

**B.I.R.O.**

**WP5: PRIVACY IMPACT ASSESSMENT**

***“A NOVEL METHOD TO EMBED PRIVACY PROTECTION  
IN THE DESIGN OF EUROPEAN HEALTH INFORMATION  
SYSTEMS:  
PRIVACY IMPACT ASSESSMENT IN THE B.I.R.O. PROJECT”***

**BRUSSELS MEETING  
(29-30th OF NOVEMBER 2008)**

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# **A NOVEL METHOD TO EMBED PRIVACY PROTECTION IN THE DESIGN OF EUROPEAN HEALTH INFORMATION SYSTEMS: PRIVACY IMPACT ASSESSMENT IN THE B.I.R.O. PROJECT**

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**Word Count: 6,182**

**Running Title: Privacy Impact Assessment in the BIRO Project**

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# ABSTRACT

## Introduction

- Privacy is a general principle whose recognition as a human right is widely acknowledged in Europe, but the way it should be implemented in the design of health information systems is rarely supported by regulatory guidelines and infrequently addressed in a systematic manner.
- In the framework of the European Public Health Program, the B.I.R.O. Consortium developed a specific work package, Privacy Impact Assessment, to consider and analyse privacy issues in the design of an internationally shared platform for health information in diabetes.

## Objectives

- To document the development of a novel Privacy Impact Assessment method for the construction of International Health Information Systems and the results of its application.

# ABSTRACT (2)

## Materials and Methods

- Parallel development of Privacy Impact Assessment and Software Development was undertaken to identify the best architecture for the EU diabetes information system. Four steps were used to provide input to software designers and developers. Structured literature search, analysis of data flow scenarios/options, creation of an ad hoc questionnaire, and conduction of a Delphi procedure allowed to defining the general structure of the system.

## Results

- Literature search isolated a core set of N=11 relevant papers. They were submitted to a panel conducting a revised Delphi procedure, leading to three candidate architectures. The corresponding information flow tables were used to build a questionnaire. A Consensus Session took place to define the best architecture, briefly described as “aggregation by group of patients”.

# ABSTRACT (3)

## Discussion

- According to the EU Data Protection Directive, anonymisation allows the processing of personal data without consent, placing anonymous data outside the scope of the data protection principles and making B.I.R.O. processing legitimate.
- Security mechanisms implemented in data transmission can be considered fully compliant with all relevant EU and international regulations.
- Further processing of personal data for statistical or scientific research purposes is also compatible with the purposes for which the data have previously been collected, as well as the transmission of data outside national borders, as B.I.R.O. centres belong to European countries that have fully implemented the Directive and relevant Conventions.

# ABSTRACT (4)

## Conclusions

- **Privacy impact assessment allowed to identify a final structure of the system that resolves privacy concerns at a broad level, involving different privacy dimensions.**
- **The architecture of the system should be considered, at the present stage of the project, as the best privacy protective among those presenting an acceptable level of information content and technical complexity.**
- **The privacy impact assessment method developed and applied within B.I.R.O. may represent a valid tool in the construction of a sustainable international health information systems, long term.**