

AF3

Advanced Forest Fire Fighting

D101.1 Ethical Monitoring of Research report – Year 1

Period: 01/05/2014 – 30/04/2015

Change Control:

Version #	Date:	Change:	Name:	Company:
0.1	30.09.2014	First draft	Dana Remes	EFPC
0.2	31.12.2014	Additions	Dana Remes	EFPC
0.3	29.04.2015	Additions	Dana Remes	EFPC
1.0	30.06.2015	Review and Finalisation of Year 1	Dana Remes	EFPC
2.0	31.01.2016	Updated after the Review Report	Dana Remes	EFPC

Release Approval:

Name	Role	Date
Dana Remes	WP10 Leader	31.01.2016
Cecilia Coveri	Project Manager	31.01.2016

Table of Contents

<u>1.</u>	<u>GENERAL OVERVIEW OF ETHICAL MONITORING OF RESEARCH WITHIN AF3</u>	<u>4</u>
<u>2.</u>	<u>STATUS OF ETHICAL ISSUES</u>	<u>5</u>
2.1	ETHICAL MANAGEMENT	5
2.2	ETHICAL MONITORING	6
2.3	ETHICAL REVIEW OF DELIVERABLES	7
2.4	ADVISORY BOARD	8
<u>3.</u>	<u>MEETING LIST FOR THE PERIOD</u>	<u>9</u>
<u>4.</u>	<u>UPDATES FOLLOWING THE PERIOD 1 REVIEW</u>	<u>11</u>

1. GENERAL OVERVIEW OF ETHICAL MONITORING OF RESEARCH WITHIN AF3

This Deliverable gives an overview of the activities of the Ethical Manager and the Ethical Monitoring within the AF3 Project.

It will be periodically issued once a year. This is Version 2 – Year 1.

We note that this project has started a bit slowly for some partners. We did address this with the Project Manager and we hope to be able to proceed much more quickly within the Second Year.

This Deliverable has been updated (V2) after discussions with the Project Officer during the Period 1 Review and after the Review Report.

In addition, there was agreement on a future amendment to correct some mistakes in the DoW.

2. STATUS OF ETHICAL ISSUES

2.1 ETHICAL MANAGEMENT

In the past, ethical issues were only identified, discussed and addressed after a research project was completed. Within FP7 this is no longer the case. It is vital that any issues are dealt with during the running of the project and approvals are gained before research takes place.

One of the most important things that the Ethical manager needs to do is be in constant contact with the Technical director in order to:

- Receive more information above and beyond the Technical annex
- Be fully informed of all work being done that needs ethical approval
- Be aware of any unplanned Ethical Issues that may arise.

Unfortunately, initially in AF3, there was a lack of communication from the Technical director as the appointed person fell ill. Elbit subsequently appointed a new Technical Director and now, things seem to be progressing. Despite the slow start, the Ethical Management started on time with the Consortium, and there have been many activities and meetings.

Dana, the Ethical manager had a one to one meeting with Yoram (The AF3 Technical Director at the Start of the Project) from Elbit to explain Ethics within FP7 and how this applies to AF3:

- Dana explained to Yoram what the differences between the Ethics screening Report and an Ethical Review are.
- Dana explained Special clause 15.
- Dana went over the AF3 Ethical issues.
- Dana briefed Yoram on the need for Informed consent and Approvals.
- Yoram wants to start with Israel for the Ethical approvals to learn the process. He suggested an informal call to the first. After the call, Yoram and Dana will produce the briefing letter for the Israeli Ethics committee.
- Yoram is to provide Dana with a full list of the research that is to be done in AF3 on a country by country basis.
- Dana and Annalisa will contact the PO to ensure that our definitions as to what “research” is, and which countries we need to get approvals from is approved so that she cannot say we missed something later.
- Yoram was interested to see if there were any current Firefighting ethical guidelines in the targeted countries already. He was concerned that AF3 would be fully compliant.
- Yoram will brief ELBIT after our meeting and try arrange meetings for EFPC with ELBIT Ethics and Health and Safety people.
- It was agreed that the Ethics within AF3 are a good thing for Elbit for when the eventually try and sell the system.
- It was agreed that Elbit and EFPC will fully contribute on the Ethics Deliverables.

After this meeting, Richard from EFPC has been in contact with ELBIT to receive information required about the chemicals used by the Pellets.

2.2 ETHICAL MONITORING

This Involves monitoring all AF3 Ethical Issues and ensuring that the ethical standards and guidelines of FP7 are rigorously applied, regardless of the country in which the research is carried out.

It was decided during Contract negotiation, that instead of having Ethics in each Workpackage, there would be a separate WP that deals with Ethics to oversee all of the other workpackages. Thus the Ethics team is on all of the Email reflectors for each WP. This way, they can monitor what is going on as decisions are being made. This is very time consuming but essential for proper Ethical Monitoring.

During the Kick-off meeting, the Ethical Manager had a 20 min session where FP7 Ethics rules were explained and the specific AF3 Ethical issues were discussed. There were many questions and it was clear that this session was essential in making sure that all the partners had an understanding of the AF3 Ethical requirements. It was requested that the Ethical Manager held regular Ethical webmeetings to follow-up on any questions the partners may have.

We note that AF3 started slowly, however, it is now on track and everything is proceeding well.

The Ethical team sent a chemical expert to conduct a field visit to Fraunhofer test laboratories at Pfinztaal for Technical and Ethical evaluation of test methods and facilities. We have requested a similar visit to Elbit but to date none have been arranged.

Fraunhofer visit Agenda:

Friday 6th March		
10:00	<i>Welcome and introduction</i>	Fraunhofer ICT
10:20	Presentation of respective partner	Fraunhofer ICT/EFPC
10:50	Overview of previous and planned tests at ICT (a) testing fire agents for pellets (deni) (b) testing fire agents for capsules (stst) (c) toxicity tests (deni + stst) (d) preliminary drop tests (vw) (e) exposure of pellets to a defined thermal stress (kes) (f)	Fraunhofer ICT

	model calculation of the dropping behavior of pellets - 10 min each + 5 minutes discussion -	
12: 30	Lunch	
13: 30	Tour of ICT laboratories	Fraunhofer ICT
	Test stands for testing fire agents for pellets	Building 08 (deni)
	Test stand for testing fire agents for capsules	Building 08 (stst)
	Combustion hall	Building 75 (vw)
	Environmental simulation	Building 69 (pu)
	Open-air test site	(kes)
16: 00	End of meeting	

In addition, during this period we evaluated the Material Safety data Sheets from ELBIT and PYRO and conducted literature and Internet searches on fire-fighting techniques and capability of PYRO and ELBIT.

2.3 ETHICAL REVIEW OF DELIVERABLES

No Deliverable should be submitted to the Commission until it has passed Ethical Approval by the Ethical team. This is to ensure Ethical Compliance.

During the first period there was a slight breakdown in the deliverable submittal procedures and this did not happen all of the time.

The Ethical team have requested that the Project manager gets these deliverables rejected by our PO and then to resubmit them after the necessary adjustments and improvements have been made.

Most deliverables that were received requested changes to be made before submittal.

The Current Deliverable Status as of 15/06/2015 of submitted Deliverables is:

Deliverable:	Title:	Passed Ethical Evaluation?
D1.1	Project Handbook	Yes
D2.1.1	Mission Analysis Report	Yes
D2.1.2	Requirements specification for the AF3 sensors and system (It includes System Requirements Matrix Baseline)	No
D2.2.2	System Architecture Definition	No

D5.1.1	Integrated Crisis Management - Advanced CONOPs Specifications	Yes
D5.1.2	International Interoperability	Yes
D5.3.1	Training methodologies specifications	No
D5.3.2	Training scenarios, material, tools and simulation specifications	Yes
D7.2.1	Helicopter AAFF Survey report	No
D7.2.2	AAFF system specifications	Yes
D7.4.1	Capsule's Specifications Report	No
D10.1.2	Informed Consent Forms Produced	Yes
D10.2.3	Evacuation Report	Yes

2.4 ADVISORY BOARD

The Advisory Board was not actioned during the first Period of the Project.

However, the Ethical team have instigated the Advisory board activation prior to the 1st Review and have added an extra member to the Advisory Board from Australia.

3. MEETING LIST FOR THE PERIOD

A big part of Ethical Management is to be fully involved in Project Management Office and attend relevant meetings in order to be on hand if required and to address issues before they become a problem.

Below is a list of meetings that The Ethics team has attended.

If required, we can give more specific information about each meeting as we kept reports on them all, but we believe that it is just working information and is unnecessary for this report.

Date:	Time:	Location:	Name:	Notes
29 & 30 May 2014	All Day	SELEX Premises in Trieste - Italy	AF3 Kickoff	
5 June 2014	11:00 CET	GoToMeeting	AF3 Ethical WebMeeting #1	Dana, Richard and Caterina
8 June 2014	10:00 CET	Telephone Call to Yoram (ELBIT)	Telephone Call	Dana Called Yoram to chase up Richard's request for Toxicology info.
8 June 2014	11:00 CET	Telephone Call to Gadi (ELBIT)	Telephone Call	Dana Called Gadi to arrange a meeting to explain the AF3 Ethicas requirements
10 June 2014	10:00 CET	Telephone call to Annalisa	Telephone Call	
10 June 2014	18:00 CET	Yoram Called	Telephone Call	Arranged a meeting for next week to explain the AF3 Ethics
11 June 2014	11:00 CET	GoToMeeting	AF3 Ethical WebMeeting #2	Dana, Richard and Caterina.
17 June 2014	10:30 CET	Meeting in Yavne	AF3 Ethical Meeting #3	Yoram and Dana discussed AF3 Ethical Issues
20 June 2014	15:00 CET	GoToMeeting	AF3 Ethical Webmeetingm #4	Paul, Myer, Annalisa, Rebecca and Dana discuss T10.2.2
10 July 2014	14:00 CET	GoToMeeting	AF3 Ethical Webmeetingm #5	Paul, Myer, Annalisa, Rebecca and Dana discuss T10.2.2
17 July 2014	14:00 CET	GoToMeeting	AF3 Webmeeting #6	Annalisa and Dana on Approvals
21 July 2014	14:00 CET	GoToMeeting	Webmeeting #7	T10.2.2 meeting Dana and Rebecca.
9 Sept 2014	14:30 – 16:30 CET	WebEx	AF3 Technical Meeting	Meeting to get some answers from the Technical Manager
2 Oct 2014	All Day	Rome	WP2 Workshop	
6 Oct 2014	09:30 – 11:30 CET	WebEx	WP6 Webmeeting	
26 Oct 2014	09:30	Telephone Call	Evacuation	Rebecca and Dana

			Report	
25 Nov 2014	All Day	Turin	WP Leaders Meeting	
27 Jan 2015	11:00 CET	GoToMeeting	Ethical Webmeeting #8	
4 Feb 2015	12:00 CET	GoToMeeting	WP4 and WP10 Webmeeting #9	
12 Feb 2015	11:00 CET	GoToMeeting	Ethical Webmeeting #10	
2 March 2015	15:00 CET	WebEx	Ethical Webmeeting #11	
6 March 2015	All Day		Ethical Safety Visit	Richard inspected Frounhoffer
9 March 2015	All Day	Rome	WP5 and WP8 Meeting	
13 April 2015	11:00 CET	Telephone Call	AF3 Issues Call	Meeting with Cecilia
20 April 2015	10:00 CET	GoToMeeting	Ethical Webmeeting#12	
29 April 2015	10:00 CET	WebEx	AF3 Financial Training	
30 April 2015	10:00 CET	WebEx	AF3 Financial Training	

4. UPDATES FOLLOWING THE PERIOD 1 REVIEW

During the Review, it was apparent that there were some mistakes made in the DoW to do with the timings of WP10 Reports.

After discussions with the PO, it was agreed that a Contract Amendment would be submitted correcting these mistakes. At the same time, it was noted that a few of WP10 Deliverables were overlapping and it was agreed that the Deliverable D10.1.4 would be merged into D10.1.1, which is updated annually, and that D10.2.1 and D10.2.2 would be merged into D10.2.1.

Please see the changes at a glance below: (**Changes are bold and in Blue**)

Original Dow			Updated DoW		
Deliverable	Title	Date Due	Deliverable	Date	Notes
D10.1.1	Ethical Monitoring of Research report	M12, M24, M36	D10.1.1	M12, M24, M36	From M24, now includes D10.1.4
D10.1.3	AF3 Required Ethical Approvals	M10	D10.1.3	M30	Approvals are requires for the Trials in Greece, Spain and Israel. Approvals will be sent to the Commission prior to the trials. Approvals could not be given in advance as the information was not available for applying.
D10.1.4	Safety of project activities report	M18	D10.1.1	M12, M24, M36	This Deliverable is being merged.
Milestone 21	AF3 Required Ethical Approvals and examples of Informed Consent submitted to EU.	M10	Milestone 21	M30	As For D10.1.3, this will be completed prior to the Trials taking place.
D102.1	Validation/approvals of pellet Chemicals Report	M12	D10.2.1	M22	This is being merged with D10.2.2 to produce 1 report "Environmental issues Report including

					Validation of Pellet Chemicals Report”
D102.2	Environmental issues report	M18	D10.2.1	M22	This is being merged with D10.2.1 to produce 1 report “Environmental issues Report including Validation of Pellet Chemicals Report”
Milestone 22	Validated medical and toxicological studies.	M12	Milestone 22	M22	

As stated above, from the Year 2 Report, D10.1.1 will be updated and cover the Ethical Management of AF3 which includes:

- a) Monitoring all AF3 Ethical Issues and ensuring that the ethical standards and guidelines of FP7 are rigorously applied, regardless of the country in which the research is carried out.
- b) Part of the Project Management Office and attending relevant meetings.
- c) Liaising with the Advisory board on Ethical Issues as appropriate.
- d) Being the AF3 contact for Ethical Issues if any Researcher, User, Participant, Ethical Body or EC has any questions or requires any information.
- e) Holding meetings with the Technical Manager and Workpackage and Task leaders as required.
- f) Review of each deliverable prior to release to ensure Ethical Compliance.
- g) The monitoring of the research carried out in the other WPs with particular emphasis on WP4 and WP7. The monitoring will assure that the research is being conducted in accordance to EU ethical standards and will include:
 - asking questions of the research team, inspecting all consent documents and records and being guided through any physical experiments associated with the project;
 - advising on and approving the research methods, including unexpected changes or opportunities that may come up during the research;
 - taking appropriate ad-hoc decisions with regard to minimising unforeseen harm that may have occurred during the research.
- h) Safety of project activities
 - Health and safety issues of the researchers that test research carried out in the other WPs with particular emphasis on WP4 and WP8.
 - The risk of physical or emotional harm to the researcher, and steps to be taken to mitigate it;
 - Arrangements for reporting and dealing with any adverse reactions to the project.