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 Template

Co-funded by the European Union

Disclaimer:

The Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project is funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the parties can be held responsible for them.

Project Acronym	HEU-EFS
Project Title	Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union
Project Coordinator	Giuditta Callea giuditta.callea@unibocconi.it
Grant Agreement Number	101112185
Project Duration	October 2023 – October 2027 (48 months)
Deliverable Number	D6.2
Work Package	6
Task	6.1
Lead Beneficiary	UB
Status	Completed
Dissemination Level	PU
Type	Other – Template, report
Due Date of Deliverable	30-09-2025
Actual Submission Date	10-10-2025
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File History				
Version	**Date**	**Status**	**Author**	**Review**
1.0	23-09-2025	V1.0	Diana Panzica (UB).	Giuditta Callea, Francesco Malandrini, Niccolò Palminteri

				Matteucci (UB), Irene Gonzalez (Edwards Lifesciences),
2.0	06-10-2025	V2.0	Diana Panzica, Francesco Malandrini (UB).	Majella Geraghty (TCD), Marta Kerstan (JnJ), Carmen Furno, Arianna Salvatori (GEMELLI FPG), Ornella Tangila Kayembe (APHP), Yasemin Zeisl (EPF), Marta Bragagnolo (GHH), Antonio Balsamo (AGENAS), Adrian Valledor (FCRB), Silvia Busoli Badiale (IMQ), Donal O'Connor, Gearóid O'Connor (HPRA), Piotr Szymanski (ESC).
3.0	10-10-2025	V3.0	Diana Panzica, Francesco Malandrini (UB), Irene Gonzalez (Edwards Lifesciences)	

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Informed Consent Form for Early Feasibility Study – Template

Part 1 General Information

Study title:
Study title in terms that are more understandable for the patient [*use common, non-technical terms: for example, explain the usefulness of the device being studied*]
Study Code:
Study unique EU identification number to be entered in EUDAMED database *[When/If the CI/PS will be validated]:*
Study approval date:
Authority that authorised the study: [*indication of the authority of the Member State in which the study is conducted, regardless of whether the study is conducted in several states*]
Study Sponsor:
Principal Investigator Name:
Co-Investigators Name:
Clinic Site:
Country and/or sub-country specific requirements (if any):

Dear Madam/Sir,

We invite you to participate in the clinical investigation, which we will explain below.

The following information sheet contains important details about this clinical investigation. Please take your time to read it carefully and discuss it with a member of the research team before you decide whether or not to take part *We kindly ask that you consider whether to participate in the clinical investigation ONLY after carefully and thoroughly reading this information sheet and having a IN-DEPTH DISCUSSION with a member of the research team, who will devote the NECESSARY TIME to ensure that you (or your Legal* Representative) *fully understand what is being proposed to you.* Our team [Insert contact details] will be happy to spend as much time as you need to help you fully understand what the study involves.

You have the right to be well informed about the purpose and characteristics of the clinical investigation so that you can make an informed and free decision about whether to participate.

The purpose of this document is to inform you about the nature of the clinical investigation, its purpose, and what participation will entail for you, including your rights and responsibilities.

We invite you to read the following carefully. The researchers involved in this project, listed at the beginning of this document, are available to answer your questions. No question you may have is trivial: do not be afraid to ask!

In addition to speaking with the clinical staff at the study site you may discuss this study and the information contained in this document with your family doctor, your family members, and other people you trust. Take all the time you need to decide. You are welcome to take home an unsigned copy of this document to think about or discuss with others before making your decision.

If you decide not to participate in the clinical investigation, you will still receive the best possible care for your condition/illness. Your refusal will in no way be interpreted as a lack of trust.

If applicable*:*

*To help you better understand this document, the clinical site [*indicate name*] provides a cultural mediator who can communicate the contents to you in the language and manner that is most convenient for you.*

If applicable*:*

If you are unable to write the informed consent form, you can provide and record your consent through appropriate alternative means, such as audio or video recordings, in the presence of at least one impartial witness. In cases where it is not possible to make an audio/video recording, the impartial witness will must personally sign and date the informed consent statement after the form itself and any other written information have been read and explained to you, and after you have verbally expressed your consent to participate in the study.

Once you have read this form, received answers to any questions you may have, and decided to participate in the clinical investigation, you or your legally independent designated representative will be asked to sign a consent form, a hard copy of which will be given to you.

The Principal Investigator

Part 2 Specific Information

This section aims to provide a summary of the key aspects of the clinical investigation we are inviting you to participate in. The following sections will provide more details so that you can give your fully informed consent to participate in the clinical investigation.

*

2.1. Preliminary information

You have been invited to participate in an early feasibility study to evaluate [*INSERT STUDY OBJECTIVE*] using the following medical device [*INDICATE NAME OF DEVICE*].

The device under clinical investigation is currently being tested [*specify how e.g preclinical tests or first in human*] and has not yet been placed on the market. This study will help us learn more about its safety and how well it works for this purpose.

-Why am I being asked to participate in this clinical investigation?

You are being invited to participate in a clinical investigation funded by [*indicate who is funding the clinical investigation*] because you have [*indicate medical condition*]/are at high risk of [*indicate risk*]. *[Provide information on the rationale for the study, where the device fits within the available therapeutic options, the reason the participant is being asked to participate, the medical condition, specific risk, clinical characteristics etc.].*

You have been included among those asked to participate in this clinical investigation because you have certain clinical characteristics, in particular [*indicate patient characteristics*].

The National Competent Authority and Ethics Committee has authorised the clinical use of this device in an early feasibility study for [*specify medical indication*], as all the conditions for conducting the clinical investigation have been met. If applicable you have undergone a clinical investigation involving emergency treatment [indicate the reasons for the emergency treatment and the impossibility of obtaining consent prior to treatment].

-***What is an early feasibility study?***

[*detailed but clear description of the early feasibility study*] *for e.g. ISO* 14155:2020 *description:* A limited clinical investigation of a device early in development, typically before the device design has

been finalized, for a specific indication (e.g. innovative device for a new or established intended use, marketed device for a novel clinical application). It can be used to evaluate the device design concept with respect to initial clinical safety and device clinical performance or effectiveness (if appropriate) as per intended use in a small number of subjects when this information cannot practically be provided through additional nonclinical assessments or appropriate nonclinical tests are unavailable].

-What is the medical device [indicate name] used for?

The medical device [*indicate name*] is used for [*insert a brief description in 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 risk class, innovative features with respect to the pathology/use on the patient* in comparison with other medical devices already on the market].

-***What are the objectives of the early feasibility study?***

The clinical investigation is being conducted to answer the following question: [*insert a brief question that summarises the primary objective of the clinical investigation in simple and understandable terms*] and [*Indicate the secondary objective(s) (if any)*].

Further information can be found at: [*indicate where*]

-What should I do before making a decision?

Before deciding whether or not to participate, it is important to read and understand all the information, including the information provided on [*insert date of interview*] by [*indicate the name of the research team member who conducted the interview*]. If you have any doubts or questions, please contact a member of the research team [*indicate contacts details*].

-***Who can I contact for further information?***

For further information, please contact: [*indicate the contact details of the organisation from which further information can be obtained*].

*

2.2. Participation and Research Information

-Is it my free choice whether or not to participate?

You are free to choose whether or not to participate in the early feasibility study. Participation is free, confidential and voluntary, and even after you have agreed to participate, you can change your mind at any time - even during the study.

If you choose not to take part—or if you decide to stop later—this will not affect the quality of your care or your relationship with your doctors in any way.

-What is the routine care approach for treating the disease* (specify the disease)*?

[*Describe the standard care approach (if any) or the use of other devices in a concise and clear manner*]

-What is the clinical investigation approach?

[*Describe the clinical investigation care approach in a concise and clear manner and specify explicitly that it is research and provide a detailed explanation of the purpose of the research*]

-If I decide not to give my consent to participate in the clinical investigation, what options do I have?

If you decide not to participate in the clinical investigation, you will still receive monitoring and treatment from the clinical centre caring for you, using the best approved (non-experimental) therapeutic methods for your condition and you will still receive the best possible care for your condition from your medical team. Your decision not to participate will not affect the quality of your care or your relationship with your healthcare providers in any way.

You may also participate in another trial or clinical investigation that may be underway.

-What happens if I decide to participate in the early feasibility study?

If you decide to participate in the clinical investigation, you will be [*Indicate use of the device*]. Once the treatment is complete, you will be monitored for up to [*Indicate number of weeks/months/years*]. The total duration of your participation may be up to [*Indicate the period (months or years) of time during which the patient will receive treatment and surgery or will be monitored*]. The planned duration of the study is *[X] year(s*), and your participation will last *[X days/months/years].* The duration of the study may be extended if the required number of patients has not yet been reached; however, the length of your participation will remain unchanged.

Before taking part in the clinical investigation, your doctor asked you to undergo some tests [*If possible, specify the type of tests*] and verified that you meet the requirements to participate. During the clinical investigation, there might be scheduled invasive procedures (e.g., biopsies, bone marrow sampling, etc.), which are described in more detail below. In addition, you will also receive aa Checklist for patients and caregivers which includes information on: what to prepare before your hospital visit or procedure; what to monitor at home, and which symptoms or situations you should report right away (critical symptoms). The entire schedule of visits and tests planned during the clinical investigation is described in the following section, "*What tests, examinations and procedures are planned for the clinical investigation?".*

*-**Early feasibility study outline***

[*The use of a schematic graphic representation of the clinical investigation is strongly recommended. If comprehensive, it can replace all or part of the written text. The outline should not be a duplicate of the clinical investigation protocol but should provide the most relevant information to potential participants, using simple and easily understandable language*].

-What will my commitment and responsibilities be if I decide to participate?

Provide information on the participant's responsibilities, in particular:

• Strictly follow the instructions and requests of the healthcare personnel conducting the clinical investigation and ensure attendance at appointments.

• Inform the doctor overseeing the clinical investigation:

- of all medications you are taking, including non-conventional medicines, other medical devices or other products,

- of any side effects that arise during the clinical investigation,

- of any visits or hospitalisations in facilities other than the trial centre,

- of your current or past participation in other clinical investigations.

• List all medicines and supplements you use — including herbal or alternative products.

• List all pathologies ad possible pathologies.

• (Where appropriate) Record in the diary every time the medical device is used at home.

• (For women, where appropriate): Avoid pregnancy or breastfeeding during the clinical investigation. If you are able to become pregnant, you will need to use reliable contraception during the clinical investigation and should not become pregnant or breastfeed while taking part. This is because the possible effects of the study treatment or device on an unborn baby or breastfeeding infant are not yet known. Please talk to your doctor or a member of the research team about contraception before joining the study.

• (For men, where appropriate): Avoid conceiving a child during the clinical investigation. If you are able to father a child, you will need to use reliable contraception during the clinical investigation and should avoid fathering a child during this time. If you have any questions, discuss them with your doctor or the study team. Suggest to define "reliable contraception" and add in the provisio If you are unsure which method is best for you, please talk with your doctor or a member of the research team before starting the study. They can help you choose the safest and most suitable option for your situation.

• (For all, where appropriate): inform your doctor promptly if you or your partner think you may be pregnant during the clinical investigation or within (insert period in months/years) of last using the medical device under clinical investigation (specify).

-What examinations, tests and procedures are planned if I participate in the early feasibility study?

This section should clearly describe to potential participants what will change in their care if they agree to join the clinical investigation. The information must be concise, consistent with the clinical investigation protocol, and written in language that is easy for lay readers to understand.

- **Highlight only study-specific procedures.**
    - Describe only those examinations, tests, or procedures that are required *specifically* for the clinical investigation.

  - Do not include standard-of-care procedures that would occur regardless of participation.
- **Describe visit frequency and duration.**
  - Indicate how often participants will attend visits and the expected length of each visit.
  - Provide the total expected duration of participation in the study.
- **Summarise key examinations and procedures.**
  - Briefly describe each in plain language.
  - Specify which are invasive (e.g., biopsies, bone marrow sampling) and note that specific consent will be obtained before such procedures.
- **Clarify participant group differences.**
  - Indicate if any tests or procedures apply only to certain participant groups.
- **Include logistical and recovery information.**
  - Estimate the duration of hospitalisation or intensive care (if applicable).
  - Outline ward care, observation periods, and follow-up visits.
  - Provide guidance for home recovery, including typical recovery time, what to monitor, lifestyle restrictions, and warning signs that require immediate medical attention.
- **Note concomitant treatments and restrictions.**
  - Identify medications or therapies that must be continued or avoided.
  - Include relevant restrictions (e.g., MRI compatibility, exercise, driving, or travel).
- **Address social and daily life considerations.**
  - Mention any foreseeable impact on daily activities such as work or travel.
  - Note any potential need for re-interventions, replacements, or device removals.
- **Attach a study calendar.**
  - A visual calendar or schematic timeline is strongly recommended to show the sequence of visits and procedures.
  - It may replace or supplement text as long as it clearly conveys the study schedule.

Ensure all information aligns with the authorised clinical investigation protocol and the informed consent form.

[*In this section, it is important to highlight to potential participants what will change in the care provided if they decide to participate in the clinical investigation.*

- Indicate the frequency and duration of each visit and include a brief and simple description of the types of examinations planned in the clinical investigation protocol.

- Do not list examinations, tests or procedures that are part of the usual care approach.

- Focus on examinations, tests and procedures that are mandatory for the main clinical investigation.

- Indicate whether specific examinations, tests or procedures will only be performed in some of the patient groups.

Ensure that the information provided in this section is consistent with the information provided in the clinical investigation protocol and other sections of the consent form.

For each individual examination or invasive procedure included in the clinical investigation, specific consent will be obtained at the time of the medical procedure.

To facilitate patient participation, it is recommended that a calendar be attached to the consent form. Indicate, further, estimated duration in intensive care (if applicable) and expected number of ward care days and observation periods. Guidance on follow-up outpatient visits. Indicate home Observation / Recovery (typical recovery timeline at home, recommended monitoring, lifestyle adaptations, or warning signs requiring immediate attention); Concomitant medications or treatments required; Duration and adherence requirements; Medical restrictions (e.g., MRI compatibility, exercise limitations), Social and daily activity considerations (e.g., driving, work, travel), Possible re-interventions, replacements, or removal scenarios].

-How many centres and patients will take part in the clinical investigation?

The clinical investigation is expected to take place in approximately [*indicate number*] centres in [*indicate number*] countries and include [*indicate number*] patients.

-How can I follow the results of the research?

A clinical investigation report and a summary presented in terms understandable to the intended user (lay summary) will be made available in the electronic system for clinical investigations, regardless of the outcome of the clinical investigation, and the clinical investigation report and summary will be available [*indicate, as far as possible, when*].

-Is consent final? Can I decide to withdraw from the clinical investigation (voluntary withdrawal)?

You can decide to withdraw from the clinical investigation at any time and for any reason, without having to provide any justification and without any formalities such as administrative procedures.

If you decide to no longer participate, please let one of the clinical investigation doctors know as soon as possible: it is important to stop the treatment safely. The doctor may consider a final check-up/examination to be appropriate.

During your participation, the doctor will promptly inform you of any changes in the clinical investigation and any significant new findings that emerge during the research, including the reasons for any changes to the protocol that may affect your decision to continue participating in the clinical investigation.

In addition, if new information becomes available that may significantly affect your health and future medical care, it will be provided to you in writing, and you will be asked to confirm your consent to participate in writing.

If you are unable to provide written consent, your agreement can be recorded in another suitable way — for example, through an audio or video recording made in the presence of an impartial witness.

In any case, your refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled.

-When do I have to give my consent to participate?

You may decide whether to give your consent after the preliminary interview with the healthcare professional from the research team and after you have had sufficient time to consider your participation following this interview. The healthcare professional with whom you will have/have had the interview is part of the clinical investigation team and is suitably qualified in accordance with national legislation.

In any case, by giving your consent to participate, you will not be waving any rights.

-Are there reasons why the clinical investigation could be interrupted against my will (suspension or early termination)?

Yes. The principal investigator may decide to stop your participation in the clinical investigation if it is in your best medical interest or for safety reasons.

For example, this may happen if:

Yes, the principal investigator or co-investigators may decide to terminate your participation in the clinical investigation if:

- Your health condition changes and participation in the clinical investigation could be potentially harmful;
- New information becomes available and it may no longer be safe or advisable for you to continue in the clinical investigation;
- You do not follow the agreed rules for participation in the clinical investigation;
- **For women:** you become pregnant during the clinical investigation — in this case, participation in the study treatment would usually stop to protect you and your baby, but your health will continue to be monitored; For men: in case of partner becomes pregnant during the clinical investigation
- The clinical investigation is interrupted by the National Competent Authorities or the sponsor.

[*In any case, explain the need/opportunity to continue the planned follow-up visits in the event of withdrawal of consent, suspension of the clinical investigation, pregnancy or other circumstances. Also indicate information on the criteria and procedures for follow-up of subjects at the end of the study (e.g., treatment available at the end of the study), in the event of temporary suspension or early*

termination of the study, for follow-up of subjects who have withdrawn their consent, and procedures for subjects lost to follow-up. These procedures must cover at least traceability].

Clearly explain the need or opportunity for participants to continue scheduled follow-up visits in situations such as withdrawal of consent, suspension of the clinical investigation, pregnancy, or other relevant circumstances.

Include information on:

- **End-of-study follow-up:** Define the criteria and procedures for follow-up of participants once the study concludes (e.g., ongoing treatment options, transition to standard care).
- **Temporary suspension or early termination:** Describe the process for participant communication, safety monitoring, and continued medical oversight if the study is paused or terminated early.
- **Withdrawal of consent:** Specify how participants who withdraw consent will be managed, including any voluntary medical assessments or safety follow-up that may be offered.
- **Participants lost to follow-up:** Outline the steps to ensure traceability and appropriate documentation of participants who are lost to follow-up.

These procedures must ensure participant safety, data integrity, and traceability in accordance with ISO 14155 and applicable regulatory requirements.

*

2.3. Risks, benefits or alternative procedures information

- What are the risks and benefits of participating in the clinical investigation?

Participating in this clinical investigation may involve both benefits and risks. It is important to carefully weigh these before making a decision. In addition, there may be additional risks beyond those described that are currently unforeseeable.

-Expected benefits

[*Describe the expected benefits clearly and concisely, referring, depending on the type of clinical investigation, to 1) benefits for the patient participating in the clinical investigation; 2) benefits for future patients and for the acquisition of greater knowledge. Describe the benefits according to the phase of the clinical investigation. Indicate the clinical benefits of the device under investigation compared to the standard of care (if any) and indicate if no direct benefits are expected. If no/negligible benefits to the individual participants in the study have been identified*].

-Potential risks and inconveniences

We want to make sure you understand some of the possible risks right away: additional information can be found in the next section, *"What risks might I face if I participate in this clinical investigation?*". [*Describe the risks in general terms*].

You will be closely monitored for each of these reactions. However, not all adverse reactions that may occur are known. You will be closely monitored throughout the study for any signs of these reactions or side effects. However, it is important to understand that not all risks or adverse reactions are currently known.

The important adverse reactions known for the experimental treatment are: [*Indicate known reactions and adverse event*]

Indicate that: The clinical investigation includes devices that have never been used on humans or Indicate History implementation and overall collected results

The device being tested will also be associated with other products (e.g. drugs) already on the market that may cause [*brief summary description*].

-What risks might I face if I participate in the clinical investigation?

[*Describe all reasonably foreseeable risks, including those related to the device under investigation, drugs used during the clinical investigation, agents and/or treatments, as well as risks associated with examinations required by the clinical investigation, such as biomarkers, tests, invasive procedures and other examinations.*

Where appropriate, include among the risks:

- *Lack of efficacy of the experimental treatment ('although we believe that the new treatment may work better on your condition than those already available, we cannot rule out the possibility that it may be ineffective in your case')*
- *Possible risks to the foetus, embryo and nursing infant in the event of pregnancy. If applicable, report that participation in the clinical investigation could harm the product of a possible conception. When necessary, specify that a pregnancy test will be performed before the start of the clinical investigation and that participants of childbearing potential will be required to use reliable contraceptive methods throughout the duration of the clinical investigation.*
- *Possible reduction or abolition of fertility: It has been proven - it is possible - we cannot rule out that the treatment you will be prescribed may make future conception more difficult or even impossible. If you wish, we can discuss the possibility of trying to remedy the problem by collecting and freezing your eggs/sperm before therapy.'*
- *Other possible negative impacts. If applicable, inform the patient that the treatment could have a negative impact on their school, work and social life (decreased attention, decreased sexual desire, etc.)*].

RISK FREQUENCY CATEGORIES.

REPORT THE FREQUENCY, WHEN KNOWN, EXPRESSING IT IN PERCENTAGE TERMS OR USING THE TERMINOLOGY PROPOSED BY THE EUROPEAN COMMUNITY [VERY COMMON (≥1/10), COMMON (≥1/100 TO <1/10), UNCOMMON (≥1/1,000 TO <1/100), RARE (≥1/10,000 TO <1/1,000), VERY RARE (<1/10,000)].

-Are there any alternative procedures appropriate to my condition, as opposed to my participation in the clinical investigation?

[*Indicate, if any, the appropriate alternative procedures or therapeutic options that may be available, their potential benefits and risks*].

*

2.4. Device/comparator description and randomization information

-Which patient groups are being compared? What is the intervention being tested?

[*Provide a clear, concise and phase-specific description of the study groups; provide a description of the inclusion/exclusion criteria. Clearly identify the intervention being studied. Enter the name and type of the product being studied and the route of administration, dosage, treatment schedule (frequency, duration of infusion, etc.); clearly identify which treatment is to be considered experimental and which is already in use in clinical practice. For randomized studies, indicate the probability of being assigned to one group or another. If randomization is not 1:1, briefly describe the assignment. Describe the type of trial in terms of randomization and control. If placebo randomization is planned, explain that there is currently no effective drug for the patient's disease and explain that the placebo is a preparation that does not contain the active ingredient. Explain whether sham randomization is planned (an inactive device that looks the same as the experimental device but has no therapeutic function). If blinded treatment is planned, explain what this consists of and provide information on the rationale for selecting this methodology (considering efficacy of the treatment)*

Clearly inform participants that they may be assigned to the experimental arm or the control/comparator arm, if applicable. Emphasize that the use of a comparator in EFS is exceptional and justified by the scientific question, regulatory expectations, and patient safety considerations].

-What is the device [*enter name*] used for?

[*Description of the medical device*]

*-**What does the clinical implementation procedure involve?***

[*Indicate Step-by-step explanation of how the device will be implanted and What the patient should expect before, during, and immediately after the procedure*]

-Are there any medical devices already in use that could be used in my case?

[*Yes or no, if yes, provide a brief description*].

*

2.5. Contact details information

-Who can I contact if I have any questions?

If you have any questions regarding the research, participants' rights or how to obtain individual documents, please contact: [*insert contact details*]

-If I participate in the clinical investigation, who can I contact in case of injury or adverse events?

In case of injury or adverse events due to the clinical investigation, please contact: [*insert contact details*]

-If I participate in the clinical investigation, who can I contact in case of an emergency?

In case of an emergency, please contact: [*insert contact details*]

*

2.6. Payment/Reimbursement or Costs to Subject information

-Will I incur any costs for participating in the clinical investigation? Will I be reimbursed for any expenses? Will I receive compensation?

[*Clarify that participation in the clinical investigation does not involve any costs and that the person will not be compensated in any way (the law expressly prohibits this); if travel/accommodation expenses are reimbursed, the terms and conditions must be specified*].

There are no costs to you for participating in the clinical investigation as these are fully covered by the trial centre (or the Sponsor, if applicable). There is also no financial compensation for participating in the clinical investigation.

(If applicable) The clinical investigation provides for the reimbursement of costs incurred to enable you to take part in the clinical investigation (e.g., travel expenses, accommodation, including for any accompanying person, etc.). [*In this case, specific arrangements must be made with the investigator or their representative, and the payment methods must be specified*].

*

2.7. System for Damages Compensation (Insurance)

-What happens if I suffer harm as a result of participating in the clinical investigation?

Participation in a clinical investigation may involve inconveniences and risks that cannot be determined in advance. For this reason, the clinical investigation provides insurance coverage to protect your participation.

In compliance with applicable laws, insurance is provided to cover any harm suffered as a result of participation in the clinical investigation, for the entire duration of the clinical investigation, covering the civil liability of the investigator and the sponsor. [*Indicate the insurance company, policy number, maximum coverage per participant, and aggregate maximum coverage, the details of which are attached. Indicate where further information can be obtained. Explanation of the medical assistance and activities provided by the facility in the event of injuries related to the study or procedure, what they consist of, and 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].

Data information

-How will my health data, including identifying data, be processed and who will have access to it during the clinical investigation?

Your participation in the clinical investigation is confidential. Your data, in particular your personal and health data, and only to the extent that it is essential in relation to the objective of the clinical investigation and for pharmacovigilance purposes, will be processed in accordance with EU Regulation 2016/679, known as the GDPR (General Data Protection Regulation), and national law.

In practical terms, documents relating to the participant will be kept in a secure location and will not bear your name in plain text, known only to researchers, but an identification code.

The anonymised data may be subject to scrutiny by regulatory bodies and used for scientific publications (journals, conferences).

Your clinical data collected for the purposes of the clinical investigation, as well as the results of the tests carried out, will be stored for the time required by regulations and subsequently destroyed. They will not be destroyed only if a) it is no longer possible to trace them back to your identity because they have been anonymised during the clinical investigation itself; b) you have given your specific informed consent.

If personal data is transferred to a third country or an international organisation, all the safeguards provided for in Article 46 of GDPR 679/2016 relating to the transfer will be adopted.

Further information is included in the attached data processing authorisation form.

-How will my biological samples taken for the purposes of the clinical investigation be processed and who will have access to them? (if applicable)

As with your health data, your biological samples, which will be pseudonymised (a technique that allows the personal and sensitive data of a natural person to be modified and masked so that it cannot be directly and easily attributed to that person), will also be used for the purposes of the clinical investigation.

Once the clinical investigation is complete, your samples will be destroyed. They will not be destroyed only if: a) it is no longer possible to trace them back to your identity because they have been anonymised during the clinical investigation itself, or b) you have given your specific informed consent and agreement with the biobank for the storage of the samples, or c) in case of use of samples for further research purposes.

Full name of the person who delivered informed consent form

_____

Date Time Signature

_____ _____ _____

The following documents are attached to this informed consent form:

- Insurance policy.
- Form for consent to the processing of personal data.

2.8. Expression of informed consent and signing

I, the undersigned, _____ born in _____, ___/___/_____ [*date of birth*] [legal representative of Mr/Mrs _____ born in _____ ___/___/___ [*date of birth*] [*if applicable*]

I DECLARE

☐ that I have received from _____ [*indicate the name and surname of the person who conducted the interview*], a member of the research team, on _____ [*insert date of the interview]*, comprehensive explanations regarding the request to participate in the research in question, as reported in the information section, which is part of this consent form, a copy of which was given to me on _____ at _____ [*indicate date and time of delivery*];

☐ which have been clearly explained to me and I understand the nature, purpose, procedures, expected benefits, possible risks and drawbacks, and alternative treatment options to the proposed clinical investigation;

☐ that I had the opportunity to ask the study investigator any questions I had and that I received satisfactory answers;

☐ that I have had sufficient time to consider the information received;

☐ that I have had sufficient time to discuss this with third parties;

☐ that my participation is voluntary and that I have not received any undue influence, including financial influence, to participate in the study (with the exception of reimbursement of expenses and loss of earnings directly related to participation in the clinical study, if applicable);

☐ that I have been informed that refusal to participate in the clinical investigation will not result in any penalty for me, nor will I lose any benefits to which I may be entitled;

☐ that I have been informed that the clinical investigation protocol and all forms used have been authorised by the relevant Ethics Committee;

☐ that I am aware that the research may be interrupted at any time, at the discretion of the research manager;

- ☐ that I have been informed that I will be made aware of any new information that could compromise the safety of the research and that, for any problems or further questions, I can contact the doctors who are treating me;
- ☐ that, for the best protection of my health, I am aware of the importance (and my responsibility) of informing my general practitioner about the clinical investigation in which I agree to participate. I am aware of the importance of providing all information (medications, side effects, etc.) concerning me to the investigator;
- ☐ that I have been informed that the results will be disclosed to the scientific community, protecting my identity in accordance with current privacy legislation;
- ☐ that I am aware that any choice expressed in this consent form may be revoked at any time and without justification;
- ☐ that I have been informed of the consequences of my withdrawal from the clinical investigation;
- ☐ that I have received a copy of this consent form;
- ☐ that I will follow the investigator's instructions;
- ☐ that I authorise the processing of my personal data for the purposes of the clinical investigation, as set out in the privacy policy provided to me on _____ [*insert date*];
- ☐ that I authorise the Competent Ethics Committee, the sponsor's representatives and the regulatory authorities to access my medical records;
- ☐ that I have been informed that my personal details will remain confidential and, to the extent permitted by law and/or applicable regulations, will not be made public. If the results of the clinical investigation are published, my identity will remain confidential;
- ☐ that I have been informed that a clinical investigation report and a summary will be presented in terms that are understandable to participants and will be made available in the electronic system for clinical investigations, regardless of the outcome of the clinical investigation, and that I have been informed of the date on which these will be available.

I DECLARE that

☐ I want to participate to the clinical investigation named _____ [*insert study title*]

[*if applicable under country or national law*] In the event that I become incapacitated, I appoint Mr/Ms _____ as the person legally authorised to make decisions on my behalf.

Full name of patient	Date	Time	Signature
_____	_____	_____	_____

*

Part 3 Specific information for frail participants

3.1 Subjects unable to write

On _____ [*insert date*], in the presence of Mr/Ms _____ [*insert name of the impartial witness*], an impartial witness, Mr/Ms _____ [*insert name of the participant*], unable to write for the following reasons _____ gave his/her consent to participate in the clinical investigation [*indicate the method used to obtain consent*].

Specifically:

- on _____, a copy of the informed consent form was provided;
- on _____, consent was given and this conversation was recorded on audio/video;
- on _____, a copy of the recording of the conversation in which consent was given was delivered.

OR

I, the undersigned _____ [*insert name of the impartial witness]* as an impartial witness, hereby

DECLARE

that Dr._____ [*insert name of the person who conducted the interview and obtained consent*], on_____ [*insert date*], has thoroughly explained to Mr./Ms._____ [*insert name of the participant*] the characteristics of the clinical investigation described in the attached information sheet, and that the subject, having had the opportunity to ask any questions deemed necessary, has freely agreed to participate in the study.

Full name of the participant unable to write

_____

Full name of the impartial witness Date Time Signature

_____ _____ _____ _____

Full name of the person who provide the information Date Time Signature

_____ _____ _____ _____

*

3.2. Incapacitated subjects

I, the undersigned, _____ born in _____, ___/___/_____ [*date of birth*] [legal representative of Mr/Mrs _____ born in _____ ___/___/___ [*date of birth*] as _____ [*attach, where applicable, a document certifying the power of representation*]

I further DECLARE

- ▢ that the incapacitated person for whom I am the legal representative and who will participate in the clinical investigation has received information appropriate to their level of understanding;
- ▢ that the incapacitated person participated as much as possible in the process of reaching a decision;
- ▢ that I have been informed that it is not possible to obtain comparable validity data from clinical studies involving persons capable of giving informed consent or by other research methods;
- ▢ that I am aware that the clinical investigation 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 investigation will result in a direct benefit to the incapacitated subject that outweighs the risks and burdens involved;
- ▢ that no financial incentive or inducement has been offered to me or to the incapacitated person, except for reimbursement of expenses and loss of earnings directly related to participation in the clinical investigation.

I DECLARE that

▢ I want that _____ [*indicate name of incapacitated subject*] participates in the clinical investigation named _____ [*insert study title*]

Full name of incapacitated subject

_____

Full name of legal representative Date Time Signature

_____ _____ _____ _____

*

3.3. Minors

I/We the undersigned, _____ born in _____, ___/___/_____ [*date of birth*] and _____ born in _____, ___/___/_____ [*date of birth*]; parent(s)/legal representative(s) of _____[*full name of the minor*] _____ born in _____, ___/___/___ [*date of birth*] as _____ [*attach, where applicable, a document certifying the power of representation*];

I/We further DECLARE

- ▢ that the minor has received the information referred to in the informed consent form, in a manner appropriate to his or her age and intellectual maturity, from researchers or members of the research team who are qualified or experienced in dealing with minors;
- ▢ that the minor participated in the informed consent procedure in a manner appropriate to his or her age and intellectual maturity;
- ▢ that I am/We are aware that the clinical investigation is aimed at studying treatments for a condition that only affects minors, or that the clinical investigation is essential in relation to minors in order to validate data obtained from clinical investigations on persons capable of giving informed consent or obtained by other research methods;
- ▢ that I am/ We are aware that the clinical investigation is directly related to a condition from which the minor concerned suffers or is of such a nature that it can only be conducted on minors;
- ▢ that I am/We are aware that there are scientific reasons to believe that participation in the clinical investigation will result in a direct benefit to the child that outweighs the risks and burdens involved;
- ▢ that I am/ We are aware that if the minor reaches the age of majority during the clinical investigation, it is necessary to obtain his or her direct informed consent in accordance with national legislation.

I DECLARE that

▢ I/We want that _____ [*indicate name of minor*] participates to the clinical investigation named _____ [*insert study title*]

_____

Full name of minor

Full name of legal representative	Date	Time	Signature
_____	_____	_____	_____
Full name of legal representative	Date	Time	Signature
_____	_____	_____	_____

*

3.4. Pregnancy - Pregnant or breastfeeding women

-Are there any additional risks beyond those already mentioned in the previous information?
[*Indication of any reasonably foreseeable risks or drawbacks, if any, for an embryo, foetus or breastfed infant*].

*

I, the undersigned, _____ born in _____, ___/___/_____ [*date of birth*]

I further DECLARE

☐ that I am aware that the clinical investigation may potentially result in direct benefits for the pregnant or breastfeeding woman, or for the embryo, foetus or breastfed, which outweigh the associated risks and burdens;

☐ that participation in the study may involve risks to me (or to the embryo or foetus, if the subject is or may become pregnant) that are currently unforeseeable;

I DECLARE that

☐ I want to participate to the clinical investigation named _____ [*insert study title*]

Full name of patient Date Time Signature

_____ _____ _____ _____

STATEMENT BY THE DOCTOR WHO OBTAINED CONSENT

_____

(Name of the participant, place and date of birth)

Study Title: _____

Sponsor: _____

Principal Investigator: _____

*

I, the undersigned, _____ [*full name of the doctor who obtained consent*] in my capacity as Principal Investigator (or delegate of the Principal Investigator or doctor belonging to the investigation team)

DECLARE

that the Patient or his/her legal representative has voluntarily consented to his/her participation in the clinical investigation.

I further DECLARE that

☐ I have provided the Patient or his/her legal representative with comprehensive explanations regarding the purposes of the clinical investigation, the procedures, the possible risks and benefits, and the possible alternatives;

- ☐ I have verified that the Patient or his/her legal representative has sufficiently understood the information provided to him/her;
- ☐ I have given the Patient or his/her legal representative sufficient time and opportunity to ask questions about the clinical investigation;
- ☐ I have clearly explained the possibility of withdrawing from the clinical investigation at any time or changing the choices made;
- ☐ I have not exercised any coercion or undue influence in requesting this consent;
- ☐ I have provided the patient or his/her legal representative with information on how the results of the clinical investigation will be disclosed to him/her.

Place, Date and Time _____

Full name of the doctor who provided information and informed consent _____

Signature _____

This form is an integral part of the informed consent form and must be kept together with it.

The Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project is supported by the Innovative Health Initiative Joint Undertaking (JU) under grant agreement No 101112185. The JU receives support from the European Union's Horizon Europe research and innovation programme and life science industries represented by MedTech Europe, COCIR, EFPIA, Vaccines Europe and EuropaBio.