

**ENRAH for SMEs Project**  
**Funded by the European Commission, FP6 2005-2007**

**Report on ethical issues in the  
ENRAH Project**

*prepared by*

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**Vienna, Austria**  
**24 January 2006**  
**version 3.0**

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## ENRAH Objectives

- *Forwarding European Research on Alternating Hemiplegia of Childhood (AHC)*
- *Partnering of AHC Patient Representatives, AHC treating neurologists, Genetic Researchers from nine EU countries in the European Network for Research on AHC (ENRAH)*
- *Involving industry, SMEs, in research on AHC and related diseases*
- *Establishing and maintaining a European Registry of AHC patients, including their disease and family profiles*
- *Facilitating of sharing of clinical data, Human Biological Materials, and clinical trial data*

*‘sharing the burden of disease’*

### Introduction

The consortium of partners composing the ENRAH Project is committed to bringing the collective strength of research across countries and disciplines to addressing Alternating Hemiplegia of Childhood (AHC). In establishing the project’s design, the consortium members agreed on a set of values (Annex I, chapter 9): to ensure 1) the **respect for, and protection of**, basic freedoms, privacy and confidentiality, and rights of all project participants, particularly the patients and families; 2) the **security** of all data and biological materials in their collection, storage, transfer, and access; and 3) the **high quality** of data for the Registry. The commitment to, and promotion of, these values provides a central framework for ENRAH’s engagements and activities.

The Report identifies arising **ethical issues** in the project and proposes a format for addressing them. It also examines the extent to which these values have been realised in the project during its first six months. The Report finds that the ethical challenges are large and constant, and there is a need for a procedural approach in order to consistently address them within the framework of the ENRAH values.

A major step toward addressing the ethical issues is the development of a **survey** (see attached) that will allow the collective interests and concerns of the members of the project to be drawn together and addressed collectively through the development of procedures.

The ethical issues have been divided into the following **categories**:

1. Clinical Data
2. Human Biological Materials (including blood samples and genetic data)
3. Data from Clinical Trials on Medicines and Other Health Interventions

## 1. Clinical Data

Clinical data refers to any information collected by a doctor or healthcare professional in the course of providing normal healthcare to a patient. Clinical data here includes **all identifiable patient information** collected for healthcare purposes by doctors or other healthcare professionals, including data related to a patient's family.

The following ethical issues have been identified with regard to clinical data:

- Ensuring appropriate consent during clinical data collection
- Ensuring the quality of stored clinical data
- Ensuring the security of stored clinical data
- Determining the procedures for transferring clinical data between healthcare and research institutions
- Ensuring appropriate patient and family access to clinical data
- Ensuring appropriate research access to clinical data
- Determining the place of family histories and genetic data among clinical data in the ENRAH Registry
- Establishing appropriate procedures for using clinical data in research
- Protecting the privacy and confidentiality of clinical data during all steps of its handling
- Determining an appropriate ENRAH approach for clinical data ownership/guardianship

During its first six months, ENRAH has become aware of some ethical and/or legal issues arise in the area of transferring clinical data across EU (and perhaps non-EU) borders, for example, between the Czech Republic and the Slovak Republic; between The Netherlands and Flanders, Belgium; and between Germany and Austria.

While there are practical advantages to consolidating clinical data across EU borders, primarily for the efficiency of the ENRAH Registry, there are also potential challenges, including at times longer distances for patients to travel, cultural and linguistic variations, and legal concerns.

The following table shows the manner in which clinical data is handled within the ENRAH project, listing the actions taken and the procedures to follow regarding those actions:

Clinical Data Handling	Procedures Drafted in Annex 1
1. Collection	✓
2. Storage	✓
3. Transfer (sharing clinical data)	✓
4. Access	✓

## **2. Human Biological Materials** (including blood samples and genetic data)

Human Biological Materials (HBMs) refers to tissues or bodily substances collected from a patient (or relative) for the purposes of healthcare or research. ENRAH includes blood samples and genetic data within this category. ENRAH promotes the appropriate storage and use of bodily and genetic materials in order to further research on AHC.

The following ethical issues have been identified with regard to Human Biological Materials:

- Ensuring appropriate consent during Human Biological Materials collection
- Ensuring the quality of stored Human Biological Materials
- Ensuring the security of stored Human Biological Materials
- Determining the procedures for transferring Human Biological Materials between healthcare and research institutions
- Ensuring appropriate patient and family access to Human Biological Materials
- Ensuring appropriate research access to Human Biological Materials
- Determining the place of family histories and genetic data alongside the tissue bank within the ENRAH Registry
- Establishing appropriate procedures for using Human Biological Materials in research
- Protecting the privacy and confidentiality of patients and their families with regard to Human Biological Materials during all steps of its handling
- Determining an appropriate ENRAH approach for Human Biological Materials ownership/guardianship
- Determining the use of genetic data obtained from Human Biological Materials
- Clarifying patient access to genetic information obtained from Human Biological Materials
- Understanding the legal context and procedures for the transfer of Human Biological Materials across national borders, both within the EU and with regard to Third Countries

During its first six months, ENRAH has become aware that some ethical and/or legal issues arise in the area of transferring Human Biological Materials across EU (and perhaps non-EU) borders, for example, between the Czech Republic and the Slovak Republic; between The Netherlands and Flanders, Belgium; and between Germany and Austria.

While there are practical advantages to consolidating Human Biological Materials across EU borders, primarily for the efficiency of the tissue bank within the ENRAH Registry, there are also potential challenges, including at times longer distances for patients to travel, cultural and linguistic variations, and legal concerns.

ENRAH also became aware during its first six months that additional HBMs samples may need to be taken from patients (particularly blood samples) for the purposes of research. These samples are needed in addition to samples taken for normal care of AHC patients. The advantages of additional samples include a more complete tissue collection within the framework of the ENRAH Registry. Foreseen disadvantages include additional discomfort for patients and inconveniences for their families.

The following table shows the manner in which Human Biological Materials are handled within the ENRAH project, listing the actions taken and the procedures to follow regarding those actions:

### Human Biological Materials Handling

1. Collection
2. Storage
3. Transfer (sharing HBMs)
4. Access

### Procedures Drafted in Annex 1

- ✓ /--  
✓ /--  
-- / --  
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### 3. Data from Clinical Trials on Medicines and Other Health Interventions

Clinical trial data refers to any information collected by researcher in the course of carrying out a medicinal or other health intervention clinical trial.

ENRAH is a platform for bringing together AHC patients and their families, clinicians and researcher involved in AHC and other (possibly) related diseases, and for small and middle size enterprises (SMEs) engaged in discovering new health interventions for AHC patients. ENRAH does not itself engage in clinical trials; nevertheless it plays an important role in preparing for, and facilitating, clinical research.

As the ENRAH Registry develops and more knowledge is gained regarding AHC, the Registry will include a section on clinical trial registration, data, and results that are related to AHC.

The following ethical issues have been identified with regard to clinical trial data:

- Ensuring appropriate consent during clinical trial data collection
- Ensuring the quality of stored clinical trial data
- Ensuring the security of stored clinical trial data
- Determining the procedures for transferring clinical trial data between healthcare and research institutions
- Ensuring appropriate patient and family access to clinical trial data
- Ensuring appropriate research access to clinical trial data
- Determining the place of family histories and genetic data among clinical trial data in the ENRAH Registry
- Establishing appropriate procedures for using clinical trial data in research
- Protecting the privacy and confidentiality of clinical trial data during all steps of its handling
- Determining an appropriate ENRAH approach for clinical trial data ownership/guardianship

During its first six months, ENRAH has realized that some ethical and/or legal issues arise in the area of transferring clinical trial data across EU (and perhaps non-EU) borders, for example, between the Czech Republic and the Slovak Republic; between The Netherlands and Flanders, Belgium; and between Germany and Austria.

While there are practical advantages to consolidating clinical trial data across EU borders, primarily for the efficiency of the ENRAH Registry, there are also potential challenges, including at times longer distances for patients to travel, cultural and linguistic variations, and legal concerns.

The following table shows the manner in which clinical trial data is handled within the ENRAH project, listing the actions taken and the procedures to follow regarding those actions:

Clinical Trial Data Handling	Procedures Drafted in Annex 1
1. Collection	-- / --
2. Storage	-- / --
3. Transfer (sharing CT data)	-- / --
4. Access	-- / --

### Conclusion

During the first six months of the ENRAH Project, a number of ethical issues were able to be identified. These ethical issues impact, in varying degrees and varying ways, on the objectives and methods of the project. The establishment of well-defined values shared by the consortium partners at the commencement of the project allows for the development of clear approaches to resolve ethical issues as they arise.

The identification of these ethical issues presents an important first step in ensuring the overall ethical soundness of ENRAH. As a next step ENRAH will survey its members with regard to their views on these issues. From the results of the survey, procedures will be developed to ensure an agreed and ethical approach to all of the issues.

By putting ethics first, ENRAH provides a reliable and sound framework for overcoming the threatening fragmentation of research and achieving a responsible environment for sharing the burden of disease and finding new treatments.