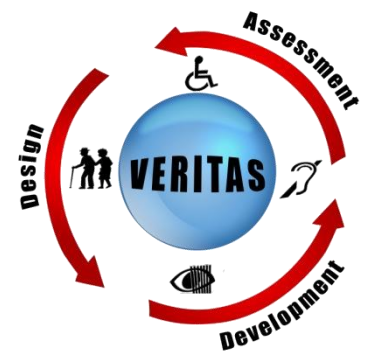




# VERITAS project

FP7 247765



## VERITAS Ethics



**Marcel Delahaye**

COAT-Basel

**Karel Van Isacker**

MCA

# Ethics activities

## (current and planned)

- M1: Establishment of Ethics Advisory Board
- M2: Development of “ethical and legal issues” template
- M3: Completion of “ethical and legal issues” template by test sites
- M5: VERITAS Ethics Manual (sent to GUIDE in Sep. 2010)
- M10: Organisation of Ethics session in the context of the Pan-European workshop; Participation of clustering projects

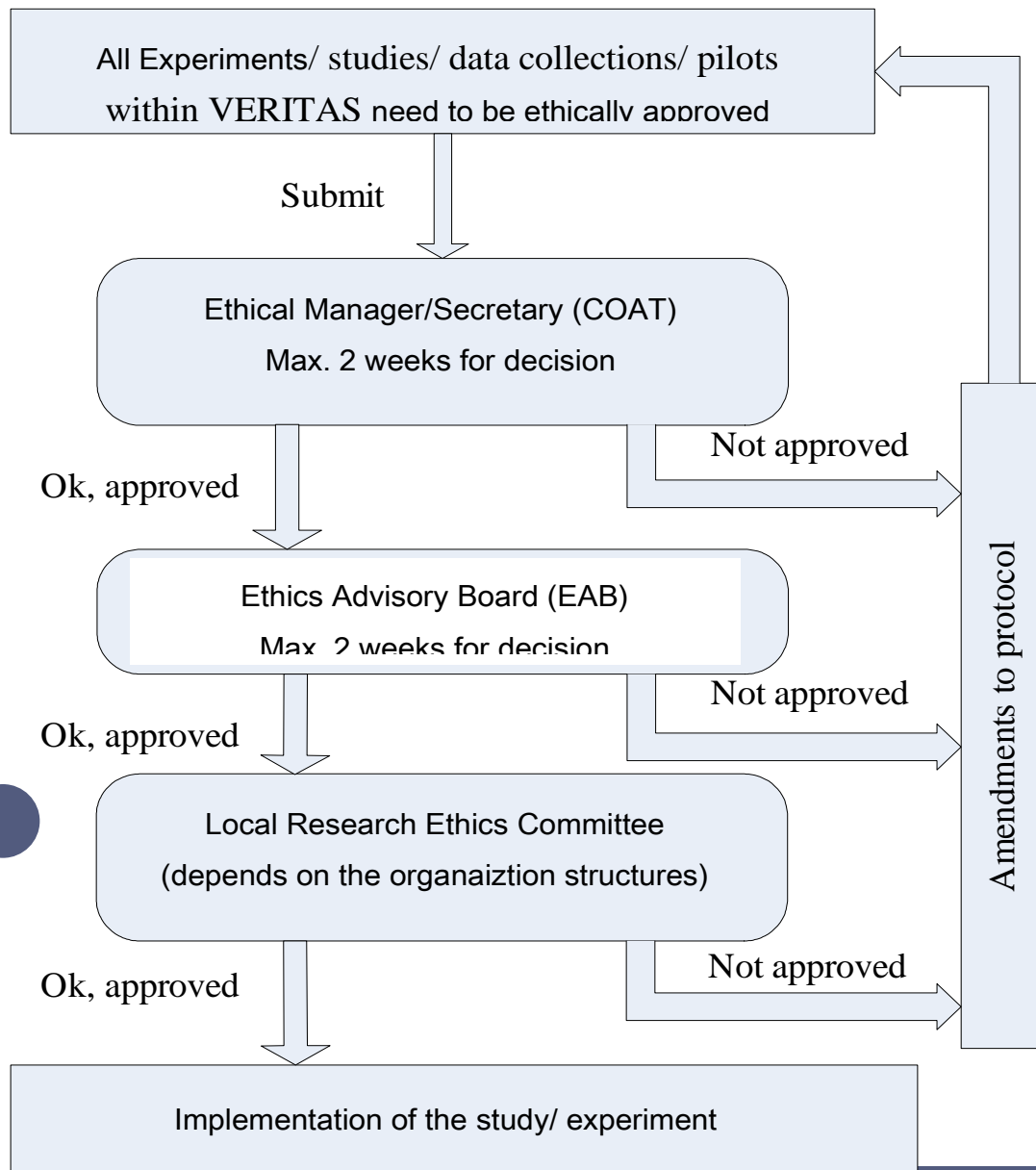


M18: 1<sup>st</sup> ethical controlling report from test sites  
M24: 2<sup>nd</sup> ethical controlling report from test sites  
M36: 3<sup>rd</sup> ethical controlling report from test sites  
Month 48: Final ethical controlling report and Ethics Manual-revised version provided



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# Ethics Management



# Ethical and Legal Issues – Main Tasks

- Project Ethical Manual has been written in Month 2:
  - to guarantee the comfort and safety of all participants, as well as the security and legal issues of their personal data with respect to the Pilot set-up,
  - Project aims have to be in balance between security enhancement of the end-user groups
- Template on Ethical Issues has been sent to the Pilot partners (2 parts):



# Template on personal information (to be filled out by all data collecting partners)

- All investigators have to fill in the template concerning private information' about:
  - What kind of data will be recorded, stored and why?
  - Will the data be transferred?
  - Data ownership?
  - Is the data connected to other information?
  - Will the data possibly commercially exploited?
  - Length of storage?
  - Where data will be stored, - according to which national legislation?
  - Who will access the data?
  - Who will supervise the data protection?



# Questionnaire on ethical and legal issues (to be filled out by all data collecting partners)

## 1. Example: *Informed consent clarifications*

Note: if private information is recorded, please use the additional document informed consent relating to private information; 'VERITAS informed consent template concerning privacy'.

Do you conduct experiments with **mentally** incapacitated participants (people unable to understand the informed consent form)?

Yes  No

If yes, no experiment will be performed.

## 2. Example: *Legislation*

Is an oral consent of an illiterate participant that is witnessed in accordance with your national legislation?

## 3. Example: *Privacy*

Please note: If private information will be recorded, the VERITAS informed consent template – to be found in the annex, has to be filled in and signed by the participant and the investigator.

## 4. Example: *Safety*

Will you provide information to the participants if you get aware of an illness?



# Project ethics Management Panel

## 2 members:

- **Prof. Dr. rer. nat. Jürgen Maes, (*confirmed*)**
  - University of the German Army Munich, Expert in Justice Psychology
- **Prof. Dr. V. Dittmann, (*confirmed*)**
  - Director of the institute for forensic medicine University Basel



# Why Ethical Issues?

- To guarantee that the project research/pilot plans is conducted according to the highest ethical standards.
- Core ethical issues:
  - I Privacy protection and confidentiality
  - II Informed consent
  - III Delegation of control
  - IV Risk assessment





# I Privacy protection and confidentiality

***Privacy: power to control what others can come to know about you***

Privacy Protection: Security is an important issue for VERITAS, since VERITAS system handles large amounts of sensitive information (medical data) that should be protected



# VERITAS security issue

Several major questions arise, for example:

- How to safeguard the integrity of the information,
- How to safeguard the confidentiality of the information (i.e. who should be allowed to see what and under what conditions),
- How to improve its availability to legitimate users, etc...



# European laws for data protection

- Data Protection Directive 95/46/EC
- Directive 97/66/EC on Data Protection in the Telecommunications Sector
- Art. 29 - Data Protection Working Party: Working Document on Privacy on the Internet



# Privacy and transparency: Personal data management

- Suggestion: Identification and recruitment of an ethics expert for data protection per pilot site
  - A named person locally responsible for ethical matters and data protection at each site
  - Training (material & courses) will be provided for these responsables



## II Informed consent

- purpose of research, expected duration, and procedures;
- possible risks, discomfort, adverse effects, and side effects (if any);
- description of any benefits to the participant or to others which may reasonably be expected from the research;
- explanations on confidentiality (and limits) of the data;
- right to decline to participate and to withdraw from the research once participation has begun and the foreseeable consequences of declining or withdrawing;
- whom to contact for questions about the research and research participants rights.



# III Delegation of Control

- VERTAS aims simulating behaviour and mental performance of people with special needs
- There is a certain danger that the user will loose autonomy. This loss of personal control will be carefully checked
- Research will carefully be controlled, that the users have a high control on all developed devices, so the dependability on Ambient intelligent devices will be held as low as possible
- **Content control:** The content of developed VERTAS objects will be continuously checked (Validity)
- **System control:** The objectivity, reliability and objectivity of the system functioning is to be guaranteed
- **Accountability:** If autonomous objects start taking decisions on their own, legal guidelines need to be drawn up, in order to resolve who is ultimately responsible for the decisions taken [Bohn et al., 2005]



# IV RISK ASSESSMENT

## Categories of risk:

- There will be no risk of physical damage within the experiments taken in VERITAS. Any equipment connected to a participant will be evaluated for personal safety. These tests will be performed for the complete configuration and not only for the individual equipment.
- Psychological consequences are carefully examined.
- Social inconveniences will be minimised (no additional stress for families, cost reimbursement for additional transportation costs, ...).

If private information is recorded, the participant will be informed according to the aspects mentioned in the informed consent template concerning privacy.

The Security of the IT infrastructure and the Privacy related information concerning the risks is described in the Ethical Manual.



# IV RISK ASSESSMENT

General safety requirement in European legislation, e.g. Directive on general product safety (2001/95/EEC)

- Obligations on manufacturers and distributors
  - safe products, information of risks

