Policy on the Management of Research Results (Scientific Publications and Data) produced by the Istituto Superiore di Sanità

ENGLISH VERSION

Introduction

The Istituto Superiore di Sanità (ISS, the National Health Institute in Italy) encourages the communication and sharing of research results (scientific publications and data), in order to give them visibility so that they may have an impact on the entire scientific community. In this regard, in 2008, the ISS published its first institutional policy for free access to the scientific publications of the Institute.

The ISS takes action to ensure that principles such as research integrity, reproducibility and reuse of its results are complied with, to encourage maximum sharing of scientific knowledge and avoid plagiarism. This objective is pursued through actions aimed at promoting the availability of scientific publications and data, by applying the logic of open access to scientific literature, through the most advanced techniques for recording and disseminating information in digital format. Since its research work is financed by public funds, the research results produced by the ISS must comply with the principle of free access and reuse, without restrictions except in the case of reasonable and justified safety and security grounds.

The ISS promotes the widest possible dissemination of research contributions in the context of intra- and inter-institutional exchange and collaboration initiatives (e.g., interactions between bio-database data and clinical data), in compliance with current legislation on personal data and intellectual property, and with the provisions contained in the Statute of the Institute, in the provisions issued by the ISS Ethics Committee and in the Regulations on conflict of interest https://www.iss.it/normativa1

In the case of specific research funding agreements entered into with third parties, such agreements shall not envisage any limitations to the publication of information and data where this is necessary for the protection of public health. These principles are recognized as essential to ensure the reliability, transparency and reproducibility of research results; the perspective is to preserve and disseminate, at an institutional level, the wealth of knowledge produced by the Institute for the advancement of scientific research and civil society and for the rationalization and better use of resources in the health field.

Scope

This policy applies to all staff affiliated with the ISS. The “Operational guidelines”, currently being drawn up and which implement the provisions of this policy, can be referred to for information about how research results are managed.

Definitions

Open access means free online availability of search results, without access restrictions, i.e. without economic restrictions (*free OA* – available free of charge, without magazine subscription costs), copyright (*libre OA* – e.g. distribution, reproduction, re-elaboration of the contents for personal use and not for commercial purposes), without prejudice to the recognition of intellectual property (right to authorship of the work) and without technological restrictions (access without authentication / registration).

Institutional repository means the PublISS digital platform https://publ.iss.it/, which is interoperable in compliance with national and international protocols and standards, intended to host the research results of the institution and related metadata.

Self-archiving means, for the purposes of this policy, the deposit, by the staff affiliated with the Institute, of the results of the research results stored in the PublISS institutional repository.

Research data include data in any format, used on the basis of a protocol defined as part of a specific research activity conducted by personnel affiliated with the ISS. These data are the positive or negative data collected or generated in digital and / or paper version and expressed in numerical, descriptive, audio or video format. The research data are defined on the basis of:

1) nature:
   - primary data (so-called raw data) – including anonymous data from clinical trials;
   - processed data (secondary, aggregated / structured data)

2) origin:
   - data generated by activities carried out within the ISS, covered by the intellectual property rights of the Institute;
   - data acquired from external parties with which the ISS has collaborative relationships, governed by terms and conditions of use (constraints and procedures)

The data that the Institute collects and processes through institutional activities governed by specific rules **do not fall into this category**.

Embargo means the period of time of variable duration in which, as set by the publisher, an article from a magazine (e.g., final editorial version or version accepted for publication) is not made accessible online or is made accessible only on certain conditions (e.g., upon payment or access is provided to subscribers only).

Institute or ISS means, in this document, the Istituto Superiore di Sanità.

Metadata mean the descriptive data (e.g., bibliographic data, identification data of the institutional affiliation) relating to the research results to be stored in the PublISS digital archive of the Institute.

Scientific publications mean journal articles, technical reports, conference proceedings, monographs, etc., subjected or not to peer review, duly approved in accordance with the internal management flow-chart of the Institute.

Research results mean scientific publications, data produced to support the research work (data sets) and other digital assets (e.g., power point files, posters, audio files, images and videos) which in any case are subject to approval procedures.

ISS Institutional repository

The ISS has set up the PublISS digital archive https://publ.iss.it/, based on the open source software DSpace, with the function of storing and providing free access to its scientific production, in compliance with the FAIR[1] principles (promoted by *European Open Science Cloud,* EOSC) and the integrity of research data. This archive ensures that the documentation contained therein has an official nature, as it is the Institute that manages the archive, certifies the authoritativeness of its contents, and guarantees the availability of the information in the network and the long-term preservation of the research results.

PublISS complies with the OAI-PMH (*Open Archives Initiative Protocol for Metadata Harvesting*) online information systems interoperability protocol adopted by infrastructures that use the open access paradigm. Thanks to the practice of authors archiving their work, the archive collects:

- bibliographic and management metadata describing the search results;
- the complete texts of scientific publications;
- the data sets.

The principles of Open Access apply to publications and research data, as indicated below.

Open access to scientific publications

The ISS is among the signatories of various international and national documents in support of open access to research results:

- Berlin Declaration in favour of open access to scientific knowledge https://openaccess.mpg.de/Berlin-Declaration (2006);
- Petition to the European Commission in support of free access to the results of publicly funded research (2007) EC petition for public access to publicly funded research results - Knowledge Exchange (knowledge-exchange.info);
- Position paper on open access to the results and data of scientific research in Italy https://www.cnr.it/it/position-statement signed by the main Italian research bodies (CNR, ENEA, INFN, etc. and by CRUI), within the framework of the MedOAnet project (2013);
- Messina 2.0 Declaration: the Italian way to open access https://decennale.unime.it/wp-content/uploads/2014/10/Road-Map-2014-2018.pdf to confirm, together with universities and institutions, support for the implementation of institutional policies aimed at consolidating the development of open access (2014).

The commitment of the ISS in favour of free access to research literature is expressed through two complementary actions:

1) self-archiving: the authors of the scientific publications themselves store them together with the metadata and the full text (final published version);
2) the publication of scientific papers in journals, monographs, etc. open access, intended as a current practice for disseminating content so that the contents are immediately accessible free of charge;

The ISS promotes open access publications through its own free and open access editorial production which includes the official magazine of the Institute, *Annali dell'Istituto Superiore di Sanità*, and all the other series of publications.

Management of Copyright

The ISS provides advice to researchers for the management of copyright to promote open and free of charge access to the PublISS digital archive of the ISS.

Creative Commons licenses (CC), so-called open licenses, are adopted for the publications published by the Institute whereby the owner of the intellectual property of a work grants a more or less wide range of reuse rights to people who want to use and build upon the work that the author has created. CC licenses are a light copyright legal tool ("some rights reserved"), in other words they are a more flexible management of copyright, aimed at promoting the free sharing and distribution of content online. The ISS adopts the CC BY-NC-ND license for its institutional series which, without prejudice to the attribution of authorship of the work to the author (CC BY), allows users to download and share the original works without making changes (CC ND no derivative), but it does not allow use of the work for commercial purposes (CC NC no commercial).
With respect to the practice of self-archiving by ISS researchers, it is reiterated that self-archiving constitutes an original right of authors for as long as they remain the copyright holders of their work. This practice does not constitute an alternative to the submission of works to journals, it is rather a parallel action that may take place before or after the submission of a manuscript.
Without prejudice to the fact that the copyright of the works published by the staff affiliated with the ISS belongs to the Institute, the latter recommends that researchers reserve the rights of open access publication useful for teaching and research, while retaining the right of self-archiving their work in the PublISS archive. This implies responsibility to check the more or less restrictive conditions envisaged by the editorial contracts for publication in the individual journals. In particular, the conditions entailed for the following types of contracts (copyright license form, from the most restrictive to the least restrictive model) are to be assessed on the conditions below indicated on the basis of which the owner of the intellectual property of a work decides which rights to reserve and which to grant free of charge:

– *copyright transfer agreement* which provides for the transfer of the rights of reuse and commercial exploitation;
– *exclusive license agreement* which leaves the copyright in the hands of the author for reuse even if not for commercial purposes;
– *open access license agreement* which applies the conditions envisaged by the Creative Commons licenses.

Open access to research data

The commitment of the ISS in favour of the free availability of research data conforms to the paradigm of open science adopted by the European Union with the implementation of the FAIR principles and is expressed in the following guidelines:

– *Public access to data*. Making the data available is a pre-condition for benefiting from public funds; in the case of research financed with non-public funds, deriving from contracts, collaboration agreements and / or conventions, the methods of accessing the data are governed by specific agreements between the ISS and third parties.

– *Incentives for sharing research results*. The practice of sharing data is preliminary to the adoption of innovative research evaluation indicators, based on qualitative criteria, in order to facilitate the access and allocation of funds granted by funding bodies, with the advantage of increasing the visibility of the scientific production and facilitate verification of the repeatability of data collection methods, avoiding unnecessary duplication.

Treatment of research data

The research data hosted on the PublISS platform are linked to scientific publications, to lines of research as well as the projects to which they refer.

ISS researchers are granted exclusivity on the data for a certain period of time, provided that no third-party rights are recognized on the data and that there are no uses prohibited by law.

Pursuant to the discipline set forth by the Privacy Code, the reuse of personal data is permitted only if it is reused by third parties who mainly carry out scientific research activities, if informing the interested parties is impossible or involves a disproportionate effort, if this would make the research impossible and if the research would be seriously undermined. Reuse must be subject to the prior authorization of the Data Protection Authority, subject to the adoption of appropriate measures to protect the rights and freedoms of the data subject, in accordance with Article 89 of the GDPR (General Data Protection Regulation). In the event that such data are used by the owner for different purposes, new privacy information sheets are to be administered to the interested parties, in order to obtain a new consent to the processing of their personal data.

In particular, in relation to the access and reuse of research data, a distinction is to be made between the cases in which the data have not yet been released to the public (unpublished data) and when, instead, they have already been published (published data):

– *Unpublished data.* The primary data of a publication are reserved to the researcher who generated them for a certain period of time (3 years, unless otherwise agreed) to ensure absolute priority of their use for further analyses.

– *Published data*. These data are made freely available to the scientific community for research purposes or for purposes of public interest. Such use must be made in compliance with the current legislation on the protection of personal data and intellectual property (e.g., patents), and with the internal regulations of the Institute and with any agreements entered into with third parties (e.g. research funding organizations); in the event that there are no uses prohibited by law or the rights of third parties, it is recommended that conditions of use be set for using the data stored on the PublISS platform by selecting the access and reuse options provided for by the Creative Commons licenses (see

Management Guidelines which are currently being drawn up). This ensures the traceability of the uses made and reference to the original authorship of the data.

The research data can be archived for an unlimited period of time; personal data will be stored after total anonymization.

In the event that the research data are to be eliminated (erased or permanently destroyed) for ethical or legal reasons (including when requested by the patient in the case of clinical data), the procedures for deleting and destroying data as well as the relevant documentation must be traceable. At the same time, one must take into account the interests of any third party funding the research and of other stakeholders, as well as the confidentiality and security aspects.

Responsibilities, rights, duties

Responsibility for the contents stored in the PublISS institutional repository, also relating to the collection, management and maintenance of publications and research data, is borne by both the researchers and the ISS, each for their respective areas of competence, in accordance with the provisions of this policy and with the following regulations:

- Regulation (EU) 2016/679 concerning the protection of individuals with regard to the processing of personal data, as well as the free circulation of data;
- Legislative Decree no. 101 of 10 August 2018, on "Provisions for adapting the national legislation to the provisions of Regulation (EU 2016/679);
- Legislative Decree no. 196 of 30 June 2003, the so-called "Privacy Code", as amended by Legislative Decree no. 101 of 10 August 2018;
- Resolution of the Personal Data Protection Authority of 19 December 2018 (Resolution no. 515/2018) laying down ethical rules on the processing of personal data for statistical and scientific research purposes;
- Provision of the Personal Data Protection Authority containing the requirements for the processing of particular categories of data, pursuant to Article 21 (1) of Legislative Decree no. 101 of 10 August 2018, Register of measures, no. 146 of 5 June 2019;
- Code of conduct for the employees of the Istituto Superiore di Sanità (Minutes no. 27 of the BoD meeting of 9/10/2018, Annex no. 1, Resolution no. 16), with particular reference to:
  - the "principles of integrity, good faith, proportionality, transparency, fairness, reasonableness, objectivity and independence in research" (Article 3 Code of conduct);
  - responsibility of researchers and technologists "responsible for the quality and transparency of their scientific and research activities, in compliance with the highest ethical standards relating to methodologies, dissemination and use of results" (Article 4 Specific provisions for personnel with the qualification of Researcher and Technologist);
  - circumstances in which there is a conflict of interest (Art. 8 Conflict of interest);
  - possession of rights deriving from intellectual property including patents, registered trademarks, know-how and / or copyright over a medicinal product (Article 10 Financial interests - definition);
- Regulation for the processing of sensitive and judicial data of the ISS;
- Ethics Code of the ISS;
- ALLEA Code of Conduct for Research Integrity;
- European Charter for Researchers;
- Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals produced by the International Committee of Medical Journal Editors.

It is also necessary to consider:

- Article 21 of the Declaration of Helsinki of the World Medical Association;
- Article 5 (2), letter c of the Decree of the Minister of Health of 8 February 2013.

Responsibility of researchers

- elaboration of a formal Data Management Plan (DMP)[2] – at the beginning of a research project, to be updated during its development[3] – related to all aspects of research data management: collection, documentation, archiving, use, access and storage (or destruction) of data, including the definition of protocols and responsibilities of the members of the project team;
- verification of compliance with the legislation on intellectual property rights and compliance with the constraints envisaged by contracts with third parties;
- compliance with the principles of research ethics and privacy.
- planning the use of data even after the end of a project (including the definition of data reuse rights), as recommended in the section "Treatment of research data".

Responsibility of the Istituto Superiore di Sanità

- promote compliance with the principles of this policy by the internal research community;
- appoint competent entities to provide support to the research activities, provide adequate resources, tools and infrastructure, provide for the training of the individuals in charge of data management;
- provide assistance for the definition of best practices for the management of research data, through training activities (e.g., for the design and drafting of the DMPs);
- develop services and mechanisms for project registration, for the filing, archiving and conservation of research results (publications and data), for the purposes of current and future access, even for projects that have been completed;
- provide access to services and infrastructure to ensure that researchers can exercise their responsibilities and therefore comply with the obligations under contracts with research funders or other legal entities.

Validity

This policy enters into force on the date of signing and will be updated every 3 years, unless new regulatory provisions require updates before the deadline.

The President of the Istituto Superiore di Sanità
Signed on 24.11.2020

Approved by ISS Scientific Committee on March 9, 2021

NOTES

1. H2020 Programme, Guidelines on FAIR Data Management in Horizon 2020
   https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
2. Data management Plan (DMP) is a document that plans the entire life cycle of research data and may be continuously updated. The DMP ensures that research data are accessible, traceable, available, authentic, citable and that they meet clearly defined legal requirements and appropriate security measures regarding their reuse. In their ideal form, DMPs will be in a machine-actionable format.
3. H2020 Programme Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020. Version 3.2. 21 March 2017. P. 9.
   https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf