

INFORMATION SOCIETY TECHNOLOGIES (IST)

PROGRAMME



SENSATION

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Ethics Manual

Ethics Manual			
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Authors		Dr. Alex Bullinger (COAT) Thomas Senn (COAT)	

	Dr. Evangelos Bekiaris (CERTH/HIT) Stavroula Maglavera (Pouliadis) Anand Kumar (Medcare BV)
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1 Executive Summary / Introduction

The SENSATION integrated project develops 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 develops an Ethics Manual which should be followed by all partners in addition to any national rules and legislation. This defines 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 has been circulated to all partners, so as to collect in a standardised way relevant requirements and procedures as well as the final consensus on SENSATION ethical test protocol.

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.

2 Definition of issues surveyed

2.1 Individual Privacy

Much medical research revolves around information about people – their age, lifestyle, health and work – drawn from medical records, scientific tests, surveys and interviews. Sometimes, the information also reveals facts about relatives and relationships. These types of information are sensitive and private for many people, although attitudes and expectations vary widely.

The protection of the privacy of subjects is a responsibility of all people involved in research with humans.

Privacy means that the subject can control the access to personal information; he/she decides who has access to the collected data in the future (Patry, 2001).

Due to the principle of autonomy the subjects have to be asked for their agreement (informed consent) before private information can be collected. Subjects who are not capable to give an informed consent should not participate in the study.

It should be also ensured that all the persons involved in research work, understand and respect the **requirement for confidentiality**. The subjects should be informed about the confidentiality policy that is used in the research.

The privacy plays a role at different levels:

- **hints** to or specific personal information of any subject in publications

It should be prevented to reveal the *identity* of subjects in research deliberately or inadvertently, without the expressed permission of the subjects.

- **dissemination** of data among partners
- **access** to data

Define and protect method of access, data formats, method of archiving (electronic and paper), including data handling, data analyses, and research communications.

Offer restricted access to privacy sensitive information within the organization of the partner.

- **protection** of the privacy within the organization of volunteers (employers, etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.

2.1.1 Confidentiality

Furthermore the subjects have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without *anonymisation*. This means that only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the subjects, but only with prior consent of those (Patry, 2001).

While common law establishes some core principles, it does not specify when confidential information may be disclosed to others, in research. Individuals and organizations using confidential information have to take responsibility for deciding what is justified and acceptable on a case by case basis (Medical Research Council, 2000).

2.1.2 Privacy and confidentiality in the behavioural sciences

In the behavioural sciences, respect for privacy and confidentiality is a central concept in the conduct of ethical research with human subjects. Difficulties with privacy issues can lead to difficulties in properly conducting research. If a subject perceives that his or her privacy is threatened this can lead to biased sampling, evasive and/or false responses, and many other impediments that can affect the validity of the results.

As already mentioned, protection of confidentiality implies informing the subjects about what may be done with their data (i.e data sharing).

As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the subjects name and its replacement with a code is no guarantee of complete confidentiality.

Some of the information subjects share is extremely personal and thus very sensitive. An informed consent must be signed. This document also commonly states that the confidentiality will be preserved and the data collected may be shared with other researchers.

A question currently under debate among behavioural scientists is whether a consent form stating that personal data will not be shared precludes sharing of data even if identifying characteristics are removed. The removal of identifying information from data gathered on an individual may not be enough since identities can be reconstructed from disparate data sources.

There are solutions to the challenge of maintaining confidentiality including substituting numerical identifiers for names, aggregating data so that the performance of individuals is not obtainable, encryption or layering data so that researchers who need identifying information can obtain it only after signing a legal document that requires honouring the confidentiality of

individuals. Researchers who do not need identifying information can have free access to aggregated data.

Important question:

How can confidentiality and control access be provided?

Two possibilities:

- The confidential information can be removed.
- Access must be restricted in some ways. (Johnson & Sabourin, 2001).

2.1.3 Personal information in medical research

2.1.3.1 General principles

Personal information must be regarded as confidential. Normally custodian of a large research database or register must ensure they have each persons explicit consent to obtain, hold and use personal information. In most clinical research cases this could be implemented in practice.

1. All medical research using identifiable personal information, or using anonymised data which is not already in the public domain, must be approved by a Research Ethics Committee.
2. All personal data must be coded or anonymised as far as is possible and consistent with the needs of the study, and as early as possible in the data processing. Only personal identifiers that are essential should be held.
3. Each individual entrusted with patient information is personally responsible for their decisions about disclosing it. Health professionals disclosing information should in particular, ensure they are familiar with the advice of the General Medical council on disclosures for research.
4. Researchers must ensure that personal information is handled only by health professionals or staff with an equivalent duty of confidentiality.
5. Principal investigators must take personal responsibility for ensuring that training, procedures, supervision, and data security arrangements are sufficient to prevent unauthorized breaches of confidentiality (Medical Research Council, 2000).

2.1.3.2 Information disclosed without consent

Based on the ethical and legal advice the Medical Research Council considers that in some circumstances it justifiable to use personal information and disclose it to a limited number of other people, without consent.

But the infringement of confidentiality must be kept to a minimum (Medical Research Council, 2000). No such information disclosure without consent is planned or accepted to take place within SENSATION.

2.1.3.3 Anonymisation and Coding

Information should be anonymised so that individual identities can not be revealed. Anonymisation provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

Coded information contains information which could readily identify people, but their identity is concealed by coding. The key to which is held by members of the research team using the information.

Anonymised data with links to personal information, is anonymised to the research team that holds it, but contains coded information which could be used to identify people. The key to the code might be held by the custodians of a larger research database.

Unlinked anonymised data contains nothing that has reasonable potential to be used by anyone to identify individuals.

As a minimum *anonymised data* must not contain any of the following, or codes for the following:

- Name, address, phone/fax. Number, e-mail address, full postcode.
- Any identifying reference numbers.
- Photograph or names of relatives.

With both linked and unlinked anonymised data it is sometimes possible to deduce individuals identities through combinations of information. The most important identifiers are:

- The *age*, if a small sample size is taken; in this case there has to be compromised between scientifically precision and the protection of the individual privacy.
- Rare disease or treatment, especially if an easily noticed illness is involved.
- Partial post-code, or partial address.

- Place of treatment.
- Rare occupation or place of work.
- Combinations of birth date, ethnicity, place of birth, and date of death.

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information- whether data contain combinations of such information that might lead to identification of individuals or very small groups. How much of this potentially identifying information can be safely included in data that is assumed to be unidentifiable can only be judged on a case by case basis taking into account the sample size, the ways in which results will be published and used (Medical Research Council, 2000).

In Annex 4 Guidelines from the *American Psychological Association*, the *german society of psychology* and the *occupational union of german psychologists* concerning the anonymisation of data can found.

2.1.3.4 Protection of personal data in member states of the EU

The legislation and the guidelines of the European States are quite heterogeneous. To what extent entities that keep records must inform any governmental authorities is heterogeneous in the different states as well. The legislation about the protection of personal data in the new EU members was not being studied yet. In the final version we will inform about this issues.

2.2 *Comfort and safety of participants and staff within the projects*

2.2.1 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.

2.2.2 Safety and bio-compatibility

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

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

2.2.3 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.

2.3 Informed consent

Respect for persons requires that subjects, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided, when adequate standards for informed consent are satisfied.

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. 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.

2.3.1 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 according to the American Psychological Association (2002) the following information shall be provided to each subject:

1. The purpose of the research, expected duration, and procedures;
2. the possible risks, discomfort, adverse effects, and side-effects (if any);
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. explanations on confidentiality (and limits) of the data;
5. Their right to decline to participate and to withdraw from the research once participation has begun and the foreseeable consequences of declining or withdrawing.

6. whom to contact for questions about the research and research participants rights.
 - Appropriate insurance or indemnity to cover the participant in trial should be provided.
 - A table of certified sensors and/or software (medical device in general) as well as the prototypes not yet certified that shall be used by the patient underlying the potential risks and legal binds that may be in effect should be also provided.

(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.

2.3.2 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 either case, 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.

2.3.3 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.
- **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.

2.4 Deception

Researchers do not conduct a study involving deception unless that they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

Researchers do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

Researchers explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data (American Psychological Association, 2002).

2.5 Debriefing

Researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the researchers are aware (American Psychological Association, 2002).

Researcher also inform the subjects about symptoms or diagnoses of diseases that have been discovered during the observation; especially if the symptoms have not discovered yet by a physician. Relevant test results will be provided to subjects General Practitioner.

If tests point strongly to a subjects incapability to drive a car, the subjects will be informed hereof and advised to undergo further testing and examination by a medical / psychological traffic expert of her choosing.

The debriefing has to be documented and will be signed by both sides.

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, informed consent as well as the 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. Appropriate insurance or indemnity to cover the participant in trial should be provided according to the regulations of the local ethics committee. In any case the SENSATION Ethics Advisory board recommends insuring the subjects.

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 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, constitute the project Ethics Advisory Board, assisted by further external experts, if needed. The Ethics Advisory Board assumes 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 of SENSATION consists of the following persons:

- Prof. Dr. V. Dittmann, director of the institute for forensic medicine University Basel.
- Dr. Alexander Bullinger of COAT-Basel (Switzerland), as leader of the Ethics Advisory Board. He is Assistant 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.
- Lic. Phil I Thomas Senn, Researcher , COAT-Basel & University of Zürich

Before conducting any experiment all partners will have to fill-in an **ethical conduct checklist** (Annex 3 of this deliverable) 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.

4 Conclusions

In this manual we have described the general standards for the ethical conduct of research. We have included the ethical principles from 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*, recommendations of the *Medical Research Council* and the *American Psychological Association* as well as excerpts of the ethical guidelines from the *german society of psychology* and *occupational union of german psychologists*. These are general principles generated by international organisations. According to the point of view of the corresponding local Ethics committees in the countries of our research partners, the emphasis of the different principles may vary very widely. Local modifications are probable. Therefore it will be very important to analyse the local regulations and guidelines concerning the ethical conduct of research that is practised by our partners in the different countries. We have sent a questionnaire on ethical and legal issues (attached in ANNEX1) to our partners, through which we are analysing the answers. This might take some time, because issues mentioned in the questionnaire have partially to be discussed of with the local ethics committees. Until now we have not received all of the questionnaires we have sent – but within the next few weeks we will be able to complete the review of these questionnaires. In the SENSATION ethics Manual-revised form we will submit the analyses of these questionnaires.

Meanwhile we have included in this *draft* an **ethical conduct checklist** that summarizes the keypoints that have to be considered when doing research with humans (attached in ANNEX 3).

5 References

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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:

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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:

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

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.....

7. Do you follow written procedures for protecting privacy?

- Yes No

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

.....

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

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

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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.

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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.

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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.

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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.

.....
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.....

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

- Yes No

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

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

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

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.....

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:

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.....

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

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.....

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:

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.....

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 and to protect against electrical or magnetic hazards?

- Yes No

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

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.....
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.....

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

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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:

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

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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:

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.....

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

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

- Yes No

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

.....
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.....

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:

.....
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.....

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:

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

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:

.....
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.....

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	Yes	No

consists for me in the legally specified scale. The insurance was constructed by for this study.		
I have spoken to: _____ Dr./Mr./Ms.		
I understand that I am free to withdraw from the study <ul style="list-style-type: none"> ◆ at any time ◆ without having to give a reason for withdrawing ◆ and without affecting my future medical care 	Yes	No
I agree to take part in the study?	Yes	No
The confidentiality of my personal data was assured to me. Personal data will be used anonymised at the publication of the study's results. I approve of the fact however under a strict compliance with the confidentiality that the responsible experts of the authorities and the ethics commission may take look for examining and control purposes in my original data.	Yes	No
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: _____

Annex 3: Ethical Conduct Checklist

1. Please give a short description of the study.

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

The study is related to SENSATION project Nr.

2. Do you conduct a study involving humans or animals?

Yes No

If no, no further arrangements/questions.

If yes, do you follow some organization / company related ethical guidelines for research?

.....

3. Is there a request for the local ethical committee?

Yes No

if no, why not?

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

Privacy & Confidentiality

4. Is the use of data which contains identifiable personal information approved by the Research Ethics Committee?

Yes No

if no, why not?

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

5. Is anonymised data which is not already in the public domain, approved by the Research Ethics Committee?

Yes No

if no, why not?

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

6. Is all personal Data coded and only personal identifiers that are essential are held?

Yes No

if no, why not?

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

7. Is personal information handled only by health professionals or personal with an equivalent duty of confidentiality?

Yes No

if no, why not?

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

8. Is no personal information disclosed without the consent of the involved subjects?

Yes No

if no, why not?

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

9. Does anonymised data not contain: Name, address, phone/fax. Number, e-mail address, full postcode; any identifying reference numbers; photograph or names of relatives?

Yes No

if no, why not?

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

Comfort and safety of subjects

10. Are the direct biological intervention (drug, heating, pressure, etc.) and other indirect interventions, like changing daily rhythm or emotional communication are evaluated for any adverse effects.

- Yes No

if no, why not?

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

Informed Consent

11. Do you follow Informed Consent as described in the existing manual?

- Yes No

if no, why not?

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

12. Did you inform subjects about purpose of the research, expected duration, and procedures?

- Yes No

if no, why not?

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

13. Did you inform subjects about possible risks, discomfort, adverse effects, and side-effects?

- Yes No

if no, why not?

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

14. Did the subjects receive a description of any benefits to the subject or to others which may reasonably be expected from the research?

Yes No

if no, why not?

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

15. Did you inform subjects about confidentiality (and limits) of data?

Yes No

if no, why not?

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

16. Did you inform subjects about their right to decline to participate?

Yes No

if no, why not?

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

17. Did you inform the participants whom they can contact for questions about research and research participants rights?

Yes No

if no, why not?

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

18. Is Informed consent documented according to 2.3.2 (Documentation of informed consent) in this manual?

Yes No

if no, why not?

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

19. Are the guidelines for compiling informed consent (2.3.3) considered by the investigators when obtaining informed consent of the subjects?

Yes No

if no, why not?

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

Deception

20. Is deception involved ?

Yes No

If yes to 14. / else 16.

21. Have the researcher determined that the use of deceptive techniques is justified by the study’s significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

Yes No

if no, why not?

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

22. Researchers do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress!

True false

Reminder: This statement must be true!

Debriefing

23. Do researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results and conclusions of the research, and do they take reasonable steps to correct any misconceptions that participants may have of which the researchers are aware?

Yes No

if no, why not?

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

Insurance

24. Is appropriate insurance or indemnity to cover the participant in trial provided according to the regulations of the local ethics committee?

Yes No

if no, why not?

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

Please send the checklist and attached any organizational or company related ethical guidelines to:

COAT Basel
Psychiatrische Universitätsklinik Basel
Ethics Advisory Board
K. Estoppey
Wilhelm-Klein Str. 27
4025 Basel

Annex 4: Anonymisation in the Code of Ethics

(American Psychological Association)

- **6.02 Maintenance, Dissemination and Disposal of Confidential Records of Professional and scientific Work**

a) [Confidentiality of records]. “Psychologists maintain confidentiality in creating, storing, accessing, transferring, and disposing of records under their control, whether these are written, automated, or in any other medium.” (American Psychological Association, 2002).

This standard requires psychologists to take reasonable precautions to protect the confidentiality of client/patient records. It (6.02a) does not establish separate standards for records that are stored electronically. But regulations could follow concerning security of electronic files (in case of thievery, virus attacks, discarding of electronic Medias) (Knapp, S. & VandeCreek, L. 2003).

b) [Confidentiality and Databases]. “If confidential information concerning recipients of psychological services is entered into databases or systems of records available to persons whose access has not been consented by the recipient, psychologists use coding or other techniques to avoid the inclusion of personal identifiers.” (American Psychological Association, 2002).

c) [Transfer of Confidential Records.] Psychologists make plans in advance to facilitate the appropriate transfer and to protect the confidentiality of records and data in the event of psychologists’ withdrawal from positions or practice.” (American Psychological Association, 2002).

Psychologists should take reasonable measures to protect their records in anticipation of retirement, disability or death. The ethics code does not give specific instructions on how this is to be done (Knapp, S. & VandeCreek, L. 2003).

The ethical guidelines

(of the german society of psychology and occupational union of german psychologists.)

- B. III. *Acquaintance of Data*

- III. 2. Recording, inquiry and storage of data

- Only after an informed consent has been signed by the patient/subject data can be recorded.

- Recordings have to be secured against illegitimate use.

- C.V. *Publication of research results*

- 2. Data that identifies personal characteristics of the subjects has to be anonymised.