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 <u>all</u> possible sections in drug or device trials by category. <u>In addition to the mandatory categories</u>, 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 4. Discussing the study with closest family members (before deciding)	**Voluntary participation**	**X**
5. Research process 6. Study schedule, duration of the study and possible follow-up time	**Research process**	**X**
7. Research methods, treatments and procedures, tests, examinations and other interventions 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	**Methods and procedures**	**X**
10. Possible adverse effects and risks expected in the study 11. Long-term effects/possible future effects (e.g. through pregnancies)	**Adverse effects and risks**	**X**
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 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	**Withdrawal**	**X**
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 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	**Investigational medicine or device (description)**	**X**

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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) *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.*	**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**

