

Open Survey on ethical implications of reusing FAIR data for health research

March 2019

Objectives:

The purpose of this survey is to gather feedback from all involved stakeholders in health research regarding their perceived importance of putting in place mechanisms to guarantee the compliance of Research Performing Organisations (RPOs) with the ethical considerations listed below when designing and performing research activities with reused data derived from publicly funded activities such as health research and routine care.

The results of this survey will be used as input for further discussion in a focus group between key experts in the field and will be included in the report "Guidelines for implementing FAIR open data policy in health research" as part of the work developed within the FAIR4Health project.

You could find further information about FAIR4Health in this link: <https://www.fair4health.eu>
In case you have further questions, we encourage you to contact the FAIR4Health coordination team making use of the form embedded in this link: <https://www.fair4health.eu/en/contact>

References:

- [1] European Commission/EACEA/Eurydice, 2018. *The Structure of the European Education Systems 2018/19: Schematic Diagrams*. Eurydice Facts and Figures. Luxembourg: Publications Office of the European Union. doi:10.2797/302115
- [2] Ienca M, Ferretti A, Hurst S, Puhan M, Lovis C, Vayena E. (2018). Considerations for ethics review of big data health research: A scoping review. *PloS one*, 13(10), e0204937.
- [3] ECRIN writing group, Bowers S, Drumi C, Hansson MG, Mayrhofer M, Ryan L. (2018). White Paper 4: Ethics. Supporting Document to D3.3 Draft Policy Recommendations. *EOSCpilot Project*.
- [4] Council of the European Union, General Secretariat of the Council. Research Integrity: Council conclusions (adopted on 01/12/2015). Available at: <http://data.consilium.europa.eu/doc/document/ST-14853-2015-INIT/en/pdf>

[5] Floridi L, Taddeo M. (2016). What is data ethics?
Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences, 374. <http://doi.org/10.1098/rsta.2016.0360>

Just a bit about you:

Are you a citizen of the European Union?

- Yes
- No

Please, indicate your educational level¹:

- I don't want to disclose it
- ISCED 1: Primary education (up to 10-13 years old)
- ISCED 2: Lower secondary education (up to 14-16 years old)
- ISCED 3: Upper secondary education (up to 18 years old)
- ISCED 4: Post-secondary non-tertiary education
- ISCED 5: Short-cycle tertiary education
- ISCED 6: Bachelors' or equivalent level
- ISCED 7: Masters' or equivalent level

Please, indicate which of the following roles better defines you (choose all that apply):

- General Audience (Patient/Citizen)
- Healthcare professional
- Health Informatics professional
- Member of Ethics Committee
- Scientific researcher
- Decision-maker in public or private companies
- European Commission Representative
- Public Health Representative
- Other: _____

¹ According to the International Standard Classification of Education (ISCED 2011) [1]. More info at: <http://bit.ly/ISCED2011>

Questions

Please rate from 1 (very low) to 5 (very high) the importance of the following items:

When processing sensitive personal data, RPOs must consider the following principles as stated in the General Data Protection Regulation (GDPR):

Lawfulness, fairness and transparency	1	2	3	4	5
Purpose limitation	1	2	3	4	5
Data minimisation	1	2	3	4	5
Accuracy	1	2	3	4	5
Storage Limitation	1	2	3	4	5
Integrity and confidentiality	1	2	3	4	5

RPOs must put in place the following measures to comply with the accountability principle under the GDPR:

To implement data protection policies and security mechanisms	1	2	3	4	5
To agree data protection contracts with third-party processors	1	2	3	4	5
To document any processing activity	1	2	3	4	5
To record and report, where necessary, any personal data breaches	1	2	3	4	5
To carry out data protection impact assessments	1	2	3	4	5
To appoint a data protection officer	1	2	3	4	5

From research integrity and good practices point of view, RPOs must demonstrate:

Honesty	1	2	3	4	5
Reliability	1	2	3	4	5
Objectivity	1	2	3	4	5
Impartiality and independence	1	2	3	4	5

Open communication	1	2	3	4	5
Duty of care	1	2	3	4	5
Fairness	1	2	3	4	5
Responsibility for future science generations	1	2	3	4	5

RPOs must implement governance systems to ensure the consideration of the following items:

Approval by a research ethics committee	1	2	3	4	5
Justification of the research topic	1	2	3	4	5
Independence (or not) of the research from clients, sponsors, etc.	1	2	3	4	5
Extent of the researcher’s responsibility for what is further done by a third party	1	2	3	4	5
Provision for research activity to be halted or closely monitored when necessary	1	2	3	4	5

RPOs must comply with the following data ethics principles²:

Data access under well-defined conditions	1	2	3	4	5
Public justification in case open access is not allowed	1	2	3	4	5
Description of data request procedure when needed	1	2	3	4	5
To monitor data aggregation for potential unforeseen results	1	2	3	4	5
Restriction of data access for commercial use	1	2	3	4	5
Intellectual Property Rights should be stated from the beginning	1	2	3	4	5
To apply as much transparency as possible in algorithmic processing	1	2	3	4	5
Resulting data should be made FAIR (findable, accessible, interoperable and reusable)	1	2	3	4	5

² A new branch of ethics that studies and evaluates moral problems related to data (including generation, recording, curation, processing, dissemination, sharing and use), algorithms (including artificial intelligence, artificial agents, machine learning and robots) and corresponding practices (including responsible innovation, programming, hacking and professional codes) [5]

Regarding science and society ethics, RPOs must consider the following issues:

Quality of scientific reporting should be endorsed	1	2	3	4	5
Resources to correctly interpret results (educational/training) should be provided to general media	1	2	3	4	5
Research outcomes should be released according to guidelines for incorporating scientific progress into policy-making	1	2	3	4	5

THANKS FOR BOOSTING THIS RESEARCH!