experience with children)</i>
	The patients will be identified among the ones followed up by the site, the study staff has great experience with minors affected by FDA
3.3	How will a legal representative be identified? <i>(This should include which roles could act as legal representative for this trial)</i>
	According to Italian law, the legal representative will be the parents or legal tutor
3.3	How will participants be consented to continue in the trial when they reach the age of legal competence?
	As soon as they turn 18, they will be consented with the adult informed consent.

4. Clinical trials where consent witnessed by an impartial witness will likely be used.

Where a participant is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. The witness is required to sign and date the informed consent document.

4.1	Why is it expected that an impartial witness might be required?
If the subject cannot read or sign the document, oral presentation may be made or signature be given an impartial witness, mentioning that the patient could not read or sign documents	
4.2	How will an impartial witness be identified?
The impartial witness will be a person of the hospital not involved in the study	
4.3	How will it be known that the potential participant gives their informed consent?
This will be documented by the impartial witness, moreover the potential participant will receive a copy of signed informed consent	

5. Clinical trials in an emergency situation

Information on the clinical trial may be given and informed consent may be obtained after the decision to include the participant in the clinical trial. This is where the decision is taken at the time of the first intervention in accordance with the protocol and, due to the urgency of the situation, the person is unable to give consent, nor can a legal representative be identified.

5.1	Describe why it would not be possible to obtain consent from potential participants or a legal representative prior to recruiting into the clinical trial.
NA	
5.2	What arrangements will be in place to obtain informed consent from the participant or from a legal representative, whichever can be obtained soonest? <i>(Where a legal representative is expected to be required due to the participant not having capacity to consent, please also complete section 2 of this document)</i>
NA	
5.3	How will it be ensured that a potential participant has not expressed any previous objection to participate in the clinical trial?
NA	

6. For 'cluster' clinical trials

Informed consent may be obtained by simplified means where this does not contradict national law, the methodology of the trial requires the randomisation of groups rather than individuals, the investigative medicinal product is being used in accordance with the terms of the marketing authorisation and there

are no interventions other than standard treatment. Clear justification for simplified consent should also be included in the protocol.

6.1	Describe how simplified informed consent will be obtained?
NA	

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