PROJECT DELIVERABLE REPORT

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* Security: PU – *Public*; PP – *Restricted to other programme participants (including JPI Services)*:
RE – *Restricted to a group specified by the consortium (including JPI Services)*;
CO – *Confidential, only for members of the consortium (including JPI Services)*

** Type: R – *Report*; P – *Prototype*; D – *Demonstrator*; - O - *Other*

INTRODUCTION

A key deliverable of ENPADASI was to define the general rules required to share data in accordance with legal and ethical aspects of the EU participating countries and with respect to national policies and to Intellectual Property rights (WP5). With the development of medical research, countries have set legislations to protect people involved in research and rules concerning the use of data collected in the studies. Knowing these rules is mandatory before being able to share already existing data and in a prospective way, the studies conducted with data sharing in mind should be carefully designed for this purpose.
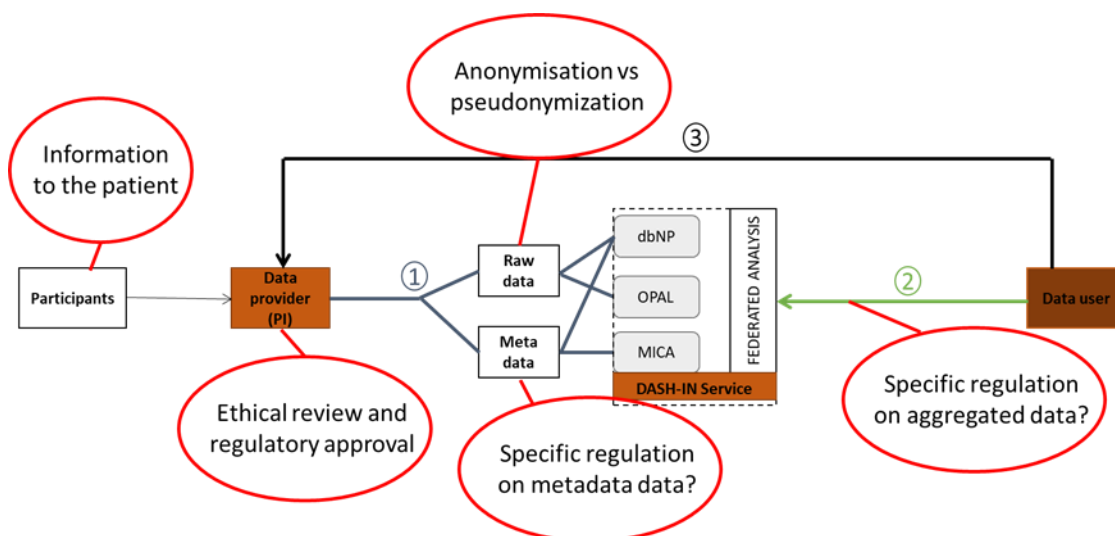
For the current deliverable, we have worked closely with our colleagues in WP5 and have now developed a suite of training materials on ethics, data protection, intellectual property related to data sharing with a focus on nutritional aspects. These documents will be used to inform and train the ENPADASI partners in the guidelines relating to the regulatory aspects of data sharing for both on-going and prospective studies.

SUITE OF TRAINING MATERIALS

The training material has been added to the WP6 section of the ENPADASI website http://www.enpadasi.eu/wp6.html and notification of this has been circulated to all 50 ENPADASI centres by the central ENPADASI management team.

ETHICS

A training document has been compiled relating to ethical and legal issues relating to sharing of data. Ethical issues differ depending on the type of data to be shared such as raw data, metadata or aggregated data.

The scheme above sets out the main ethical and data sharing issues facing the future data users and providers and to which is covered in the training manual.

Issues that are specifically addressed relate to the difference between anonymisation and pseudonymization and the related considerations for appropriate data protection.

The process of informed consent is critical with regard to secondary use of data and sharing of such data. Issues related to this are summarized in the training manual.

A list of definitions relating to ethics and legal issues of data sharing is also available in the training manual.

DATA PROTECTION

A training manual has been compiled relating to data protection issues that arise in the secondary use of data. There is understandably some overlap between data protection and ethics.

The training manual includes detailed information in this regard for both providers and users of data within the consortium. A checklist of minimum information for data protection and ethics in the DASH-IN research infrastructure is illustrated below and is available in the manual.

Label	Unit	Comments
Legal		
Does the data provider have the agreement of ENPADASI consortium to share data?	Yes/No	
Are there limitations for a secondary use of data?	Yes/No	
If yes, please enumerate limitations for secondary use of data	Text	
Should a Data Transfer Agreement (DTA) be signed between the data provider and the data user before any re-use of data?	Yes/No	
Data		
Will you make metadata publicly available?	Yes/No	
Are data stored in the ENPADASI database?	Yes/No	
If Yes, which database?	DbNP/OPAL	
Which kind of data are available?	Data/Biosamples/other	
Is data anonymised?	Yes/No	
If yes, provide the technique	Text	
Is data pseudononymised?	Yes/No	
If yes, provide the technique	Text	
Embargo period after the finalization project	MM/YYYY	

A list of the data protection agencies for each partner country is available in the manual together with a list of terms and conditions for data access.
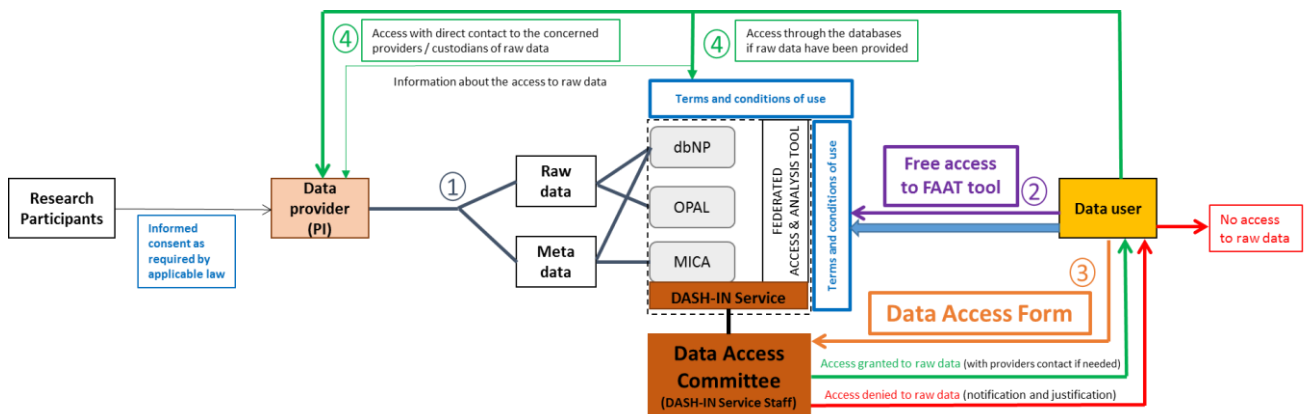
INTELLECTUAL PROPERTY

Currently most datasets available within the ENPADASI partners were retrieved in project/consortia that lacked a paragraph stating the data sharing regulations and therefore the intellectual properties rights (IPR) are undefined. This lack of establishment of those rules makes data sharing after the finalization of a project problematic. Generally data sharing can be separated in metadata sharing and raw/individual data sharing. Therefore those types of sharing are described independently. The training manual provides information on these issues and suggests some recommendations for prospective studies.

A generic paragraph that should be included in consortia agreements has been included in the training manual.

DATA SHARING POLICIES

A comprehensive document is available in the training manual covering a number of aspects relating to data sharing including data access. The diagram below illustrates the issues to be considered and is included in the manual.