

Guidelines for raising FAIR adoption in health data and health-related research performing organisations (HRPOs)

PRINCIPLES

1. To implement a data policy, including FAIR, implies managing a complex change. The policy needs **strategic vision and leadership**.
2. There are no policies without **resources** and **incentives** supported by necessary infrastructure.
3. It is necessary to rely on the right **knowledge and skills** about FAIR data and research data management in the current Open Science landscape.
4. Before implementing any FAIR data policy, the institution needs a clear action plan identifying the main **actors** and a credible timeline.
5. The policy must be **written** and approved by the institution.

STEPS

1. Define the **vision and objectives** of the policy. This should include:
 - a. A description of the current research performed in the institution: research funders and their policies regarding research data; types of research outcomes that the institution produced in the last 5 years; types of data used/reused by the researchers; current infrastructures used at institutional level (virtual research environments (VREs), data repositories, etc.).
 - b. A definition of the objectives of the policy, such as: comply with funders' requirements; improve transparency and reproducibility; include datasets in health research infrastructures; increase return on investment into data acquisition by maximising use of data; minimise waste by improving visibility and accessibility of research already completed or underway; address health consumer/research participants' expectations that maximum value will be achieved by their contribution to research (e.g. improved health outcomes); enable data citation; facilitate research translation by making data more readily available for systematic review, etc.
 - c. The adoption of a comprehensive approach to enabling mechanisms that can enhance data sharing and productivity while reducing risk.
2. Determine the agreed level of **data governance, openness, transparency and re-usability** for research data produced in the HRPO, including licensing and provenance as well as the intended mechanisms for personal data protection (e.g. GDPR compliance).
3. Identify/name a **responsible person/unit for the FAIR data policy** as well as the envisaged team to put it in practice. Design an action plan, state resources to be committed for Research Data Management and a feasible timeline.
 - a. Define clearly the roles and responsibilities of the data creators, data owners and data processors in a FAIR context.

- b. Use existing frameworks to promote, establish and define roles and competencies wherever possible.
4. **Raise awareness** among researchers, as well as providing adequate training and assistance (data stewards, data scientists, or similar in the institution). Definition of needed skills and a training programme.
5. Identify and describe current and **required data infrastructures**. This includes data storage and architecture definition but also the provision of tools to make data description and formatting easy and affordable for researchers.
 - a. Use of existing infrastructures is encouraged, but attention must be paid when using commercial solutions when dealing with sensitive data with respect to data ownership considerations.
 - b. Gap analysis should be performed where possible to determine current and desired readiness levels.
6. Establish **responsible Research Data Management practices** within the institution and define FAIR for implementation. This should include:
 - a. Analysis of the scope of the FAIR principles, that includes concepts like: data selection/curation, long-term stewardship, legal interoperability and the timeliness of sharing.
 - b. Creation of a standard institutional template for Data Management Plans (DMPs).
7. FAIR data require several technical decisions and standards adoption: the policy should include decisions, at institutional level, around **technical standards**. For example:
 - a. PID policy and control for identification of data, publications and other outputs, as well as researchers themselves.
 - b. Metadata policy for data accessibility and interoperability: selection of metadata vocabularies, best practices on metadata completeness, etc. These decisions might include a technical analysis in domain relevant (health) standards including metadata schemas, data modelling and vocabularies.
 - c. All research data should be deposited in a trustworthy repository.
 - d. Anonymisation/pseudonymisation and access control mechanism decisions need to be clearly defined in line with the HRPO's own policies.
8. Devise **credit and reward mechanisms** in order to incentivise researchers and promote FAIR data management/sharing.
9. **Write the policy** on FAIR research data management:
 - a. Submit it for approval by governance bodies.
 - b. Disseminate the policy inside the HRPO.
 - c. Monitor uptake and compliance through e.g. DMPs.
10. Ensure **FAIR data assessment** within the institution, using existing tools, or devising in-house metrics where necessary. Re-align and consolidate the policy with funder mandates to guarantee that publicly-funded research data are made FAIR (and open), except for legitimate restrictions.

Selected Resources

Competencies and skills	<ol style="list-style-type: none"> 1. https://eosc-fair4s.github.io/ 2. https://www.digcomptest.eu/index.php 3. https://www.unesco.org/en/communication-information/digital-competencies-skills
Gap analysis and infrastructure readiness	<ol style="list-style-type: none"> 4. ARDC Institutional Underpinnings Framework 5. https://sparceurope.org/evaluate-your-rdm-offering/ 6. https://ardc.edu.au/services/advisory-services/rise-workshop/
Data Management Plans (DMPs)	<ol style="list-style-type: none"> 7. http://dmponline.dcc.ac.uk 8. http://argos.openaire.eu 9. https://dmptool.org/ 10. https://ds-wizard.org/
Metadata catalogues/ registries	<ol style="list-style-type: none"> 11. https://bartoc.org/ 12. https://rdamsc.bath.ac.uk/
Example metadata	<ol style="list-style-type: none"> 13. http://ecrin-mdr.online/index.php/Summary_Tables
Licences	<ol style="list-style-type: none"> 14. https://chooser-beta.creativecommons.org/
Trustworthy repositories	<ol style="list-style-type: none"> 15. https://www.re3data.org
Anonymisation/ pseudonymisation	<ol style="list-style-type: none"> 16. https://amnesia.openaire.eu/
Access control	<ol style="list-style-type: none"> 17. https://ukdataservice.ac.uk/learning-hub/research-data-management/data-protection/access-control/
FAIR assessment/ metrics	<ol style="list-style-type: none"> 18. https://www.f-uji.net/ 19. https://ardc.edu.au/resources/aboutdata/fair-data/fair-self-assessment-tool/ 20. https://op.europa.eu/en/publication-detail/-/publication/ced147c9-53c0-11eb-b59f-01aa75ed71a1
Training and guidance	<ol style="list-style-type: none"> 21. http://www.dcc.ac.uk 22. http://openplato.eu