

AF3

Advanced Forest Fire Fighting

D10.1.2 – Informed Consent Forms

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	DISSEMINATION LEVEL	
PU	Public	<input checked="" type="checkbox"/>
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CO	Confidential, only for members of the consortium (including the Commission Services)	<input type="checkbox"/>

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1. EXECUTIVE OVERVIEW

The AF3 Project Ethical Manager, together with the AF3 EU Project Officer, agreed that for the AF3 Project One Informed Consent form would be produced that would be split into two parts:

Part 1: Would cover the members of staff that implement the pellet distribution system into the aircraft.
Part 2: Would cover Staff and Pilots who will be testing the system in real time.

Each partner will translate them into their local language to ensure that it is fully understandable to the participants.

This deliverable contains an initial version of the Informed Consent template and the Information Sheets in English. As the trials will not take place for another year, we are going to have to update the Informed Consent forms, and thus this deliverable, nearer the time once information is available from the technical partners.

2. INTRODUCTION

2.1 INFORMED CONSENT REQUIREMENTS

Normally an informed consent form is required only in the following cases:

When the research involves:	
Patients	
Children	
Incompetent/Incapacitated persons	
Healthy volunteers	
Immigrants	
Others (i.e. Prisoners)	
When the research uses/collects:	
Human Genetic Material	
Biological samples	
Personal data	

AF3 only uses Healthy volunteers, however, it does not Use or Collect Human Genetic Material, Biological Samples or Personal Data.

Within AF3, a new pellet distribution system will be implemented into aircraft that will then have test flights to check that the system is stable and that does not impact the flying of the aircraft.

After the pellet distribution system has been successfully implemented into the aircraft, there will be further flights that test the working of the pellet distribution system in a real trial.

In line with this, AF3 will produce One Informed Consent form would be produced that would be split into two parts:

Part 1: Would cover the members of staff that implement the pellet distribution system into the aircraft.

Part 2: Would cover Staff and Pilots who will be testing the system in real time.

Copies of the Informed Consent Form and Information Sheets included are written in language and terms understandable to the participants.

2.2 ORGANIZATION AND INSURANCE ISSUES.

All Partners must be aware of risks involved while conducting the trials. The consequences of risks are to be borne by the partner individually and not to be shared with the project or other partners.

If needed, the partners should be insured.

3. PROCEDURE

Procedures have to be put into place on how to actually get the informed consent forms filled in.

Informed consent is more than simply getting a signature on a consent form. It is a process of communication where the participant has the opportunity to ask questions to elicit a better understanding of their role, so that he or she can make an informed decision to proceed or to refuse.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- Participants must understand the nature of the trial and the risks and benefits involved if they are to make an informed decision about their participation. The details should be presented in simple language by someone who is knowledgeable about both the study and informed consent.
- This process requires a "consent document" that explains the nature of the research and any risks and benefits to the participant.
- Because informed consent is an ongoing process, it starts before any forms are signed, and it continues through the completion of the subject's involvement in the trial. The consent document is only a confirmation of the consent process.

4. INFORMATION SHEET

The Advanced Forest Fire Fighting project (AF3) intends to provide an extraordinary improvement to the efficiency of current fire-fighting operations and to the protection of human lives, the environment and property by developing innovative technologies and means to ensure a high level of integration between existing and new systems.

To reach this objective the AF3 project focuses on the following areas:

- Innovative active countermeasure: implementation of the novel AAFF (Advanced Aerial Fire Fighting) system to accurately and safely disperse extinguishing materials from high altitude by aircrafts and helicopters in any condition: day and night, regardless of weather, smoke and configuration of terrain. It will enable a quick 24H response, minimizing fire duration and damages. The AAFF system can be adapted to a wide variety of aircrafts or helicopters.
- Innovative passive countermeasures: fast build-up of preventive defensive lines of capsules to prevent the spreading of fire from forest to populated areas
- Early detection and monitoring: integration and deployment of diverse systems including satellites, aeroplanes, UAVs, and both mobile and stationary ground systems for the early detection of fire and for monitoring the propagation of smoke and toxic clouds.
- Integrated crisis management: the innovative AF3 Core Expert Engine will perform overall coordination of all fire fighting missions.

Your role is within this project is to XXXXXXXX¹ this will allow AF3 to XXXXXXXX²

There is some risk involved for this participation in the AF3 Project.

<Name of person explaining orally the information> will explain fully your participation including the possible risks and be available to answer any pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

Your participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

¹ To be added in the updated version

² To be added in the updated version

5. INFORMED CONSENT TEMPLATE

5.1 INTRODUCTION

All trial members of staff following detailed oral information, will receive in their own language:

- a commonly understandable written description of the project;
- the related trial and testing procedures;
- the possible risks;
- details on any insurance;
- advice on unrestricted disclaimer rights on their agreement.

Then, after leaving them enough time for reflection, they will be asked to give informed written consent in order to participate in the project pilot tests and trials.

5.1.1 Template

<2 sections to be added specific to the two phases³>

	Please circle as necessary	
I was informed on the nature of my duty for the AF3 Trial and about possible advantages and disadvantages as well as about possible risks verbally and in writing by the test leader.	Yes	No
I have read and understood the written information handed out for the AF3 Trial. My questions in connection with my participation were answered satisfactorily. I can keep the written information and receive a copy of my written declaration of consent.	Yes	No
I had sufficient time to take my decision	Yes	No
In case an incident arises contrary to expectation an insurance consists for me in the legally specified scale. The insurance was constructed by for this study.	Yes	No
I understand that I am free to refuse or withdraw from the trial ♦ at any time ♦ without having to give a reason for withdrawing ♦ and without affecting my future employment	Yes	No
I agree to take part in the AF3 trial	Yes	No
	Yes	No

Signed

Date.....

Name (in block letters).....

³ To be added with updated version

6. REFERENCED DOCUMENTS

EU FP7 SENSATION Project Deliverable D5.6.1 - Template on ethical and legal issues and informed consent form

EU FP7 Informed Consent guidelines

<http://www.research.umn.edu/consent/mod2soc/mod2sec1.html>