Data Collection and Archiving for Research Activities on Non-Corporate Information Systems

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In the context of clinical studies (or research activities in general), our organization has the obligation and the interest to pursue a proper management of data in order to ensure **data protection** (with reference to current regulations: European Regulation 2016 / 679 (GDPR) and D.Lgs . 101/2018) and protection of **intellectual property** .

STIT (Servizio Tecnologie Informatiche e Telematiche, local ICT Department) institutionally has the duty of:

- Selection, Design and implementation of solutions for the correct management of data (conformant to regulations and organizational guidelines)
- Validation of solutions provided by third parties, when their adoption is mandatory for the specific context/study.

The adoption of third-party storage / transmission hardware and software devices for data collection and archiving should be limited to cases in which the study **formally imposes the adoption of such systems**, and therefore does not allow the adoption of systems provided by the organization.

In this case STIT:

- Checks the compliance of the proposed devices with current regulations; if the system does not fully comply with regulations, the local PI will be asked to adapt the given data management methodologies, or otherwise be held responsible for any improper data management resulting from the non-compliance; in this case the non-compliance will be notified to the competent departments and management.
- Adopts every possible technical solution to adapt the proposed device in order to comply with regulations and organization guidelines.

STIT requires the promoter / proponent to fill in the following form during the formal approval process of the study (which may or may not include Ethics Committee). This form should always be filled and sent to STIT before any data collection activities are started (at least one month advance).

Since the technical verification, installation and configuration of any hardware or software systems can take some time, it is highly recommended that STIT should be involved as soon as possible, after the approval of the form. STIT cannot be held responsible for any delays in the data collection process.

Only after having filled, submitted and having received formal validation of the form by STIT, the necessary technical support for the activation of the hardware and software devices will be made available.

Note: "Storage / transmission hardware devices" in this context means any device capable of storing data in electronic format, either permanently or for the purpose of immediate transmission to third parties.
Example: systems such as Desktop PC, Laptop, Tablet, Smartphone are to be considered as devices requiring the filling of the following form. Systems such as

barcode readers, printers, smartcards or similar devices do not require any filling of the form.

For hardware devices that do not fit the above definition (i.e. devices that do not manage any data), you can directly contact IT Support for the necessary technical verifications and installation / configuration (if possible).

AUTHORIZATION REQUEST FORM FOR THE INSTALLATION AND USE OF INFORMATION STORAGE SYSTEMS / DATA TRANSMISSION SYSTEMS FOR RESEARCH PURPOSES

Basic Study Information (MANDATORY)

Form Filling Date	
User filling out (and role)	
Study name	
Ethics Committee Approval Date	
Principal Investigator (local)	
PI Department (local)	
ICT Technical Reference Person (local) NB the local ICT technical reference person should be a member of the team, identified by the PI, who can be contacted for further information on IT issues	
Sponsor or supplier of the hardware / software system	
ICT Technical Reference Person (of the sponsor or supplier) (name and contact information phone / email)	
Number of ASMN users involved	

Classification of the system

	Type of instrument (select one or more entries)	Storage / Transmission Hardware ◯ Software ◯

Requirements for STIT authorization

(refer to flow chart for authorization workflow)

1	Is the device / software system used to collect, store or transmit personal data ? (1)				Yes ◯ No ◯
if 1 is Yes	1.1	Are the archived data anonymous ? (2)			Yes ◯ No ◯
if 1 is Yes	if 1.1 is No	1.1.1	Does the system required access credentials in compliance with italian and european regulations?		Yes ◯ No ◯
if 1 is Yes	if 1.1 is No	1.1.2	Is electronic transmission (if applicable) implemented using secure (encrypted) technologies ?		Yes ◯ No ◯
if 1 is Yes	if 1.1 is No	1.1.3	Does the system include long-term storage of personal data ? (3)		Yes ◯ No ◯
if 1 is Yes	if 1.1 is No	if 1.1 .3 is Yes	1.1.3.1	Does the system allow storage on AUSL organization data centers ?	Yes ◯ No ◯
if 1 is Yes	1.2	Are personal data being processed original? (4)			Yes ◯ No ◯

if 1 is Yes	if 1. 2 is Yes	1.2.1	Does the system include tools for data extraction/reporting or data transmission to AUSL information systems?	Yes ◯ No ◯
if 1 is Yes	if 1. 2 is Yes	1.2.2	Does the system provide data backup according to italian and european regulations? (5)	Yes ◯ No ◯
Technical framework of the system				
2	Does the system require network connection?			Yes ◯ No ◯
if 2 is yes	2.1	Does the system require internet connection?		Yes ◯ No ◯
if 2 is yes	2.2	Type of connection required		WiFi ◯ Wired (Ethernet) ◯
Regulations Compliance Details				
3	(if answer to 1.1.1 is yes) Does the system allow connection to company authentication systems (via domain session or LDAP integration)?			Yes ◯ No ◯
4	(if answer to 1.1.1 is yes and 3 is no) Specify authentication technology and regulatory compliance.			
5	(if answer to 1.1.2 is yes) Specify secure transmission technology.			
6	(if answer to 1.1.3.1 is yes) Specify storage technology (e.g. DB on server, storage on network filesystem)			

Signature of person filling the form

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Note:

(1) Please refer to the definition of "personal information / personal data" included in European regulations. Attention: demographics data are to be considered personal data.
(2) "Anonymous data" is any data that can not be directly or indirectly related to a specific individual. Pseudononymized data (use of codes to identify individuals) is considered, for the purpose of this form, as anonymous data.
(3) Long-term archiving means any storage that goes beyond the simple need for immediate processing and / or transmission. The temporary copy of a data for the sole purpose of transmission does not constitute long-term storage.
(4) Original data means any set of personal data that is not stored on any other system within the organization (electronic or paper).
(5) If no data is stored on the system ("no" answer to 1.1.3), the question is not applicable and “Yes” can be selected even in the absence of data backup systems.

Authorization Workflow