NEMESIS

Empowering the Changemakers of Tomorrow

D8.1: Ethics requirements

Requirment No. 5

NEMESIS project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 770348.

Document details	
Project Acronym:	**NEMESIS**
Project Name:	**New Educational Model Enabling Social Innovation Skills development**
Project URL:	**www.nemesis-edu.eu**
Project Type:	**Innovation Action (IA)**
EU CALL:	**CO-CREATION-01-2017**
Grant Agreement No.:	**770348**
Project Start Date:	**October 2017**
Project End Date:	**January 2021**
Deliverable:	**D8.1**
Due date of Deliverable:	**Month 3**
Actual Submission Date:	**Month 4**
Name of Lead Beneficiary for this deliverable:	**Friedrich-Alexander-University Erlangen-Nürnberg (FAU)**
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Revision:	**0.3**
Dissemination Level:	**RE**

Document History			
Version	**Date**	**Comment**	**Modifications made by**
0.1	2/01/2018	1st draft	Aristidis Protopsaltis FAU-ILI
0.2	15/01/2018	2nd draft	Aristidis Protopsaltis FAU-ILI
0.2	24/01/2018	Review and corrections	Ioanna Garefi STIMMULI Ivan Diego Rodriguez Valnalon
0.3	29/01/2018	Final draft	Aristidis Protopsaltis FAU-ILI

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1. Executive Summary

Ethics is an integral part of the NEMESIS project from beginning to end since working with participants is vital for the project's success, and ethical compliance is seen as pivotal to achieve real research excellence. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research.

The purpose of the Ethics requirement deliverable is to outline the ethical requirements related to NEMESIS project and how the NEMESIS consortium will address these requirements. The NEMESIS project will be conducted in compliance with fundamental ethical principles, especially the Article 19 "Ethical principles" of Regulation No. 1291/2013/EC of the European Parliament and of the Council which states the fundamental principles of the H2020 ethics in research.

2. Introduction

The aim of this document is to describe the ethical approach and data management procedures that the NEMESIS consortium will follow throughout the duration of the project, to achieve research excellence. This deliverable defines a consistent plan and set of procedures to guarantee the ethical compliance with the EC fundamental ethical principles throughout it duration.

The ethical requirements and the data management and security procedures presented in this document are applicable to all the activities of the project. Hence, compliance to these procedures is mandatory for all partners.

3. Ethical Standards

The ethical standards and guidelines of Horizon 2020 will be rigorously applied, in all consortium countries where the NEMESIS research is carried out. All participant institutions are required to comply with the EU directive 95/46/EC on data protection and with any updates on standards or requirements it might receive during the lifetime of the project.

Additional ethical standards relevant to the NEMESIS are:

1) Current Legislation and Regulations in the country where the research will be carried out;
2) European Legislation;
3) International Conventions and Declarations.

In particular the relevant European legislations are:

- Article 19 "Ethical principles" of Regulation No. 1291/2013/EC of the European Parliament and of the Council which states the fundamental principles of the H2020 Ethics in research[1];
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [2];
- Ethical issues of healthcare in the information society. Opinion of the European Group on Ethics in Science and New Technologies No. 13, "Ethical issues of healthcare in the information society" [3];
- The Charter of Fundamental Rights of the European Union (2000)[4];
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)[5];

[1] REGULATION (EU) No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
[2] DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
[3] Wagner, Ina (1999) *Ethical issues of healthcare in the information society. Opinion of the European Group on Ethics in Science and New Technologies No. 13, 30 July 1999.* [EU Commission - Working Document]
[4] CHARTER OF FUNDAMENTAL RIGHTSOF THE EUROPEAN UNION 2000/C 364/01
[5] DIRECTIVE 2002/58/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

- Recommendation No. R (97) 18 of Committee of Ministers to Member States concerning the protection of personal data collected and processed for statistical purposes, adopted on 30 September 1997[6];
- Directive 96/9/EC of the European Parliament and the Council of 11 March 1996 on the legal protection of databases[7];
- The project will be carried out in accordance with the Declaration of Helsinki (DoH) of human rights, 2013[8].

More precisely, the EC's ethical requirements are stipulated in Article 34 – Ethics. We address the ethical issues outlined in Article 34.1 and Article 34.2. Article 34.1 and 34.2 is provided below for easy referencing.

Article 34.1 *Obligation to comply with ethical and research integrity principles*

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity), and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells). The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity. This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;

[6] RECOMMENDATION NO.R (97)
[7] DIRECTIVE 96/9/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL
[8] World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA. 310 (20): 2191–2194.

- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account; use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

Article 34.2 *Activities raising ethical issues*

Activities raising ethical issues must comply with the 'ethics requirements' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the Commission (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

4. NEMESIS Ethical procedure

The NEMESIS project will touch on issues in human research ethics by collecting data from respondents via its surveys and interviews that will take place in WP1, WP2 and WP5, during pilot implementation in the co-creation labs and the implementation of the other learning activities in WP4, the engagement and dissemination activities and data collected through the project's platform. In particular, during these activities data will be collected from Social Innovation Practitioners, SI organizations, teachers, school leaders and parents. Interviews might be recorded and in that case all collected data from the research activities will be securely stored on FAUbox, which is the FAU's electronic cloud based storage systems fully respecting the privacy and data protection rights, according to EU regulations complying with Directive 95/46 EC and Ethics guidelines in data storage and treatment within H2020.

However, data will be also selected from students. NEMESIS will pay particular attention on ethics since it aims at testing the educational model with students of primary and secondary education (aged from 7 to 18) who are unable to give informed consent. Students' personal data will be gathered through the educational activities including the development of their digital stories. To ensure protection of sensitive data, the project from the very beginning will share a detailed description of the pilots to all partnering schools. Since pilots involve the participation of children, parents will be asked to sign a permission form (informed consent, see appendix 1) allowing their child to participate in the project. On the other hand, children will also be informed about their involvement in the project activities and their agreement will be essential so as to ensure that they are not subjected to any form of coercion. The NEMESIS consent and assent forms will be adapted from the templates of World Health Organization (WHO)[9] and can be found in Appendices 1 and 2.

The principles that will be used will be in line with ethical guidelines of the European Educational Research Association for upholding high academic and professional standards. The main principles are as follows:

- The project will respect the autonomy of research subjects. Participation will be absolutely voluntary and anonymous.
- The project will avoid any harm to the participants. Students or schools will not encounter any positive or negative consequences because of participation in the project.
- Privacy and data protection will be secured. Identification of individual participants is impossible and data will be stored following the project ethical guidelines.

Teachers and parents will be given information about the researchers' contact information, the research topic, the method of collecting data and the purpose for which data would be collected, how it would be archived for secondary use and the voluntary nature of participation. The participants could also ask for additional information about the study and the researchers.

In addition, the project will respect the available ethical principles for conducting research with human participants in the pilot countries Greece, France, Portugal, Spain and the UK.

In relation to informed consent, the consortium will adhere to the following principles. Research activities will be conducted with individuals or entities having legal competence, which includes the requirement that they will be in a position to understand their role in the project and the implications of releasing data. Participants will be given information in the form of an information sheet and online including information on who will benefit from their participation in the research and what risk or burden they are undertaking by participating (among others). **In the case of students, informed consent will be obtained by their parents**. The consortium will outline the procedures that will be implemented in the case of incidental findings. Participation in the project will be fully voluntary and all participants will be given the opportunity to ask questions and receive understandable answers before making decisions about their participation. The consortium will follow principles of informed consent such that participants have the right to withdraw and

[9] http://www.who.int/rpc/research_ethics/informed_consent/en/

terminate their participation in the research at any time and will be reminded about their right before participation.

In relation to data protection, the following principles will be put in place. As stated above, individuals will be contacted as a result of the research and engagement activities. More specifically, collection of personal data may take place during the various initiatives of the project; the surveys focus groups, interviews, workshops and final conference. Participants will be given information about how their data will be collected, protected during the project and either destroyed or re-used at the end of the research. In the latter case, they will be reminded that they may withhold such data; and that any such additional activities will remain strictly within the bounds covered by their informed consent form. If a plan to reuse data is considered, participants will be given information about this as soon as it becomes available and be given the opportunity to consent or withdraw their data. As part of each communication the participant receives from the project, they will be given an opportunity to opt-out of further communications and have their data deleted. All issues pertaining to ethics approval will be forwarded to the Project Board for notification and approval. As part of the consortium efforts to ensure ethical and data protection compliance throughout the project, the consortium has included a task and associated deliverable in WP7 to verify and further develop an internal ethics review, data protection and procedure document (Data management and RRI plan).

4.1. Ethics Manager and Ethics Expertise

The NEMESIS consortium has foreseen at the proposal stage the role of an Ethics Manager (EM). The role of the EM will be to guarantee that the project is proceeding in a responsible and ethically acceptable manner according to the recommended Responsible Research and Innovation aspects, the EC ethical guidelines and Charter of Fundamental Rights of the European Union among others. This role will be assigned to Mr Ivan Diego (Valnalon).

Additionally, the NEMESIS consortium will strengthen the expertise in the ethics and IT by involving the head of the Research Unit for Media Education and head of ILI Prof. Dr. Rudolf Kammerl. Chair for Pedagogy with the Focus on Media Education, with part of his research covering digital learning in primary schools. His expertise will guide us in addressing successfully the complex ethical issues arising in the NEMESIS project.

Furthermore, ILI will contact the Department of Compute Science at FAU, to seek further support with the issues of privacy, confidentiality and data safety and security. The identified contact is Prof F. Freiling who is the chair of IT Security.

Finally, Mr Fred Neuman, head of technical development at ILI, and the ILI team have been successfully dealing with the issues of student privacy, data safety, data security and confidentiality since they are responsible for the University's LCMS, StudOn, where all the necessary measures have been taken to create a safe, confidential and secure environment.

4.2. Procedures and criteria for identifying and recruiting research participants

The project consortium recognizes the importance of ethical issues related to ICT research and technological developments. It fully respects ethical principles such as data security, the right to privacy or the protection of private virtual identity.

NEMESIS will not only respect current national and international regulations and laws (presented in section 3) while conducting the research, the partners will, in particular, respect the ethical principles expressed in the Charter of Fundamental Rights of the European Union and in the European Human Rights Convention[10], especially for ethics and ICT, ethics guidelines provided by the Union member states participating in the project and those provided by the teaching authorities supporting this project. Assuming (as a prerequisite) that a research project has some serious potential to make significant advances in technologies that could impact the quality of life, it is often agreed that respect of privacy and individual rights, and good ethical practice in general, is based on four key principles:

1. Respect for autonomy: based on people's decisional capacity
2. Beneficence: balancing the benefits against potential risks
3. Non-malifience: the imperative to do no harm
4. Justice: ensuring fairness in the distribution of risks and benefits

The principles outlined above should always pertain regardless, and the areas that require particular attention in any project like NEMESIS should at least cover the following issues:

- Potential participants should be fully informed of the study, and any attendant risks;
- Participants should have the capacity to understand the implications of taking part, and any potential future impact;
- Any decision should be entirely voluntary, as should the right to withdraw at any point without prejudice.

NEMESIS will involve the collection of human collaborative patterns, including data, audio and visual records of what takes place in those settings. The personal information is important to be treated with care and to be adequately addressed by the trust and privacy issues. All provided information will be confidential, IDs or alias will be used to replace names. This procedure is not new to the consortium, and especially to the coordinator, FAU, since we have been doing this in previous projects without any problem, and always with the full awareness and consent of the participants.

In the following, we summarise the specific measures that will be taken in NEMESIS. During the project, partners will work with teachers and educators to ensure that those involved in NEMESIS will:

- voluntarily give informed consent of their participation,
- be given the right to opt out of the project at any time for any (or no) reason,

[10] http://cordis.europa.eu/fp7/ethics-ict_en.html

- not be discriminated in terms of achieving the learning outcomes as set by their national curriculum,
- Anonymization and censoring,
- Data access and storage,
- Data sanitisation.

As part of the consortium agreement, all NEMESIS partners will take all the necessary steps to ensure that all participants understand the project objectives, and the processes employed during NEMESIS to achieve them and how we intend to report on the outcomes.

Where activities during the piloting/evaluation phase in various countries warrant ethical approval, this will be completed at the lead national partners' institutions according to institutional and/or national ethical regulations. Furthermore, agreement by all partners to adhere to local ethical regulations prior to the commencement of the project was a requirement of the NEMESIS consortium agreement that has been signed by all consortium members.

Identification, initial contact, screening and recruitment of potential human participants form the basis of the informed consent process. The research team is responsible for creating a recruitment environment that is not only effective but is also ethical and complies with the EU and national regulations. Therefore, attention will be paid at the appropriate procedures for the initial identification, contact, screening and recruitment of potential participants. Both the screening and the recruitment process will demonstrate respect for the dignity and autonomy of the potential participants by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment and/or screening purposes.

For the recruitment of the research participants, the following methods will be used:

- Advertisements, flyers, information sheets, notices, internet postings and/or media;
- Direct recruitment of potential study participants;
- Recruitment letters.

NEMESIS, however, is in a privilege position to have 3 schools and school cluster organisations and a local educational authority as full partners that will serve as test beds. They have already given their consensus at a higher level. Additionally the consortium will seek individual consensus from all the students or students' parents and teachers that will take part in the piloting phase. If class time will be taken for research participation, alternative activities will be provided for those who decline.

4.3. Informed consent procedures

In relation to informed consent, the consortium will adhere to the following principles. All activities will be conducted with individuals or entities having legal competence, which includes the requirement that they will be in a position to understand their role in the project and the implications of releasing data. Participants will be given information in the form of an information sheet and online including information on who will benefit from their participation in the research and what risk or burden (if any) they are undertaking by participating (among others). The consortium will outline the procedures that will be implemented in the case of incidental findings and whether there will be any potential for commercial exploitation of the research. Participation

in the project will be fully voluntary and all participants will be given the opportunity to ask questions and receive understandable answers before making decisions about their participation. The consortium will follow principles of informed consent such that participants have the right to withdraw and terminate their participation in the research at any time and will be reminded about their right before participation. The informed consent and assent forms can be found in Appendices 1 and 2.

4.3.1. Consent

Because we are collecting personal data, and because we recognise that giving consent is more than just ticking a box once and for always, NEMESIS is planning the following approach to gaining and maintaining consent of those using the online platform: we respect that individuals may change how they feel and so we want to make sure that we engage with our users and develop a relationship with us.

Procedure

Upon signing up in the NEMESIS platform, users or participants will be presented with the *Participant Information* brief above electronically at first, but with an option to receive softcopy or hardcopy as shown. They will then be presented with the following dialogue:

Requirement from the ethics report: Templates of the informed consent forms and information sheet must be submitted.

> Now that you have seen our privacy policy, do you have any questions? You can email us here, and we will get back to you as soon as possible. Note that the email address you provide will only be used for this purpose and will not be retained.
>
> If you're happy, please continue:
>
> I have read and understood the information about the platform and the privacy policy and have asked any questions.
>
> I understand that information I provide, such as my name, contact details will remain between me and the platform, and will not be shared with any other platform users or any third party.
>
> Finally, I understand that information like my age-group, my school, my country, will be used by the platform to facilitate the creation of an online learning community.
>
> If you are happy with all of these, please select
>
> **I'm happy to proceed**

Otherwise please select

No Thank You

At quasi random periods, between 20 and 50 days, we will present users on sign on with one of the following:

> Thank you for using the NEMESIS platform. If you have any questions, or want to discuss anything at all about how we have used any data on you or what data we hold, please just email us using the link below and we'll come back to you as soon as we can.
>
> We hope you're still enjoying the NEMESIS platform? If not, you can always contact us via the link below to discuss any concerns or issues. And of course, you can always leave at any time and delete your profile.
>
> Sometimes, it's good to think about how things are going and whether you are getting what you want out of our service. If you've any feedback, please contact us via the link below. And if you want, you can always look at our privacy policy via this link: <link>

As the final step of registration, users will be presented with the following screen.

> I have read and understood the information about the platform and the privacy policy and have asked any questions. I understand what data will be collected and how it will be used. I understand that at any time I may withdraw or request support or feedback.
>
> If you agree, please enter your name in the following box:

The user is invited to enter any sequence of letters (all letters and a minimum of three) so that they enter more than a single keystroke.

4.4. Assent for children

Where children are to be included as participants, arrangements for taking consent and, where appropriate, assent should be clear and the different information, consent and assent documentation will be clearly labelled for use. Informed assent is the expressed willingness to participate in the research. For younger children who are by definition too young to give informed consent, but old enough to understand and agree to participate in research activities, the child's parents "informed assent" will be sought. In determining whether children are capable of assenting, the ages, maturity, and psychological state of the children involved will be taken into account. Children will be provided with essential information and asked whether or not they wish

to participate in the research. Adequate provisions will also be made for soliciting the permission of each child's parents or legally authorized representative.

4.5. Procedures for data collection, storage, protection, retention and destruction

4.5.1. General Data Management

In common with other projects of this kind, and following the recommendations of local and international data protection procedures[11],[12] , NEMESIS will be structured around a data controller (FAU) ultimately responsible to end users for their data and to the rest of the consortium for agreeing and enforcing guidelines to the data processors. Data processors will be partners (Valnalon, ASOCCE, SEi, CEIP Los Albares, HJS, AEMaia) directly responsible for the processing of personal data in accordance with the guidelines approved by the data controller.

Data will be stored with the servers of the ILIAS platform, located in Germany at ILI's premises, and data processing will be done in accordance with the laws of the country of the data source (i.e., the users) in combination with the appropriate laws of the country where the servers are installed. All data will be stored on secure, password-protected servers and not third party will have access. There will be appropriate backups and firewall protection. The ILIAS platform is an open sources platform but it will be installed locally, protected by password and firewall and not third party, outside the consortium will have or be able to access the data.

Finally, personal data collected during the project will be destroyed at the end.

Responses provided in questionnaires, interviews, workshop and focus group might be recorded. In case of recordings, the recorded data will not include any personal identification; hence it will not be possible to identify participants afterwards. Information will be processed during the phase of data analysis and will be shown in project reports. It will not be possible to identify the source of the information. The results of this investigation may be published in scientific journals or conferences and may be used in further studies. Nothing of the provided personal data will be handled out to third parties.

4.5.2. Data access and storage

Participants will be informed as part of the consent process that this material was intended for release to the Technology Enhanced Learning (TEL) research community. Early versions (prior to anonymization and censoring) will be kept on password-protected file systems. Data storage and handling processes will ensure protection and confidentiality: All data will be stored on secure, password-protected servers at ILI's premises and not third party will have access. There will be appropriate backups and firewall protection. If data is to be released outside NEMESIS, a second

[11] https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf

[12] http://ec.europa.eu/justice/data-protection/data-collection/obligations/index_en.htm

approval process will be carried out for all involved participants. Data will be used for research purposes only, and we will hold the data only for the time of research, and as long as the scientific community can benefit from these data.

4.5.3. Anonymization and censoring

Segments of collected data that participants wish to be deleted will be erased. The content will be removed from the data records and replaced by a "deleted" tag. Participants will be identified exclusively by an ID code or alias throughout the data documentation (except where their names naturally occurred in a voice stream). All names and contact information will be deleted from the demographic database prior to release.

4.5.4. Data sanitisation

Data sanitisation will be used to protect the privacy and confidentiality of students' data. The sanitisation method to achieve that is the one proposed by the German Federal office for IT Security. It is called the VSITR standard, which overwrites the hard-drive with 7 passes. For the first 6 passes, each overwrite reverses the bit pattern of the previous pass, inverting the bits in order to destabilize the remnants of data that may exist on the edges of the track of the disk to which the data is written. The final pass amplifies the effect, overwriting the entire disk with "01010101"; this is widely considered to be a secure method of erasing data.

4.6. Preventing misuse of research findings

The NEMESIS consortium is committed to avoid and prevent any misuse of research findings. To avoid the misuse of research findings the following steps will be taken:

4.6.1. Plagiarism

Plagiarism will be avoided at all documents. If there is a word-for-word copying beyond a short phrase or six or seven words of someone else's text, that section will be enclosed in quotation marks or indented and referenced, at the location in the manuscript of the copied material, to the original source.

4.6.2. Integrity of Data

All records should include sufficient detail to permit examination for the purpose of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions. Meticulous record-keeping is a sound scientific practice which provides an accurate contemporaneous account of observations that become a permanent reference for the researcher, who otherwise might not remember several weeks, months, or years later exactly what had been observed or what methods had been used.

All data should be recorded contemporaneously with the production or observation of the data.

Questionnaires should be stored without identifiers, using only code numbers to link them to computerized files. Records, including transcripts of taped interviews, can be redacted to remove names and other key identifiers. The rules and procedures for carrying out such redactions should be available to anyone who reviews the data.

4.6.3. Use and Misuse of Data

NEMESIS researchers are acquainted with the relevant quantitative methods available for processing data, including graphical and tabular methods of presentation, error analysis, and tests for reliability. Research integrity requires not only that reported conclusions are based on accurately recorded data or observations but that all relevant observations are reported. It is considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions, including the purposeful withholding of information about confounding factors. NEMESIS partners are committed to avoid that. Whenever necessary, help is will be provided by ILI-FAU.

4.6.4. Storage and Retention of Data

Data should be stored securely for at least five years after completion of the project, submission of the final report.

4.6.5. Authorship and Other Publication Issues

Publication of research results is important as a means of communicating to the scholarly world so that readers may be informed of research results and other researchers may build on the reported findings. The NEMESIS reported data and methods will be sufficiently detailed so that other researchers could attempt to replicate the results. NEMESIS publications should be timely but should not be hastened unduly if premature publication involves a risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations.

FAU-ILI has a long standing tradition in publishing scientific results and is committed to guide other partners that might need assistance in with authorship and publication issues.

5. Appendix 1

Informed Consent Form for _____

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child

to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

Purpose

Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

Type of Research Intervention

Briefly state the intervention. This will be expanded upon in the procedures section.

Selection of Participants

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

Voluntary Participation

Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

Procedure

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

Risks and Discomforts

Explain any risks or discomforts including any limits to confidentiality.

Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

Reimbursements

State clearly what you will provide or not provide the participants with as a result of their participation.

Confidentiality:

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

Sharing of Research Findings

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

Right to refuse or withdraw

Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted). State also that the proposal has been approved and how.

PART II: Certificate of Consent

Certificate of Consent

I have read the foregoing information, and I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I_____have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands what the participation of their child/children entails:

I confirm that the parent was given an opportunity to ask questions about the NEMESIS study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____

Print Name of Researcher/person taking the consent_____

An Informed Assent Form will ____ OR will not ____ be completed.

6. Appendix 2

NEMESIS Project 

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

Informed Assent Form for _____

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you do and clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

Choice of participants: Why are you asking me?

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

Participation is voluntary: Do I have to do this?

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

I have checked with the child and they understand that participation is voluntary __(initial)

Procedures: What is going to happen to me?

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

I have checked with the child and they understand the procedures _____(initial))

Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

I have checked with the child and they understand the risks and discomforts ____(initial)

Benefits: Is there anything good that happens to me?

Describe any benefits to the child.

I have checked with the child and they understand the benefits_____ (initial)

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided.

Confidentiality: Is everybody going to know about this?

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

Sharing the Findings: Will you tell me the results?

Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You may want to re-emphasize that participation is voluntary and any limits to this.

Who to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below._____(initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____

Date:_____

day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands what will be done:

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____

Day/month/year

Copy provided to the participant _____(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)