# Informed consent procedure template

## How to use this document

This document should be completed and submitted for all Clinical Trials of Medicinal Products (CTIMPs).

It may be submitted as a separate document or it may be copied into the protocol.

It is not mandatory to use this template but where this template is not used, all of the information below should be included in the protocol as a minimum. 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.

## For all clinical trials

|  |  |
| --- | --- |
| How will potential participants be identified and will this involve access to identifiable information? |  |
| How and by whom will potential participants be approached? |  |
| How long will participants be given to decide whether to take part? |  |

## For clinical trials which will involve incapacitated subjects

|  |  |
| --- | --- |
| Procedure to obtain consent from legal representative |  |
| Procedure to involve the subject in the consent process |  |

## For clinical trials which will involve minors

|  |  |
| --- | --- |
| Procedure to obtain consent from legal representative |  |
| Procedure to involve the subject |  |

## For clinical trials which require consent to be witnessed by an impartial witness

|  |  |
| --- | --- |
| The reason for using an impartial witness |  |
| The process for selection of an impartial witness |  |
| Procedure for obtaining consent |  |

## For clinical trials in emergency situation

|  |  |
| --- | --- |
| The procedure for obtaining consent of the subject or legally designated representative to continue in the trial |  |
| Description of the procedures to be followed to identify the urgency of the situation and how this will be documented |  |

## For ‘cluster’ clinical trials

|  |  |
| --- | --- |
| Describe the simplified means for obtaining informed consent |  |