innovative health initiative

HEU EFS
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

Harmonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion **(HEU-EFS)**

WP6 - Methodology development: ethical and legal aspects

DELIVERABLE 6.2

Set of templates for the EU EFS Programs – Informed Consent Form Checklist

COCIR efpia EuropaBio MedTech Europe Vaccines Europe

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Disclaimer:

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Informed Consent Form Checklist

*Please return the completed form to*_____[Entity/Office or Name and Surname and his/her qualify] *by e-mail* [*insert e-mail address or other like address, register electronic mail, website upload etc.*]

Relevant regulatory references a) **Required per Regulation (EU) 2017/745 on medical devices** b) **Required per International Organization for Standardization (ISO) 14155** c) **International Conference on Harmonisation's international guideline for Good Clinical Practice (ICH-GCP) guidance E6(R3)** d) **Helsinki declaration** *** Note: Some elements do not have a specific origin and therefore will not have a footnote, but are suggested by legal experts**

Part 1: General Information

Instructions: *Complete blank sections of Part 1 of this checklist. If any of the sections cannot be completed, please specify the reason.*

Study Title:	
Study Code:	
Study unique European Union (EU) identification number to be entered in EUDAMED *[When/If the CI/PS will be validated]*:	
Study approval date:	
Authority that authorised the study [ART. 71 MDR Authority of the Member State where the study is conducted, regardless of whether the study is conducted in several States]:	
Sponsor:	
Principal Investigator and Co-Investigator(s):	

Clinical site:	
Country and/or sub-country specific requirements (if any):	

Part 2: Specific Information

Instructions: *Check the appropriate box for each element within the Informed Consent Form (ICF). For any "No" or "NA" (not applicable) answers, please type a comment into the statement box as to the reason it is not included (i.e., does not apply to type of study or site declines to include).*

2.1. Preliminary information			
Y	**N**	**NA**	
□	□	□	The subject has been invited to participate in an early feasibility study (EFS) to evaluate [INSERT STUDY OBJECTIVE] of [INSERT NAME OF DEVICE]. Indicate that the device is being tested and has not yet been authorised [a) art 62; b) art. 5.8.1; b) art. 5.8.2; c) art. 2.5; c) art. 2.8.1; d) art. 9; d) art. 10; d) art. 11; d) art. 22].
□	□	□	The National Competent Authority and Ethics Committee have authorised the clinical use of this device in an EFS for a specific medical indication [a) art. 62; b) art. 5.8.1; b) art. 5.8.4; c) art. 2.8.1; d) art. 10; d) art. 23].
□	□	□	Declaration that all conditions for conducting the Clinical Investigation (CI) have been met [a) art. 62; art. b) 5.8.4; c) art. 2.8.1; d) art. 22].
□	□	□	Description of what this EFS entails [a) art. 62; art. b) 5.8.4; d) art. 22].
□	□	□	Name of the device and brief description in a language understandable to a lay user of the characteristics, intended purpose and medical conditions, mechanism of action, implantable or non-implantable, active or non-active, and indicate the risks class, innovative features with respect to the pathology/use on the patient in comparison with other medical devices already on the market [a) art. 62; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Description of the early feasibility study (including collection of biological samples) and indication that further information is available [indicate where] [a) art. 62; b) art. 5.8.2; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].

□	□	□	Indication that before deciding whether to participate in the early feasibility study, it is important to have, read and understood all the information including those given in the interview [a) art. 62; b) art, 5.8.1; b) art. 5.8.2; b) art. 5.8.4; c) art. 2.8.1; d) art. 26].
□	□	□	Date of the interview and name of the member(s) of the investigating team
□	□	□	Contact details of an organization from which further information can be obtained [a) art. 62; b) art. 5.8.2; c) art. 2.8.10; d) art. 26].
2.2. Participation and Research Statements			
□	□	□	Statement that participation is voluntary and confidential [a) art. 62; b) art. 5.8.5; c) art. 2.8.3; d) art. 25].
□	□	□	Statement that the study involves research [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	Explanation of the purposes of the research [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Expected duration of the subject's participation [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Description of the study procedures to be followed [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Approximate number of subjects and countries involved in the study [a) Annex XV, Chapter II, par. 3.6.3; art. b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Identification of all experimental procedures [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Statement that the subject has been informed that a clinical study report and a summary presented in terms understandable to the intended user (lay summaries) will be made available in the electronic system for clinical investigations, regardless of the outcome of the clinical study, and that the subject has been informed, to the extent possible, of when the clinical study report and summary will be available [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 35; d) art. 36].
□	□	□	Circumstances in which the subject's participation may be discontinued by the investigator or sponsor without regard to the subject's consent (e.g., for medical reasons) [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Indication that the subject may withdraw from clinical study at any time, without any prejudice and without having to provide any justification, by revoking consent without any formal requirements [a) art. 63; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].

□	□	□	Information about criteria and procedures for follow-up of subjects following the end (e.g. treatment available at the end of the study), temporary halt or early termination of an study, for follow-up of subjects who have withdrawn their consent and procedures; for subjects lost to follow-up. Such procedures shall for implantable devices, such procedures should cover as a minimum traceability [a) Annex XV, Chapter II, par. 3.15; b) art. 5.8.5; c) art. 2.9.1; d) art. 26].
□	□	□	Indication of any consequences of a subject's decision to withdraw from the research and procedures for communicating the termination of the trial and revoking informed consent (e.g., notification to the member(s) of the investigating team study doctor) [a) art. 63 b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	Statement that significant new findings developed during the research, including the reasons for any changes to the protocol, which may affect the subject's willingness to continue participating, will be provided to the subject or his or her legally recognized representative in a timely manner [b) art. 5.8.5; c) art. 2.8.2; c) art. 2.8.10; d) art. 26].
□	□	□	If new information becomes available that can significantly affect a subject's future health and medical care, that information shall be provided to the affected subject(s) in written form. If relevant, all affected subjects shall be asked to confirm their continuing informed consent in writing [b) art. 5.8.6; c) art. 2.8.6; d) art. 26].
□	□	□	Statement that the subject does not give up legal rights by signing the consent [b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled [a) art. 63; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	Statement that the preliminary interview with healthcare professional of the investigating team(s) takes place before the informed consent is given [a) art. 63; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	Statement that the subject had sufficient time to consider their participation after interview [a) art. 63; b) art. 5.8.5; c) art. 2.8.6; d) art. 26].
□	□	□	Statement that the healthcare professional provided providing the information must be part of the trial team and be adequately qualified in accordance with national law [a) art. 63; b) art. 5.8.4; c) art. 2.7.1; d) art. 26].
□	□	□	Statement that the subject during the interview has fully understood the information received from the member(s) of the investigating team doctor and has received any

			information leaflets and instructions on how to contact the member(s) of the investigating team doctors if they have any questions as described in section 2.5, and as written in the ICF [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.7; d) art. 26].
□	□	□	Statement that the subject undertakes to follow medical protocols.
2.3. Risks, Benefits or Alternative Procedures			
Y	**N**	**NA**	
□	□	□	Description of any reasonably foreseeable risks, anticipated adverse device effects, inconveniences or discomforts to the subject [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26]. .
□	□	□	Statement that participation in the study may involve risks to the subject which are currently unforeseeable, [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Declaration that clinical study includes devices that have never been used on humans or indicate history implementation and overall collected results
□	□	□	Description of risks associated with the clinical procedures required by the protocol that may be different to standard practice [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Description of any clinical benefits to the participant due to the device in comparison with standard of care (if any); if no direct benefits anticipated, this should be stated [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Disclosure of appropriate alternative procedures or courses of treatment that may be available to the subject and their potential benefits and risks and inconveniences [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
2.4 Device/Comparator Description and Randomization			
Y	**N**	**NA**	
□	□	□	Description of the trial treatment(s), including any comparison groups, and the method of assignment, if any, to each treatment. Also explain how patients are allocated to the experimental arm or the control/comparator arm, or placebo (if applicable). [a) Annex XV; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Description of the procedure, investigational device and comparator, if any [a) Annex XV; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
2.5 Contact details			

Y	N	NA	
□	□	□	Contact details for questions about the research, participant rights, or how to find each document [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Who to contact in the event of a research related injury to the subject [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	Who to contact in emergency case [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].

2.6. Payment/Reimbursement or Costs to Subject

Y	N	NA	
□	□	□	The anticipated payment/reimbursement, if any, to the subject for participation in the trial. Note: The anticipated payment/reimbursement language will need to be aligned with language in the Master Clinical Trial Agreement (MCTA) [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 15; d) art. 26].
□	□	□	Any additional costs to the subject that may result from participation in the research. [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 15; d) art. 26].

2.7. Damages Compensation System (insurance)

Y	N	NA	
□	□	□	Explanation of the compensation system in the event of injuries related to the study or procedure, and what it consists of, or where further information can be obtained [a) Annex XV, par. 3.16; b) art. 5.8.4; c) art. 2.8.10; d) art. 15; d) art. 22].
□	□	□	Explanation of the medical care and activities provided by the facility in the event of injuries related to the study or procedure, and what they consist of, and what they consist of, or where further information can be obtained.
□	□	□	Indication of the insurance contract taken out by the investigator/sponsor and indication of the types of damage covered by the insurance contract, indication of the maximum coverage limits [a) art. 69 – Annex XV, Chapter II, par. 4.3; b) art. 5.8.4; c) art. 2.8.10; d) art. 15; d) art. 22].

2.8 Signature Section			
Y	**N**	**NA**	
□	□	□	Voluntary agreement to participate in the clinical study and follow the investigator's instructions [a) art. 63; b) art. 5.8.5; c) art. 2.8.3; d) art. 25].
□	□	□	Declaration that the subject has not received any undue influence, including financial influence, to participate in the clinical study (except for compensation for expenses and lost earnings directly related to participation in the clinical study) [a) art. 63; b) art. 5.8.4; c) art. 2.8.3; d) art. 25; d) art. 26].
□	□	□	A statement declaring that refusal of participation incurs no penalty for the subject and no loss of benefits to which the subject is otherwise entitled and a statement declaring that discontinuation/withdrawal and thereby revoking the informed consent at any time incurs no penalty for the subject [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	A statement with regard to the possible consequences of withdrawal [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 26].
□	□	□	A statement confirming that the subject agrees to the use of the subject's relevant personal data for the purpose of the clinical study [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 24].
□	□	□	A statement confirming that the subject agrees that sponsor's representatives, regulatory authorities and Ethics Committee (EC) representatives will be granted direct access to the subject's medical records [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.1; c) art. 2.8.10; d) art. 24; d) art. 36].
□	□	□	Investigator signature and date with statement that the investigator has explained the study to the subject and answered their questions [a) art. 62; b) art. 5.8.4; c) art. 2.8.7; d) art. 26].
□	□	□	Subject signature and date and statement that the consent has been explained to the subject, questions answered, and the subject understands the study and acknowledges the information provided during the informed consent process and has had ample time to consider participation [a) art. 62; b) art. 5.8.5; c) art. 2.8.7; d) art. 26].
□	□	□	A statement that authorized representatives of the institution, the regulatory authority(ies), and the study sponsor and its representatives will be granted direct

2.8 Signature Section			
Y	**N**	**NA**	
			access to the subject's original medical records for verification of clinical investigation procedures and/or data [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 26].
□	□	□	A statement that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential [a) art. 63; b) art. 5.8.4; c) art. 2.8.10; d) art. 24].
□	□	□	Declaration that the subject has been informed that a clinical study report and a summary presented in terms understandable to the intended user will be made available in the electronic system for clinical studies, regardless of the outcome of the clinical study. [a) art. 63; b) art. 5.8.4 c) art. 2.8.10; d) art. 24; d) art. 35; d) art. 36].
□	□	□	Declaration that the subject has been informed, to the extent possible, of when the clinical study report and summary will be available [a) art. 63; b) art. 5.8.4 c) art. 2.8.10; d) art. 24; d) art. 35; d) art. 36].
□	□	□	Declaration that the participant undertakes to inform the investigating team about any changes related to their health status subsequent to the ICF signature (e.g. pregnancy).
□	□	□	Declaration that the study subject has been informed about the processing of all their personal data and its use in the clinical investigation and that they have received the privacy policy form in clear and understandable language and therefore authorize the processing of their personal data and their dissemination for research purposes [a) art. 63; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 24]. PFA Annex.
□	□	□	Declaration that the subject will receive a signed and dated copy of the consent [a) art. 63].
2.9 Country and/or sub-country specific requirements (if any):			
Y	**N**	**NA**	
□	□	□	

Part 3: Specific Information for frail participants

Instructions: *Check the appropriate box for each element within the ICF only for the specific frail participant. For any "No" or "NA" answers, please type a comment into the statement box as to the reason it is not included (i.e., does not apply to type of study or site declines to include).*

3.1. Subject unable to write [a) art. 63; b) art. 5.8.3.3; c) art. 2.8.8; c) art. 2.8.9; c) art. 2.8.13; d) art. 27; d) art. 28; d) art. 29]			
Y	**N**	**NA**	
□	□	□	Indication of the impartial witness.
□	□	□	Indication of the method of obtaining consent.
□	□	□	Date and signature of the witness.
□	□	□	Recording of the conversation in which consent is obtained.
□	□	□	Indicate the date on which a copy of the consent was provided.
□	□	□	Indicate the date on which a copy of the recording of the conversation in which consent was obtained was provided.
3.2. Incapacitated subjects [a) art. 64; b) art. 5.8.3.2; c) art. 2.8.8; c) art. 2.8.13; d) art. 30]			
Y	**N**	**NA**	
□	□	□	Indication of a legal representative who signs the ICF on their behalf.
□	□	□	Declaration by the legal representative that the incapacitated person has received the information in a manner appropriate to their ability to understand it
□	□	□	Declaration by the legal representative that He or She has been informed that data of comparable validity cannot be obtained from clinical studies involving persons capable of giving informed consent or by other research methods.
□	□	□	Declaration by the legal representative that He or She is aware that the clinical study is directly related to a clinical condition from which the subject suffers and that there are scientific reasons to believe that participation in the clinical study will result in a direct benefit to the incapacitated subject that outweighs the risks and burdens involved.
□	□	□	Declaration by the legal representative that the incapacitated subject participated as much as possible in the informed consent process.

□	□	□	Declaration by the legal representative that no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical study.
□	□	□	Attach to the informed consent the legal declaration of the representative that they have the power of representation and, where necessary, an official document from the authority.
□ 3.3 Minors [a) art. 65; b) art. 5.8.3.2; c) art. 2.8.12; d) art. 28; d) art. 29; d) art. 30]			
Y	**N**	**NA**	
□	□	□	Declarations by the representative that minors have received the information referred to standard ICF in a form appropriate to their age and intellectual maturity from the investigators or members of the investigation team who are qualified or experienced in dealing with minors.
□	□	□	Declarations by the representative that He or She is aware that the clinical study is intended to study treatments for a medical condition that affects only minors, or that the clinical study is essential in relation to minors in order to validate data obtained from clinical studies on persons capable of giving informed consent or obtained by other research methods.
□	□	□	Declarations by the representative that He or She is aware that the clinical study is directly related to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors.
			Declarations by the representative that He or She is aware that there are scientific reasons to believe that participation in the clinical study will result in a direct benefit to the minor that outweighs the risks and burdens involved.
□	□	□	Declarations by the representative that the minor has participated in the informed consent procedure in a manner appropriate to his or her age and intellectual maturity.
□	□	□	Information that if the minor reaches the age of majority during the clinical study, his or her direct informed consent must be obtained in addition to that of the legal representative according to national law.

3.4 Pregnancy - Pregnant or breastfeeding women [a) art. 66; b) art. 5.8.4; c) art. 2.8.10; d) art. 28; d) art. 29]			
Y	**N**	**NA**	
□	□	□	Declaration by the subject that they are aware that the clinical study may potentially result in direct benefits to the pregnant or breastfeeding woman concerned, or to the embryo, fetus or newborn, that outweigh the risks and burdens involved.
□	□	□	Statement that the participation in the study may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
□	□	□	Indication of the reasonably foreseeable risks or inconveniences, when applicable, to an embryo, fetus, or nursing infant.
3.5 Country and/or sub-country specific requirements (if any):			
Y	**N**	**NA**	
□	□	□	

Part 4: Annex

4.1. Privacy consent [a) art. 63, Annex XV, Chapter II, 4.5; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 24] EU REGULATION 2016/679 (GDPR)			
Y	**N**	**NA**	
□	□	□	Consent to the processing of personal data, with particular reference to the fact that, as this is an EFS, the data will be used for research purposes.
□	□	□	Study participants need to be informed about what personal data is being collected, how it is used, and with whom it is shared/who has access to that data, storage of data and duration of storage, etc.
□	□	□	The participants can grant 'blanket permission' to their data for specific types of research (if applicable), apart from the permission given to the specific clinical study, and how they can withdraw consent in such cases or if they can opt out of specific further uses of their data.

4.1. Privacy consent [a) art. 63, Annex XV, Chapter II, 4.5; b) art. 5.8.4; b) art. 5.8.5; c) art. 2.8.10; d) art. 24] EU REGULATION 2016/679 (GDPR)			
			Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular: • organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed; • a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects; and; • a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

Form completed by	
Professional qualification	
Optional comments	
Editing date	
Signature	

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