

FPM-E-002-EN v3.0 30.03.2021

15-17 years old - Table of Contents for a Trial Information Sheet – template:

Appendix to the Informed Consent Form

PLEASE NOTE! This table of contents lists all possible sections in drug or device trials by category. In addition to the mandatory categories, the applicable categories should always be selected based on the study protocol

Table of contents by number	Category	Mandatory (X)
1. Title of the study, study ID, EudraCT number and protocol version	Heading	X
2. Invitation to participate – why invited?	Invitation to participate	X
3. The voluntary nature of participation and rights of subjects	Voluntary participation	X
4. Discussing the study with closest family members (before deciding)		
5. Research process	Research process	X
6. Study schedule, duration of the study and possible follow-up time		
7. Research methods, treatments and procedures, tests, examinations and other interventions	Methods and procedures	X
8. Ways to prevent and eliminate pain/unpleasantness/fear during the study (e.g. methods for pain alleviation)		
9. Methods to collect blood/other samples and compliance with minimum volume requirements for blood samples		
10. Possible adverse effects and risks expected in the study	Adverse effects and risks	X
11. Long-term effects/possible future effects (e.g. through pregnancies)		
12. How to prepare for study visits (e.g. laboratory tests that require fasting, diaries, etc. monitoring before visits). Need for contraception and/or barrier protection during the trial conduction	Preparation and needed actions	
13. Particular risks to be considered in the study methods and procedures; ionizing radiation, risks to the fetus, gene tests, tissue or biobank samples and similar	Special risks related to the methods	
14. Tasks for trial participants in line with the study protocol (diaries, surveys, use of electrical applications, etc.)	Tasks for trial participants	
15. Expected benefits of the study for study participants	Benefits	X
16. Withdrawing from the study	Withdrawal	X
17. The participant can decide to withdraw (you do not have to give a reason)		
18. The study can be terminated on medical grounds (e.g. following possible adverse effects; actions)		
19. Treatment after termination and continuation of treatment		
20. Description of the current treatment and alternative treatments	Current treatment and other alternatives	X
21. Special circumstances during the study (if possible / expected; acute emergencies / emancipated children and decision-making / childbirth / breastfeeding / other unexpected situations)	Special circumstances	
22. Investigational medicinal product and reference product(s) or placebo or medical device	Investigational medicine or device (description)	X
23. Information about the (medicinal) products used in the study as well as other possible reference products or devices		
24. Study design and its effect on the use of the investigational medicine and reference product as well as other medicinal products		

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25. Information about the study sponsor	Sponsor	X
26. Information about the organization(s) conducting the trial (all centers / sites) and the local study team	Study organization	X
27. Background, nature and purpose of the trial (medical background in case of a clinical medicinal product/device trial) 28. Extent of the trial (countries/centers) and number of trial subjects 29. Selection of trial subjects, requirements and suitability	Background and extent	X
30. Evaluation and review of the study protocol by independent authorities, approval and permission from ethical committee	Independent evaluation and authorization	X
31. Data protection in the trial 32. Protected confidentiality of trial information	Data protection - see a separate Appendix: Information leaflet on the processing of personal data	X
33. Collection of trial data / information and material (all sources), storage, use, further use (e.g. use of stored electronic data/samples for further studies, inside or outside the EU/EEA) 34. Extent of rights and rights of all beneficiaries, other parties and persons 35. Coding of information and storage of the code key 36. Data retention period and erasure 37. Controller 38. Right of access to one's own information and right of disclosure 39. Data protection officer	Collection, coding, use, storage, disclosure and erasure of data and right of access - see a separate Appendix: Information leaflet on the processing of personal data	X
40. Insurance cover for trial subjects 41. Patient insurance during the trial 42. Pharmaceutical injury insurance during the trial 43. Other possible additional cover	Insurance	X
44. Funding of the trial, costs and parties with financial responsibility	Funding of the study	X
45. The trial is free of charge (free medication and study visits) 46. Possible trial related costs to the study participant and their reimbursement, grounds for reimbursement (e.g. reimbursement for meal or travel costs) <i>Note: Rewards / incentives / financial inducements prior the trial are forbidden - it is possible to offer a gift of small value (e.g. stickers, movie tickets, etc.) as a thank you for participating after the end of the study.</i>	No costs and compensation	X
47. Termination of the trial and further care 48. Notification of study results (will the subject receive information about the study results related to themselves or not)	Termination, further care and informing of trial results	X
49. Further information and contact details of the study team	Further information and contact details	X
50. Ensuring that the information has been understood and possible further questions before signing	Ensuring accurate understanding	X
51. Instructions for signing (signature by the adolescent), informing the guardian of participation and receiving a copy of the consent	Signature and informing the guardian	X