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# N4U

**neuGRID for you: expansion of neuGRID services and outreach to new user communities**

**Combination of Collaborative Project and Coordination and Support Action**

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## History Record

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| Version 1 | 09/07/2012 | C. Bagnoli translated and edited the protocol analysis carried out by N. Picchi |
| Version 2 | 11/07/2012 | G. B. Frisoni reviewed the document |
| Version 3 | 12/07/2012 | C. Bagnoli edited the document |
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# Table of Contents

# 1. Executive Summary

FP7 neuGRID produced 3 documents about data protection: first, a review on privacy and data protection issues in Europe, with regard to medical research and particularly to research using health infrastructures and healthgrids (D2.1 *Review document on data protection - legal and procedural issues* -; see Annex a); then, from this analysis, a specific and unified data protection protocol (D2.3 *Protocol for ensuring data protection/safety in neuGRID*; see Annex b) was developed in January 2009; and, finally, at the end of the project (January 2011), a report monitoring the implementation of the protocol in the neuGRID e-infrastructure (D2.4 *Report of implementation of the neuGRID protocol for data protection/safety*; see Annex c) was released.

During the first year of FP7 N4U, these documents were reviewed so that FP7 N4U, whose aim is further developing and deploying the e-infrastructure created in FP7 neuGRID, might have an appropriate and updated data protection protocol which is compliant with European regulations. The result of this review is that neuGRID data protection protocol is still compliant with European regulations and thus operational procedures compliant with the criteria defined in this protocol shall be considered compliant with data protection regulations in force too.

# 2. Introduction

## *2. 1 Purpose of the Document*

D3.2 *Ethical Issues and Data Protection Protocol - v1* describes the results achieved in T3.5 "Review of neuGRID Data Protection Protocol and Adaptation to N4U". These results have been achieved thanks to a set of meetings, teleconferences, and e-mail exchanges between CO1 FBF personnel involved in N4U and an external lawyer who was hired ad hoc to review and, if needed, adapt neuGRID data protection protocol so that these guidelines or their revised version might be used in N4U.

## *2.2 Document Organisation*

The deliverable has 7 chapters. The first sets the document in the context of N4U. The second describes purpose, structure, and future updates of the document. The third aims at illustrating the basis upon which the review of neuGRID Data Protection Protocol was carried out, which is further described in the fourth chapter. The fifth chapter presents conclusions. The sixth chapter lists all source material used to review neuGRID Data Protection Protocol. Finally, the seventh chapter shows the documents related to data protection which were developed during FP7 neuGRID.

## *2.3 Document Review*

According to the Description of Work (DoW), updates of this document will be released in September 2013 (M27) under the name of D3.4 *Ethical Issues and Data Protection Protocol - v2*, and at the end of the project lifespan (December 2014, M42) under the name of D3.5 *Ethical Issues and Data Protection Protocol - v3*.

## 3. Methodological Approach

The documents related to neuGRID protocol for data protection/safety and produced during FP7 neuGRID have been analysed by a lawyer to verify their compliance with current European regulations. These documents (neuGRID's D2.3 "Protocol for ensuring data protection/safety in neuGRID" and D2.4 "Report of implementation of the neuGRID protocol for data protection/safety") describe the decision-making process and its principles related to handling and protection of personal sensitive data in the frame of a project associating partners from different countries and collecting medical sensitive data from subjects coming from different countries.

The legal analysis was based on three fundamental features characterizing handling sensitive medical data:

- Data anonymization;
- The duty to inform the persons concerned and the collection of their written consent;
- The secondary use of collected data.

## 4. Review of neuGRID data protection protocol

Despite the critical issues involving data needed in the project and the need to balance between the rights of the persons concerned and research purposes, criteria being compliant with EU directive in force and its transposition in Italian regulations were identified for the above-mentioned fundamental features characterizing handling medical sensitive data.

The analysis shows that the most rigorous approach was used to protect subjects' privacy. Potential new issues related to project's progress are also considered, such as the issue of de-facing brain images to prevent recovering the face of each subject and possibly retrace his/her identity. In addition, neuGRID protocol was submitted to local Ethics Committees so that they might express their remarks, integrations, or comments.

Operational procedures compliant with the criteria defined in neuGRID data protection protocol shall be considered compliant with data protection regulations in force, with the exception of measures in national regulations. This analysis was based on the assumption that partners know and comply with measures in their national regulations. For instance, as far as Italy is concerned, the assumption was that CO1 FBF complies with Italian Legislative Decree 196/03 and the "Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes".

Nevertheless, the compliance with the EU Directive allows to state that the decision making process and its principles as described in neuGRID data protection protocol might be consistent with national regulations of countries where N4U partners are based (including Switzerland and the US), since data protection regulations adopted there is not wider than European data protection regulations.

Finally, it might be appropriate to highlight that Italian law can overcome the issue of collecting informed consent from subjects by adopting the procedure of authorization set forth in section 110 of Italian personal data protection code (Legislative Decree 196/03):

> *"**Section 110 (Medical, Biomedical and Epidemiological Research)***
>
> *1. The subject's consent to health data treatment shall not be required for processing data disclosing health with a view to scientific research activities in the medical, bio-medical or epidemiological sectors if the said research activities are explicitly provided for by legislation that specifically refers to the processing, or else are included in a bio-medical or health care research programme pursuant to Section 12-bis of legislative decree no. 502 of 30.12.92, as subsequently amended, and forty-five days have elapsed since communication of said activities to the Garante under Section 39. Additionally, consent shall not be necessary if subjects cannot be informed on specific grounds and the research programme has been the subject of a reasoned, favourable opinion by the*

*geographically competent ethics committee as well as being authorised by the Garante also in pursuance of Section 40.*

*2. Where a subject exercises his/her rights in pursuance of Section 7 with regard to the processing operations which are referred to in paragraph 1, updates, corrections and additions to the data shall be reported without modifying the data themselves if the outcome of the above operations does not produce significant effects on the outcome of the research."*

This opportunity should reasonably be set forth in regulations in the other Member States too, considering what is stated in directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, article 13, paragraph 2:

*"2. Subject to adequate legal safeguards, in particular that the data are not used for taking measures or decisions regarding any particular individual, Member States may, where there is clearly no risk of breaching the privacy of the data subject, restrict by a legislative measure the rights provided for in Article 12 when data are processed solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics."*

## 5. Conclusions

This document quotes the documentation about data protection produced during previous FP7 neuGRID and illustrates how the review of neuGRID data protection protocol was carried out.

This analysis brings out the fact that, currently, neuGRID data protection protocol might still be considered valid. In fact, the anonymization of data, the duty to inform the persons concerned and the requirement to collect their written consent, and the secondary use of data are still compliant with EU-directive being currently in force. For this reason, an adaptation of neuGRID data protection protocol to N4U was not necessary.

## 6. References


- 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;
- FP7 neuGRID's D2.1 "Review document on data protection (legal and procedural issues)";
- FP7 neuGRID's D2.3 "Protocol for ensuring data protection/safety in neuGRID";
- FP7 neuGRID's D2.4 "Report of implementation of the neuGRID protocol for data protection/safety";
- Italian personal data protection code, Legislative Decree no. 196 of 30 June 2003;
- Italian "Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes".

# 7. Annexes

- neuGRID's D2.1 "Review document on data protection (legal and procedural issues)". Please see file D2.1.pdf.
- neuGRID's D2.3 "Protocol for ensuring data protection/safety in neuGRID". Please see file D2.3.pdf.
- neuGRID's D2.4 "Report of implementation of the neuGRID protocol for data protection/safety". Please see file D2.4.pdf.