

# INFORMATION SOCIETY TECHNOLOGIES (IST) PROGRAMME



## SENSATION 507231

### Template on ethical and legal issues and informed consent form

Deliverable No.		D5.6.1	
SubProject No.	SP5	SubProject Title	Horizontal Activities
Workpackage No.	WP5.6	Workpackage Title	Ethical and Legal issues
Activity No.	A5.6.1 A5.6.2 A5.6.3	Activity Title	Project Ethical Policy Legal issued and IPR Organisational and insurance issues
Authors		Dr. Alex Bullinger (COAT) Dr. Evangelos Bekiaris (CERTH/HIT) Stavroula Maglavera (Pouliadis) Anand Kumar (Medcare BV)	
Status		Draft	
File Name:		SENSATION-D5_6_1-V1.doc	
Project start date and duration		01 January 2004, 48 Months	

## Table of Contents

<b>1. INTRODUCTION.....</b>	<b>4</b>
<b>2. DEFINITION OF ISSUES SURVEYED .....</b>	<b>4</b>
2.1 INDIVIDUAL PRIVACY.....	4
2.2 BIOLOGICAL OR OTHER ADVERSE EFFECTS .....	5
2.3 SAFETY AND BIO-COMPATIBILITY.....	5
2.4 HYGIENE AND LABORATORY SAFETY .....	5
2.5 INFORMED CONSENT.....	5
2.6 ETHICS CONTROL COMMITTEE.....	5
2.7 ORGANIZATION AND INSURANCE ISSUES. ....	6
2.8 METHODOLOGY.....	6
<b>3. INFORMED CONSENT .....</b>	<b>6</b>
3.1 GENERAL REQUIREMENTS FOR INFORMED CONSENT.....	6
3.2 DOCUMENTATION OF INFORMED CONSENT .....	8
3.3 GUIDELINES FOR COMPILING THE INFORMED CONSENT FORM.....	8
<b>4. SENSATION ETHICS ADVISORY BOARD.....</b>	<b>10</b>
<b>5. REFERENCES .....</b>	<b>10</b>
<b>ANNEX 1: QUESTIONNAIRE ON ETHICAL AND LEGAL ISSUES .....</b>	<b>11</b>
<b>ANNEX 2: SENSATION INFORMED CONSENT FORM TEMPLATE.....</b>	<b>18</b>

## Executive Summary

The SENSATION Integrated Project will develop technologies to monitor brain state and other bio-parameters **unobtrusively** through the development of novel sensor technologies, innovative signal processing and computational intelligence algorithms, with a special focus on sleep time/environment as well as real time applications (alertness monitoring, detection and prediction), including medical applications. **Brain machine interfacing and biofeedback are not to be performed** within the project and are only considered within its future roadmap. Sleep time offers an unused window of opportunity: sleep time and sleep environment are predictable, controllable, available and measurable. SENSATION research has applications in many areas: Medical, Transport, Automotive, Insurance, Tourism, Sleep Environment (e.g. mattresses, sheets), Infants Industry, Geriatrics, Entertainment, Music, Learning, Sports, and in the Pharmaceutical Industry.

The objective of SENSATION WP5.6, entitled "Ethical and legal issues" is to guarantee that all ethical and legal requirements are fulfilled during the project conduct. There are two types of ethical issues related to the project conduct:

- The *first* has to do with the pilot set-up, to guarantee comfort and safety of participants and/or professionals who take part in them, as well as the security of their personal data, acquired during the pilot evaluations.
- The *second* ethical issue concerns the proposed SENSATION novel tools, as well as the use of the research data, in a way that guarantees privacy and state of the art therapy according to local and European law.

WP5.6 will develop an Ethics Manual which should be followed by all partners in addition to any national rules and legislation. This will define the processes necessary to resolve any ethical, legal and organisation/insurance issues.

A first step towards the definition of this manual is the review of the partners' ethical test protocols as well as of any national requirements of the Member States where the research is performed and of international legislation and rules. All these will be then matched, so as to define the required processes.

The present D5.6.1 presents the questionnaire which will be circulated to all partners, so as to collect in a standardised way relevant requirements and procedures.

Furthermore, all the test subjects will have the ability to give informed written consent to participate in the project pilot tests and surveys. This deliverable also includes the main guidelines of the informed consent form, which should be signed by all test participants. This form, adapted according to national legislation, should be approved by the SENSATION Ethics Advisory Board before the test conduct, in addition to any other required national procedure.

## 1. Introduction

The SENSATION Integrated Project will develop technologies to monitor brain state and other bio-parameters **unobtrusively** through the development of novel sensor technologies, innovative signal processing and computational intelligence algorithms, with a special focus on sleep time/environment as well as real time applications (alertness monitoring, detection and prediction), including medical applications. **Brain machine interfacing and biofeedback are not to be performed** within the project and are only considered within its future roadmap. Sleep time offers an unused window of opportunity: sleep time and sleep environment are predictable, controllable, available and measurable. SENSATION research has applications in many areas: Medical, Transport, Automotive, Insurance, Tourism, Sleep Environment (e.g. mattresses, sheets), Infants Industry, Geriatrics, Entertainment, Music, Learning, Sports, and in the Pharmaceutical Industry.

The objective of SENSATION WP5.6, entitled "Ethical and legal issues" is to guarantee that all ethical and legal requirements are fulfilled during the project conduct. There are two types of ethical issues related to the project conduct:

- The *first* has to do with the pilot set-up, to guarantee comfort and safety of participants and/or professionals who take part in them, as well as the security of their personal data, acquired during the pilot evaluations.
- The *second* ethical issue concerns the proposed SENSATION novel tools, as well as the use of the research data, in a way that guarantees privacy and state of the art therapy according to local and European law.

A first step towards the definition of this manual is the review of the partners' ethical test protocols as well as of any national requirements of the Member States where the research is performed and of international legislation and rules. All these will be then matched, so as to define the required processes.

## 2. Definition of issues surveyed

### 2.1 Individual Privacy

The protection of the privacy of test volunteers is responsibility of all involved in SENSATION project. The privacy plays a role at different levels:

- hints to or specific personal information of any individual in publications
- dissemination of data among partners
- access to data – method of access, data formats, method of archiving (electronic and paper)
- restricted access to privacy sensitive information within the organization of the partner
- protection of the privacy within the organisation of volunteers (employers etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.

The ethics manual and procedures of the project must safeguard the individual privacy.

## **2.2 Biological or other adverse effects**

Any interaction with a living body (human being or animal) for the purpose of research must be evaluated for direct biological or other indirect (non-)biological effects on the test volunteer. Both the direct biological intervention (drug, heating, pressure etc.) and other indirect interventions like changing daily rhythm or emotional communication should be evaluated for any adverse effects.

All of these effects, if acceptable, must be clearly informed in the informed consent irrespective of the degree of impact.

## **2.3 Safety and bio-compatibility**

Any equipment or sensor connected to a patient must be evaluated for patient safety and bio-compatibility. Any prototype or equipment purchased must be tested for patient safety against electrical or magnetic hazards. These tests must be performed for complete configuration and not only for individual equipment.

Sensors applied to the patient must meet the standards for bio-compatibility so as to avoid any harm to patient. These harm can be directly visible like skin-damage, burns, rash, etc. or indirect that can cause 'perfusion' of foreign materials.

## **2.4 Hygiene and laboratory safety**

The methods and procedures within a laboratory must safeguard both volunteers and staff against contamination, spread of disease, infections, hazards from the equipment like fume, electrical shock etc.

Various hygienic procedures like sterilisation should be followed according to standards set within the framework of the laboratory and legal requirements.

## **2.5 Informed consent**

Any volunteer must be informed in details of the experimental procedures and all possible consequences of the procedures. Without a consent from the volunteer, no experiment must be performed.

The written information as well as the sought informed consent correspond to the revised version of the *Helsinki Declaration* of 1964. The volunteer should be also informed if the instruments and the sensors and in general the medical devices to be used are prototypes or are CE approved for reasons of patient safety procedures.

## **2.6 Ethics control committee**

Any organization performing experimental work with human beings or animals must have an ethics control committee that must evaluate all the aspects mentioned here and formally approve the experimental procedures.

## **2.7 Organization and insurance issues.**

All partners must oblige to the privacy, safety and bio-compatibility requirements. They should be aware of risks involved while conducting the studies. 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.

## **2.8 Methodology**

A questionnaire has been developed and circulated to all partners, so as to collect practices and legislation in the various countries regarding the issues above. This questionnaire is included in Annex 1.

## **3. Informed consent**

All test volunteers following a detailed oral information, will receive in their own language:

- a commonly understandable written description of the project;
- the project goals,
- the planned project progress;
- the related testing and examination procedures;
- the possible risks and side-effects (if any);
- explanations on confidentiality of the data;
- 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 surveys.

The written information as well as the sought informed consent correspond to the revised version of the *Helsinki Declaration* of 1964, as lastly amended in Edinburgh in October 2000. The *Convention of the Council of Europe on Human Rights and Biomedicine* and the *UNESCO Declaration on Human Genome* have been considered. All rules and procedures according to the *Ethics Committee of the American Psychological Association* have been considered, as published in the *American Psychologist*, May 1996, pp. 529-548 and effective by June 1, 1996 (additionally see: APA ethics code draft 5 by June 2001). Participants with legal guardian aides as well as participants who cannot rationalise the test course and goal based on any impairment of their cognitive abilities will be excluded from any project study.

### **3.1 General requirements for informed consent**

In order to involve a human being as a subject in research, the investigator should obtain the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The

information that is given to the subject or the representative shall be in language understandable to the subject or the representative. 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.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

- (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) a description of any reasonably foreseeable risks or discomforts to the subject;
- (3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- (9) a table of CE marked or in general certified sensors and/or software (medical device in general) as well as the prototypes not yet certified by a certification body that shall be used by the patient underlying the potential risks and legal binds that may be in effect.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- (1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) any additional costs to the subject that may result from participation in the research;
- (4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) the approximate number of subjects involved in the study.

### **3.2 Documentation of informed consent**

Informed consent shall be documented by the use of a written consent form approved by the SENSATION Ethics Advisory Board and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form shall be a written consent document that embodies the elements of informed consent required in the previous section. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

A template is included in **Annex 2** of this deliverable. Parts 1 and 2 will be pre-filled, while Part 3 will be completed by the investigator and the subject. This template will be of course translated into the national language of the country where the experiment is to be performed. The template will be adapted each time to the local specialities of each national ethical committee. However, before each experiment this template should be approved by the SENSATION Ethics Advisory Board, in addition to any other national procedures and permissions required.

### **3.3 Guidelines for compiling the informed consent form**

The following comments may help in the development of an approach and proposed language by investigators for obtaining consent:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or non-standard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent

process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g. subpoena) of the names or other identifying characteristics of research subjects.
- **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided.**
- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the investigator, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.
- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations.** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.

## 4. SENSATION Ethics Advisory Board

All used assessment tools and protocols within SENSATION Pilots will be verified beforehand by its **Ethics Advisory Board** regarding their impact to users' well-being before being applied to the pilot sites. Three renowned experts in the field, chaired by an experienced ethics coach, will constitute the project Ethics Advisory Board, assisted by further external experts, if needed. The Ethics Advisory Board will take responsibility for implementing and managing the ethical and legal issues of all procedures in the project, ensuring that each of the partners/clinics provides the necessary participation in SENSATION and its code of conduct towards the participants/patients. All relevant liaisons with the Commission will be through the ethics coach. The Ethics Advisory Board will define an Ethics Manual (ethics code of conduct of research), leading to the recognition of key ethical and legal issues (i.e. use of tested patient's medical and personal data in project deliverables and publications, ethical use of SENSATION tools and the development of a relevant project policy towards resolving these issues). This will be used to scan all project partners' deliverables and conduct.

Key members of the Consortium will oversee as external experts its ethical policies, including:

- Dr. Alexander Bullinger of COAT-Basel (Switzerland), as leader of the Ethics Advisory Board. He is Medical Director of the Department of Clinical Psychiatry at the University of Basel and he is the leader of relevant Ethics Advisory Boards in various other research projects.
- Dr. Thomas Penzel of Hospital of Philipps-University Marburg, which has a high reputation on "Ethics in Medicine".
- Prof. Alain Muzet of CNRS-DR10, who will safeguard that all tests performed in France abide to the "loi Huriot-Sérusclat" of 1988 and have proper permission from the CCPPRB Committee ("Comités Consultifs de Protection des Personnes se Prêtant aux Recherches Biomédicales"), to be used also as basis for the projects Ethics Manual.
- Prof. Giedrus Varoneckas of IPR (Lithuania), who is a member of the Ethics Committee of the Council of the Institute of Psychophysiology and Rehabilitation.

Before conducting any experiment all partners will have to fill-in an **ethical conduct checklist** (included within the Ethics Manual of the project) and send it to the Ethics Advisory Board of the project. Before starting the test they should have a written permission from both their own Ethical Committee and the project Ethics Advisory Board.

## 5. References

Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Part 46, Protection of Human Subjects,  
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116>

# Annex 1: Questionnaire on ethical and legal issues

To be filled-in by all SENSATION partners

**1. At which level of organization, ethical controls are audited?**

- laboratory or workgroup
- division or department
- institution
- regional
- national

**2. Is there an international or national legislation, which you must follow when performing tests with human subjects?**

- Yes
- No

If Yes, please give details (reference number and short description of procedure):

.....  
.....  
.....  
.....  
.....  
.....

**3. Is there an ethics controlling body in your country?**

- Yes
- No

If Yes, please give details about the procedure:

.....  
.....  
.....

**4. Is there an ethics controlling committee within your organisation?**

- Yes
- No

If Yes, please give details about the procedure:

.....  
.....  
.....

**5. Is there an established ethical control procedure which you must follow before performing tests with human subjects?**

- Yes                       No

If Yes, please give make a brief description of it:

.....  
.....  
.....  
.....  
.....  
.....

**6. Is there an established Data Protection Authority which you must follow before performing tests with human subjects and their personal data?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**7. Do you follow written procedures for protecting privacy?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**8. Do you follow or are aware of any official national or international guidelines on protecting privacy?**

Yes                       No

If Yes, please give make a brief outline and provide references.

.....  
.....  
.....  
.....  
.....

**9. Do you clarify to the participants that all data collected in the activities they are participating is kept confidential and that their anonymity will be protected?**

Yes                       No

If Yes, please give make a brief outline and provide references.

.....  
.....  
.....  
.....  
.....

**10. Do you identify persons and their professions who are authorised to have access to the data collected?**

Yes                       No

If Yes, please give make a brief outline and provide references.

.....  
.....  
.....  
.....  
.....

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

Yes                       No

If Yes, please give make a brief outline and provide references.

.....  
.....  
.....  
.....  
.....

**12. Is every experiment evaluated for any biological or other effects?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**13. Do have written procedures for maintaining hygiene within your own group or institution?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**14. Do have written procedures for safety for employees and volunteers within your own group or institution?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**15. Do you have procedures, facilities and expertise to test or verify equipment for patient safety to protect against electrical or magnetic hazards?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**16. Do have procedures, facilities and expertise to test the patient safety of prototypes you develop?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**17. Do have procedures and expertise to verify bio-compatibility of sensors you use?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**18. Are you aware of formal regulations on hygiene and laboratory safety?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**19. Do you have procedures to perform risk-assessment concerning breach of privacy, safety and bio-compatibility?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**20. Is your organisation insured against risks as a result of breach of privacy, safety and bio-compatibility?**

Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....

If No, please explain the reasons briefly or what corrective actions you take?

.....  
.....

**21. For conducting results ethically and manage the risk, do you need to involve other organisations (unit, division, department etc.) that also control and decide your research activity?**

- Yes                       No

If Yes, please give make a brief outline of it:

.....  
.....  
.....  
.....  
.....  
.....

## **Annex 2: SENSATION Informed consent form template**

### **1. GENERAL INFORMATION**

*this part will be pre-filled by the investigator for each study*

The SENSATION Ethics Advisory Board reviewed this pilot study from the standpoint of the protection of human research subjects. The SENSATION Ethics Advisory Board found the study to be in compliance with the regulations of \_\_\_\_\_.

**1.1 This version of the consent document was prepared on:**

**1.2 This version of the consent document was approved by the SENSATION Ethics Advisory Board on:**

**1.3 Names of the investigators responsible for this project:**

### **2. INFORMATION ON THE RESEARCH STUDY**

*this part will be pre-filled by the investigator for each study*

**2.1 Title of the study**

**2.2 What is the purpose of this research study?**

You are asked to take part in a research study under the direction of \_\_\_\_\_ . Other professional persons who work with him/her may assist or act for them.

These investigators are undertaking a research study to determine whether \_\_\_\_\_ . We expect to find \_\_\_\_\_ , which could lead to better methods of diagnosis / treatment / monitoring.

**2.3 Who can take part in this study?**

**2.4 Why should I consider joining this study as a research subject?**

**2.5 Do I have to become a subject in this study? If I joined the study, can I change my mind and drop out before it ends?**

**2.6 What exactly will be done to me, and what kinds of treatments or procedures will I receive, if I agree to be a research subject in this study?**

**2.7 What kinds of harm can I experience in this study, and what will the investigators do to reduce the chances of harm?**

**2.8 What will the investigators do to make sure that the information they will collect on me will not get in wrong hands?**

**2.9 What kinds of benefit can I expect personally from taking part in this study?**

**2.10 What kinds of benefit to others can come out of this study?**

**2.11 What will the investigators do, if I get injured in the study?**

**2.12 Will I get paid for taking part in this study?**

**2.13 Will I or my health insurance company be charged for any of the costs of this study?**

**2.14 Once I start in this study as a subject, what do I do if I want to find out more about the study, or to complain about the way I get treated?**

**2.15 If I decide not to become a subject in this study, what may happen to me, or what other choices do I have if I need treatment?**

**2.16 Who gets to keep this document, once I sign it?**

### 3. DOCUMENTATION OF CONSENT

*this part will be filled by the subject and the investigator*

#### 3.1 Research subject's identity, and the identity and dated signatures of the subject affirming that consent was given

The information shown below identifying the subject should be entered in the designated spaces at the time of execution of the consent document.

Subject's Name: \_\_\_\_\_

Subject's Birth Date: \_\_\_\_\_

Subject's Reference Number: \_\_\_\_\_

#### 3.2 Patient Consent Form

**Title of the study:**

**Place of the study:**

	Please circle as necessary	
I was informed the effect to be expected, about possible advantages and disadvantages as well as about possible risks verbally and in writing by the test leader about the aim, course of the study.	Yes	No
I have read and understood the written information handed out for the study mentioned above. My questions in connection with the study have been 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 have spoken to:	Dr./Mr./Ms.	
I understand that I am free to withdraw from the study ♦ at any time ♦ without having to give a reason for withdrawing ♦ and without affecting my future medical care	<b>Yes</b>	<b>No</b>
I agree to take part in the study?	<b>Yes</b>	<b>No</b>
The confidentiality of my personal data was assured to me. Personal data will be used anonymised at the publication of the study results. I approve of the fact however under a strict compliance with the confidentiality that the responsible experts of the authorities and the ethic commission may take look for examining and control purposes in my original data.	<b>Yes</b>	<b>No</b>
If aftereffects appear, I will contact Dr./Mr./Ms.		

Signed .....

Date.....

Name (in block letters).....

**3.3 Investigators' confirming statement**

I have given this research subject information on the study, which in my opinion is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights of a research subject. There has been no coercion or undue influence. I have witnessed the signing of this document by the subject.

Investigator's Name: \_\_\_\_\_

Investigator's Signature: \_\_\_\_\_

Date: \_\_\_\_\_