Policy on the management and sharing of research data and software code

May 2021
Summary

This policy sets out the Institut Pasteur’s guidelines on the management and sharing of research data and software code. It summarises the best practices that the Institut Pasteur requires or recommends researchers to implement throughout the research process.

The Institut Pasteur supports scientists in the application of this policy. The policy refers to fact sheets (full list in the appendix of the document) to give scientists the operational resources they need to implement the best practices.
1. Context

The international research community is rallying to ensure the preservation, sharing and reuse of the products of scientific research. This global movement involving researchers, policymakers and funders aims to improve the quality, integrity and reproducibility of research.

At the Institut Pasteur, the research ecosystem (research entities, platforms, national reference centres etc.) uses, manipulates and generates large quantities of digital data and relies on the development of software code\(^1\) that varies in complexity (from short scripts to complex applications). Some data produced at the Institut Pasteur are appropriable, which means they are and/or can be protected by intellectual property rights (inventions, software, databases); other data are covered by secrecy (personal data, knowledge, business secrecy etc.).

In the absence of a standard set of rules, a review\(^2\) of habits and practices in research data management and sharing within the Institut Pasteur was conducted in 2019. The review highlighted disparities in the processing and management of data and software code among a wide range of respondents.

The Institut Pasteur works closely with public bodies in higher education (universities) and public research institutions (CNRS, INSERM, INRAE etc.) through functional research units such as mixed units (UMR, USR etc.) and through public–private partnerships. Furthermore, many collaborations take place with international institutions, including those in the Institut Pasteur International Network. Research also benefits from external funding from public and private funding bodies, which may, in exchange for the granted funding, require data and software code generated by projects to be managed and opened up in accordance with the principle "As open as possible, as closed as necessary".

The Institut Pasteur thus considered it essential to define guidelines for managing and sharing research data and software code that would be consistent with those of the Institut Pasteur's partner institutions and aligned with the requirements of research funding bodies and journal publishers. The goal is to guide researchers and ensure that data and software code is structured and managed in accordance with the FAIR principles\(^3\) and "open" wherever possible.

Establishing best practices for managing research data and software code is beneficial on several levels. This methodology:

- improves the quality, integrity and reproducibility of research, since data are precise, complete, authentic and reliable;
- reinforces data security and guards the Institut Pasteur against the risk of data loss or theft;
- makes data accessible and comprehensible in the long term, whether they are made public or not;

\(^1\) The term "software code" used in this policy refers to software components, whether they are scripts, programs or workflows, and more complex software.

\(^2\) The results of the review are available on the intranet.

\(^3\) Terms marked with an asterisk are defined in the appended glossary.
facilitates the reuse of data, either by the initial investigator or by colleagues within the Institut Pasteur, or by other scientists if the data are made public, and thus avoid data duplication, saving time and resources.

In addition, well-managed data can be shared and distributed within the scientific community, which:

- increases the visibility and impact of the scientist's work;
- encourages scientific collaboration and enables interdisciplinary research;
- makes it possible to conduct new research not considered by the initial investigator, resulting in innovations.

2. Area of application

This policy applies to all scientific personnel (researchers, engineers, project managers, doctoral students, post-docs etc.) working at the Institut Pasteur in Paris (the campus on rue du docteur Roux and the Hearing Institute, pasteurians or OREX) and institutions attached to it through legal arrangements (the Institut Pasteur in French Guiana, Guadeloupe and New Caledonia), regardless of the entity they are attached to (research unit, G5, platform, national reference centre etc.). In the remainder of the document, the term "Institut Pasteur" will be taken to refer to both the Institut Pasteur in Paris and its attached institutions mentioned above.

The policy covers all research data, i.e. factual records (numerical scores, textual records, images and sounds) used as primary sources for scientific research, and that are commonly accepted in the scientific community as necessary to validate research findings. It applies to all data generated or collected during the course of research projects conducted at the Institut Pasteur and funded through external or internal grants. It also applies to all software components (scripts, programs or workflows) and to more elaborate software developed at the Institut Pasteur.

3. Objectives of the policy

This policy constitutes a ready-to-use reference document specifying the guidelines and best practices that the Institut Pasteur recommends for the management and sharing of research data and software code.

It specifies the roles, rights and responsibilities of each stakeholder:
- the role, rights and responsibilities of scientists in processing and managing research data and software code;
- the role, rights and responsibilities of the institution in adopting and implementing the policy.

The policy was developed in order to raise awareness of best practices among scientists by involving them and giving them the operational resources to implement them. It is associated with fact sheets listed in the appendix.

4. Role, rights and responsibilities of the scientist

4.1. PLANNING AND THINKING AHEAD

The Institut Pasteur asks that a Data Management Plan® (DMP) be put in place at the beginning of each research project funded by an external funding body or the Institut Pasteur and coordinated by a member of the Institut Pasteur. The DMP must be initiated as early as possible in the project, and a first version must be placed in the dedicated area on the Institut Pasteur servers within the first six months of the project. The DMP is then updated regularly until the project ends. At the end of the project, the scientists must decide whether the final version of the DMP is confidential, can be distributed internally or can be made publicly available on the research.pasteur.fr website.

The Institut Pasteur asks each research entity to draw up a general data management plan. This entity DMP, more concise than a project DMP, is under the responsibility of the entity manager. It allows practices within the entity to be standardised, guides new arrivals in managing and sharing their research data and makes it easier to put project DMPs in place.

4.2. REUSING AND CREATING DATA

The Institut Pasteur encourages scientists to reuse existing data before creating their own, in order to avoid duplicating data. Scientists can consult many sources to find data suited to their needs.

Data reuse must comply with the legal framework, including regulatory or legal provisions and contractual requirements. In addition, datasets that are reused must be cited in publications, following the template proposed by the Institut Pasteur wherever possible. The Institut Pasteur considers datasets to be legitimate, citable products of research in accordance with the Joint Declaration of Data Citation Principles®.

The creation or collection of new data must also take place in compliance with the legal framework. Scientists must check whether legal constraints apply to their research project before any data are created or collected. Specifically, the Institut Pasteur emphasises that in the case of research involving human beings and/or personal data (information relating to an identified or identifiable person) or generating new data from pre-existing samples, the scientists must inform the Data Protection Officer (DPO) before the project begins and may seek help with this process from the Clinical Core at the Center for Translational Science (CRT-CC).

To make it easier to use and reuse data, the Institut Pasteur encourages the use of open, standard and interoperable formats® and the creation of metadata® based on standards® in the field as soon as the first data are generated.

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5 Data Citation Synthesis Group: Joint Declaration of Data Citation Principles. Martone M. (ed.) San Diego CA: FORCE11; 2014 https://doi.org/10.25490/a97f-egyk
4.3. USING, PROCESSING AND STORING DATA

The Institut Pasteur strongly recommends using the infrastructure provided by the Information Systems department to process and store research data and scientific software, regardless of how sensitive the data are. The information classification directive defines the sensitivity level of data and the handling rules that apply.

Before publication, research data must be stored and distributed using tools appropriate to their sensitivity level and must only be accessible to authorised people. Access permissions must be defined for the data at the beginning of the project. The Institut Pasteur recommends ensuring that research data are regularly backed up in managed, controlled storage areas. They must also be handled, transferred and exchanged using tools appropriate to their security level.

Each entity has its own storage space on the Information Systems department's servers for the entity's data, and can request the creation of a new space for each research project, with access limited to the people involved in the project. To ensure that everyone can easily find the data they need, the Institut Pasteur recommends organising these storage spaces on the basis of a classification scheme*. To make it easier to find and identify data, it is also advisable to adopt precise, shared naming rules*.

The Institut Pasteur recommends setting up appropriate data quality and consistency checks in databases and tracking and documenting all actions carried out on data. Metadata describing the processes applied to the data should be created and linked to the data as soon as they are created and for as long as they are processed. In particular, data concerning human beings, if possible managed with the Institut Pasteur eCRF, must be tracked and managed according to best practices in clinical research and the regulations in force.

4.4. DISTRIBUTING, PUBLISHING AND SHARING DATA

The Institut Pasteur encourages the distribution, publication and sharing of research data and software code with free access according to the principle "as open as possible, as closed as necessary".

Certain data cannot be shared, or only under specific conditions. The publication or sharing of data must take place in compliance with the applicable legal framework, where relevant. In particular, before data are shared or made public, the Institut Pasteur asks scientists to check:

- That the data are not sensitive or confidential;
- That the data do not allow research subjects to be identified directly or indirectly;
- That the data cannot be protected under industrial property rights (such as a patent application);
- That the data cannot be exploited economically;
- That sharing the data is compatible with the terms and conditions of the research contract.

It is also important to verify that the method used to share or publish the data is appropriate to their sensitivity level.
For all data that can be published or shared, not being subject to the restrictions above:

The Institut Pasteur acknowledges that not all data can be shared. In all cases, whether the research is publicly funded or not, scientists are advised to publish at least the data underlying the publications* at the same time as the articles (raw data – if not confidential – and analysed data). As long as scientists have carried out the above checks, they are free to publish or share any other data. They are particularly encouraged to publish negative results (data that will not give rise to a scientific article).

The Institut Pasteur asks that datasets be shared with a wide audience using appropriate sharing mechanisms: databases, data repositories* etc. Sharing data does not necessarily mean that that data will be accessible to anyone with no restrictions. Some data repositories allow access to data to be controlled (access upon request or subject to approval by a scientific committee, for example). If access to the data must remain restricted, the Institut Pasteur asks that the metadata be accessible so that the existence of the data and the conditions for access are known.

Scientists must publish high-quality, reusable datasets that are correctly described, documented and contextualised. To comply with the requirements of funding bodies, the publication of data must follow the FAIR principles*. Datasets made available to the public must always be associated with a distribution and usage licence*.

The Institut Pasteur encourages the publication of data papers*, peer-reviewed publications that present and describe a dataset* and can be cited in the same way as any other publication.

**Special case of public health emergencies:**
According to the principles set out by GloPID-R⁶ (Global Research Collaboration for Infectious Disease Preparedness), the Institut Pasteur requires data relating to public health emergencies to be shared and made available as quickly as possible, with the fewest possible restrictions on access. However, the quality of the data must be checked before they are made available. A balance must be struck between the need for rapid sharing and compliance with FAIR principles*.

### 4.5. PRESERVING AND ARCHIVING DATA

At the end of each research project, and before the entity is closed, the Institut Pasteur asks scientists to preserve the data produced in a specific preservation space to ensure their permanence. To ensure data are comprehensible and reusable, the data deposited in this space must be correctly described and documented and recorded in a sustainable format*.

The Institut Pasteur asks scientists to check the regulations and legal or contractual constraints on preservation applying to their data. In particular, in the case of personal data (i.e. data about an identified or identifiable person), the law requires data to be sorted so that they are only preserved if they are "adequate, relevant and limited" to what is necessary for the purposes for which they were collected or processed.

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In all cases, before data are deposited in the preservation space, the Institut Pasteur asks scientists to sort their data, only preserving data whose preservation is mandatory or beneficial in the long term:

- Data subject to legal or contractual obligations relating to preservation;
- Data with evidential value (proof of prior existence, for example);
- Data that can be used for the reproducibility of scientific work;
- Unique data that are non-reproducible or difficult to reproduce.

4.6. MANAGING SOFTWARE, SCRIPTS AND PROGRAMS

The Institut Pasteur encourages scientists to reuse existing software or software components before developing new ones, verifying in advance the restrictions resulting from their licences. Directories exist to help scientists find the resources they need.

When scientists reuse third-party software or software components, they must cite each software component reused in their publications, following the template proposed by the Institut Pasteur wherever possible. The Institut Pasteur considers software to be legitimate, citable products of research in accordance with the Software Citation Principles7.

The Institut Pasteur encourages all scientists developing software components, whether they are scripts, programs or workflows, to follow best development practices, including versioning, documentation and testing, using standards in the field wherever possible. It is advisable to submit software created at the Institut Pasteur to the software forge provided by the Institut Pasteur, from when it is created to any later distribution.

To avoid introducing vulnerabilities, development must take place according to the best practices outlined in the guide to secure development.

Before software is distributed, the Institut Pasteur asks scientists to verify whether it could be used for industrial applications (in accordance with the restrictions imposed by funding bodies). If it could, the scientists undertake to inform the Institut Pasteur’s Patents and Inventions Department first, without delay, and to make an invention disclosure with them.

If the software can be distributed, the Institut Pasteur recommends making the source code public, providing packages and registering the software in a software catalogue. Published software must always be given a distribution and usage licence*. The choice of licence may have repercussions for the future exploitation of the software (commercial, academic, free, paid-for etc.).

Regardless of its licence, distributed software can be exploited in a number of ways: start-up creation, support and training, development of specific features, capitalising on skills etc. In all cases, if scientists are contacted by an industrial company about software they have published, they must contact the Technology Transfer department.

To enable others to find and cite the correct version of the software code (e.g. the version used and cited in a publication), the Institut Pasteur recommends submitting this version to HAL-Pasteur. The code will automatically be transferred to Software Heritage to ensure it is

permanently available and citable. Software Heritage gives each software component a unique, persistent* identifier.

To plan all the stages in the life cycle of the software (from idea to possible distribution), the Institut Pasteur recommends establishing a Software Management Plan* (SMP) as soon as the design of research software begins. The SMP must be placed in the dedicated area on the Institut Pasteur servers.

5. Role, rights and responsibilities of the institution

5.1. PROVIDING INFRASTRUCTURE

The Institut Pasteur provides scientists with appropriate, robust, economically viable infrastructure for managing and storing research data and software code. The Information Systems Department supports scientists and offers tools to make this infrastructure easier to use.

5.2. PROVIDING SUPPORT AND TRAINING

The Institut Pasteur supports scientists in the application of this policy. Each fact sheet (full list in the appendix) explains the departments to contact, the tools available and the training that exists. Specifically, the Institut Pasteur undertakes to develop training programmes about data management.

The Institut Pasteur also provides research teams with operational support to help with the various aspects described in this policy (see the contacts in each fact sheet).

5.3. RECOGNISING AND PROMOTING BEST PRACTICES

The Institut Pasteur considers that datasets and research software are legitimate products of research eligible for evaluation. In addition, the Institut Pasteur recognises that the activity of data management and coding is an integral part of the research process and contributes to the quality of research.

Consequently, starting in 2021, the COMESP (Committee for the Assessment of Staff Scientific Activities) will be sensitive to various initiatives for managing and making available datasets and research software, including the introduction of data management plans and software management plans for research projects conducted at the Institut Pasteur.

In addition, the entity’s data management plan and any other initiatives put in place to manage and distribute data and software code will be taken into account in the entity’s evaluation.

The Institut Pasteur also recognises software as exploitable products of research, which may give rise to remuneration depending on the enterprise agreement in force.
6. Glossary

Data paper (or data article)
A peer-reviewed scientific publication that aims primarily to describe one or more datasets. The data described must be accessible, either in the form of appended data files or via a permanent link to the data repository where they are stored. The data paper can be published in a data journal (a journal that only publishes data papers) or a conventional scientific journal.

Data underlying publications
Data needed to validate the results presented in scientific publications.

Data repository
A repository for storing research data and enabling them to be found and reused thanks to a metadata description. There are many data repositories of different types: disciplinary, multidisciplinary, specific to a publisher, institutional etc.

Sustainable format
A format can be considered "sustainable" if it is open (its internal specifications are freely accessible), widely used and standardised (if possible).

Open, standard and interoperable formats
An open format is a format whose functional and technical specifications are public and available free of charge (or at a low cost). An open and standardised format (e.g. the ISO 19005 - standardised PDF/A format) is interoperable – data recorded in this type of format are independent of the software used to create them; they can be read and modified by any software designed to process this type of file (image, text, audio etc.).

Unique, persistent identifier (or PID for Persistent IDenfifier)
A unique, persistent identifier enables a digital resource to be identified uniquely and cited. It guarantees a stable link to the online resource by establishing a permanent correspondence between the resource's identity and its location on the web.

Dataset
A dataset is a grouping of similar or connected data gathered together to form a coherent whole. A dataset must always be accompanied by metadata so that it can be easily understood and reused.

Distribution and usage licence
A distribution licence is a legal instrument that supplements copyright. It enables the rights-holder of a work to grant to users in advance certain rights to use the work.

Metadata
Metadata are structured information that describes data or a resource. Metadata accompany data to enable the scientific community to access, understand and reuse them.

Classification scheme
The classification scheme is the tree structure of directories and files, with names anyone can understand, common to a project or an entity. The classification scheme helps anyone to find data more easily and to pass on information in a context of regular staff turnover (doctoral students, post-docs, fixed-term contracts etc.).
Data Management Plan
The Data Management Plan is an evolving summary document that helps to organise and foresee all the stages in the data life cycle. It is drafted at the beginning of a research project and regularly updated. It explains how the research data collected or generated are managed during and after the project.

Software Management Plan
A Software Management Plan is an evolving document describing a piece of research software, how it is designed and developed, its goals, who it is for, the results expected and obtained, its potential distribution, intellectual property information etc. throughout the life cycle of the software.

FAIR principles
The FAIR principles (Findable, Accessible, Interoperable, Reusable), published in 2016, constitute guidelines and best practices for improving the reuse of research data. With slight adaptation, the principles can also be applied to research software.

Naming rules
Adopting precise, shared naming rules is essential in order to locate and identify data, avoid problems during transfer and enable data to be preserved in the medium and long term. A few rules to be respected: give a brief, explicit name, do not use spaces or special characters, indicate the version etc.

Metadata standards
Metadata standards are models that specify all the metadata needed to describe a resource. For example, the Minimum Information about a Genotyping Experiment (MiGen) describes all the metadata required to be able to understand and reuse data arising from a genotyping experiment.

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# Appendix to the policy on the management and sharing of research data and software code

## Fact sheets

The fact sheets are available on the Institut Pasteur's intranet (limited access).

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<th>FACT SHEET TITLE</th>
<th>BRIEF SUMMARY</th>
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<td><strong>The project data management plan: a tool to help you plan the management of your research data</strong></td>
<td>A Data Management Plan (DMP) is a document that defines how a project's data are managed. This fact sheet answers a number of questions: - What information is required in a DMP? - How do I use the template provided by the Institut Pasteur? - Which tools can I use? - When does the DMP need to be written and where should the different versions be submitted?</td>
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<tr>
<td><strong>Setting up a data management plan in your entity</strong></td>
<td>An entity data management plan (entity DMP) is a document that defines how an entity's data are managed (an entity may be a research unit, a national reference centre, a research platform etc.). This fact sheet explains what an entity DMP is for and how to use the template available from the CeRIS library.</td>
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<td><strong>Sources for finding data and software components that can be reused</strong></td>
<td>Before generating data or developing software, it is advisable to check whether existing datasets or software produced by other scientists could be reused. This fact sheet helps you find the resources you need: - the different sources you can consult - the steps to take for effective research.</td>
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<tr>
<td><strong>Legal issues related to data reuse</strong></td>
<td>This fact sheet lists the questions that every scientist should ask before reusing a dataset, in order to verify that the reuse is done in compliance with the legal framework in force.</td>
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<td><strong>Citing a dataset or research software</strong></td>
<td>Before generating data or developing software, it is advisable to check whether existing datasets or software produced by other scientists could be reused. This fact sheet sets out a template for citing reused datasets or software in your publications.</td>
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<td><strong>Collecting data in the context of health research involving personal data</strong></td>
<td>This fact sheet clarifies the concept of personal data and presents a brief introduction to areas requiring attention before data collection begins.</td>
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<td>Describing your research data: metadata and documentation</td>
<td>This fact sheet helps you understand different ways of describing scientific data, with documentation and metadata. The sheet covers the following subjects: - Which metadata should be linked with data? - Why link metadata as well as producing documentation?</td>
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<td>Nature and format of data in the biomedical field</td>
<td>To be able to manage data correctly, it is important to define them precisely in advance: which types of data, and which formats? This fact sheet provides a non-exhaustive list of data types and formats in the biomedical field. It also clarifies the difference between open formats and closed formats.</td>
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<td>Information classification directive</td>
<td>(Document in French) The purpose of information classification is to identify sensitive information and harmonise information management and protection practices within the Institut Pasteur. It provides a means of objectively determining the sensitivity level of information using different scales, and defines corresponding rules on information handling.</td>
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<tr>
<td>Tools and infrastructure for the management, storage and sharing of data and software code at the Institut Pasteur</td>
<td>This fact sheet summarises the different tools and infrastructure available at the Institut Pasteur for the management, storage and sharing of data and software code. The tools are classified into different families: scientific information system, high performance computing cluster, scientific software development, scientific software catalogue, web communication, collaborative work, container hosting, machine/application hosting.</td>
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<td>Organising storage space for data accessibility and sustainability</td>
<td>Each entity has its own storage space on the Information Systems department's servers. This fact sheet gives advice on how to organise this storage space: - by putting a classification scheme in place - by adopting precise, shared naming rules - by creating a preservation space and regularly transferring finalised data to it.</td>
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<td>Best practices for data management in REDCap</td>
<td>This sheet summarises best practices for data management and focuses particularly on the use of REDCap®: the questions to ask in advance, how to improve data quality in your projects and, above all, how to get your REDCap® projects into &quot;production&quot; before collecting any real data to guarantee their integrity.</td>
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<td>Legal issues related to data dissemination</td>
<td>This fact sheet lists the questions that every scientist should ask before publishing or sharing a dataset, in order to verify that the dissemination is done in compliance with the legal framework in force.</td>
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<td>Transferring information from the Pasteur IS</td>
<td>(Document in French) This document aims to summarise information about methods of transferring data from and to the Institut Pasteur information system.</td>
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<td><strong>Sharing data with wide audiences via data repositories</strong></td>
<td>The best way of sharing data with a wide audience is to deposit them in a data repository. This fact sheet explains why and how you can share your data using a repository, internally or externally.</td>
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| **How to make your data FAIR and choose a distribution licence?**     | The FAIR principles (Findable, Accessible, Interoperable, Reusable) constitute guidelines for improving the reuse of research data. After a detailed explanation of the FAIR principles, this fact sheet answers the following questions:  
  - What can you do in practice to make your data FAIR?  
  - How should you choose a distribution licence? |
| **The data paper: a publication for presenting and describing data**  | A data paper (or data article) is a peer-reviewed scientific publication that aims to describe one or more datasets. This fact sheet explains why and how to publish a data paper. |
| **Archiving of data from human research**                            | This fact sheet details the retention periods and procedures for data from clinical research and human research.                                 |
| **Best practices in software development**                           | "Best practices" are a set of informal rules that can be applied when developing software. This sheet explains what these rules are, why it is important to put them in place and which tools are available to help you implement them. |
| **Development, management and exploitation of research codes and software: resources and expertise at the Institut Pasteur** | (Document in French) This fact sheet specifies the people to contact and the tools available at the Institut Pasteur for the development, management and exploitation of research codes and software. |
| **Guide to secure development**                                      | (Document in French) This guide aims to raise awareness among developers and train them in computer security. It consists of several subsections:  
  - principles of secure development  
  - top 10 vulnerabilities  
  - rules for writing secure code  
  - library of security functions and tests |
| **Protect and transfer your inventions**                             | This page provides answers to questions frequently asked by Institut Pasteur researchers on various aspects relating to the protection and promotion of their research results. |
**Distributing software: best practices and choosing a licence**

Distributing software means making it easy to find and accessible for users, developers and organisations. This fact sheet answers the following questions:

- how can I make my software available and tell people about it?
- how do I choose a licence for my software?

**Capitalising on software**

The potential commercial development of your software is not based solely on the source code you have developed, but also on your knowledge and your ability to develop innovative new features. This sheet specifies the cases when you can contact the Business Development team and areas that need attention if you are considering marketing your software commercially, including the choice of licence.

**Ensuring your source code is cited, visible and sustainable with HAL and Software Heritage**

To enable others to find and cite the right version of your software code, it is advisable to submit this version to HAL-Pasteur. The code will automatically be transferred to Software Heritage to ensure it is permanently available and citable. This fact sheet explains why, and what to do in practical terms.

**Why and how to draft a software management plan**

A Software Management Plan (SMP) is a reference document that describes the (best) practices put in place when software was developed. This sheet answers several questions:

- What is a SMP for?
- Which template is recommended?
- When should the SMP be drafted, and where should the different versions be submitted?