

Terms of Use

Depositor User of the Institutional Repository ARCA DADOS

1 INTRODUCTION

This instrument presents the Terms of Use (“Term”) of the Institutional Repository ARCA DADOS, hosted on the website <https://dadosdepesquisa.fiocruz.br>

In these Terms of Use are defined the obligations and responsibilities of the Depositor, who is the User object of this Term, and who can deposit the research data and make it available for the access of third parts, without prejudice to the provisions of applicable laws.

2 ON THE REGISTRATION

2.1 ON THE CATEGORIES OF USERS. The ARCA DADOS can be used by the following Users:

- a) **Common User** - whose privileges on the system are to access, use and download data, hereby simply named Common User, and who will be the object of a specific term of use;
- b) **Depositor User** - whose privileges are to deposit and manage the deposited Datasets; this User is hereby named Depositor User, who is the object of this instrument; and
- c) **Data Curator** - is the one responsible for the curatorship and activities directed to management, preservation and security of data.

The Depositor User, by registering, accessing and depositing Research Data on the Institutional Repository ARCA DADOS, **expressly manifests acceptance**, fully and without reservations, of all norms, conditions, and policies comprised in the present Term and any Alterations, as well as commits to respecting all applicable norms to the kind.

By accepting the terms of this instrument, the Depositor User **declares and guarantees**, under penalty of liability, that there are no obligations or impediments attributed by law, agreement, contract, or other instrument that are impeditive to the acceptance of this Term, and that the Institutional Repository

ARCA DADOS will be used responsibly and adequately according to the institutional norms and the protection of rights of owners and data.

In case of non-acceptance of the present Term, the Depositor User shall not access, use and/or deposit Research Data on the Repository, under penalty of liability and eventual adoption of applicable measures.

2.2 ON THE DEPOSITOR USER'S PERSONAL DATA

The Depositor User is aware and agrees that:

a) Providing personal data is necessary for the identification and individualization of each User and aims to guarantee the prevention of fraud and the User's security, in the processes of identification and authentication of your Registration;

b) Your personal data are necessary and can be preserved for the use of the operator in the elaboration of studies of the system Users, aiming at the improvement of this service supply. Such studies will be performed, whenever possible, with Users' anonymized data;

c) Your personal data may be shared, exclusively, among bodies and entities of the federal public administration - direct, autarchies, and foundations - and the other Federal Powers, with the purpose of: simplifying public services supply; guiding and optimizing the elaboration, implementation, assessment, and monitoring of public policies; enabling the analysis of conditions of access and maintenance of social and fiscal benefits; promoting the improvement of quality and trustworthiness of data in custody of the federal public administration; and increasing the quality and efficiency of internal operations of the federal public administration.

By depositing the set of Research Data on ARCA DADOS the Depositor User agrees and recognizes that personal data such as name, institutional link, and electronic mail (e-mail) will be available to other Users and can be part of the deposited dataset, considering the rights of authorship and designation, and to make it possible for other users to make contact, if applicable.

2.3 ON THE TREATMENT OF THE DEPOSITOR USER'S PERSONAL DATA

Fiocruz complies with rigorous technical, administrative and data security protocols, with measures and countermeasures for the protection of personal data against non-authorized accesses and accidental or illicit situations of destruction, loss, alteration, communication or any other form of inadequate or illicit treatment of the aforementioned data. Nevertheless, Fiocruz cannot ensure data maintenance without risks of interruptions, failures or losses resulting from system operations and is exempt from any responsibility regarding these issues, or from use of third parts unforeseen in this Term.

All rights are granted to the Depositor User over the ownership of personal data, in the form of art. 18 of Law nº 13,709/2018 (LGPD); for further information on

the owner's rights over personal data access the General Law of Personal Data Protection: [Lei Geral de Proteção de Dados Pessoais - LGPD](#)¹.

Claims of and requests for further information on the treatment of personal data can be addressed, from Monday thru Friday, from 10am to 5pm, to the Responsible for the Treatment (Encarregado do Tratamento) of personal data at Fiocruz as follows:

Name:

Post:

Sector or Service:

Address:

Telephone:

E-mail:

3 ON THE REPOSITORY

The Institutional Repository ARCA DADOS is intended for storage of Research Data, which includes, without limiting to: data generated in activities conducted and/or funded by Fiocruz, activities developed by its researchers, scholarship holders, collaborators, students, employees and other bonds, in its research centers and laboratories, and in activities developed in partnership with other institutions; and data generated by third parties who request access and registration to the Steering Committee (Comitê Gestor) of ARCA DADOS, at whose discretion authorization may be granted to use and deposit data on the Repository ("Research Data").

Developed and maintained by Oswaldo Cruz Foundation ("Fiocruz"), the Institutional Repository ARCA DADOS was constructed based on the Harvard University open software DATAVERSE, adopting in its development the best international practices of data storage, protection and publication.

3.1 ON THE DEPOSIT

Fiocruz reserves the right to request, at any time, additional information to Depositor Users and about the dataset of deposited Research Data, including, but not limited to, when necessary for the system operation or to comply with determination of a public authority or applicable law.

Only Depositor Users previously authorized and registered can send and deposit Research Data on the Repository.

¹ http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/L13709.htm

3.2 ON THE OBJECT OF DEPOSIT

The Depositor User declares that the Research Data, object of the deposit, were collected, produced, processed, organized, and utilized in the context of the indicated research, and commits to present for deposit, together with these data, additional information and descriptions that inform about the origin and context of obtainment, collection method, registers, transcription, codification and/or processing, and the different versions, among other data characteristics, and with which research organizations or development agency previous sharing of the data has been established.

On the availability of Research Data for the Repository, the Depositor User declares and commits to comply with the following conditions:

- a) To deposit Research Data that were treated and comply with the conditions and technical requirements established by those responsible for ARCA DADOS. The contents deposited on the Repository should contain metadata describing the contents, origin, formats etc., with the purpose of giving support to the diffusion and preservation of the contents;
- b) Research Data produced in another context or with another purpose, should have the origin indicated in the metadata set, with no violation of rights of the original controller or data owners;
- c) The Depositor User should have each and every necessary authorization for the deposit, sharing and publication of the Research Data on the Repository, including, but not limited to, the authorizations of possible co-authors and/or owners; also, the Depositor User ensures that the sharing of the Research Data does not infringe intellectual property rights of third parties.
 - i. The sharing of such data, if made previously to the deposit, does not offend any confidentiality clause agreed in the research funding contract, as well as any other confidentiality pact signed with partners and collaborators of the research;
- d) The sharing of data does not jeopardize the object, rights or values (legal assets) under tutelage by legal confidentiality relating to intellectual property or businesses secrets, or contractual obligations or agreements, according to analysis that should be previously submitted by the Depositor User to Gestec-NIT System. The Depositor User states that:
 - i. The deposited data do not express results with potential to contribute or generate innovative products or processes or with characteristics that are superior or more advantageous than those existing in the market;
 - ii. The deposited data do not express information related to negotiations, prospective or intelligence reports, as well as business plans that if revealed could jeopardize the Institution's initiatives or future investments;

iii. The deposited data do not express information related to the outcomes of tests and other data, unrevealed, whose elaboration would have involved considerable effort, produced with the aim of presenting to governmental regulatory entities as a condition to approve the commercialization of products and services.

iv. Had consulted the Gestec-NIT System previously to the Deposit of Research Data and has obtained a written opinion on the convenience of disclosing or sharing the Research Data;

v. Has obtained formal authorization of competent authority for the deposit and sharing of the Research Data, and the authorization should accompany the referred Research Data;

e) The data, object of the deposit, do not refer to research and scientific or technological development projects whose secrecy would be essential to the security of the society and the State, or to national strategic interest. The Depositor User states that:

i. Sharing such data does not hinder or cause risk to research and scientific or technological development projects, nor to systems, assets, installations, or areas of national strategic interest.

ii. Sharing such data does not express information classified as confidential according to [Law nº 12.527/2011, Access to Information Act](#)², as well as does not cause risk to the security of the society or the State.

f) The Depositor User transfers, expressly and unequivocally, all possible available rights of ownership over the deposited dataset, whereby it is essential to sign the term of transfer of rights in favour of Fiocruz, for the effectiveness of depositing and sharing according to the prescribed terms and conditions. The respective signed term of transfer should accompany the Research Data to be deposited.

g) Data collection, organization, production, utilization, and treatment, object of the deposit, have rigorously complied with the ethical criteria established by the instance of ethical analysis of the research, to which the project has been submitted;

i. In the case of personal data referring to an identified or identifiable individual, these data were collected, produced, organized, utilized, and treated in accordance with the consent of the holder and observance of the purpose indicated in the act of its his/her manifestation.

ii. The Depositor User is committed to depositing the dataset related to the registers of consent provided by holders of personal data for the treatment and sharing of their data.

iii. The user ensures the maintenance in active transparency of all information about the type of data, the way of utilization, and the procedures for the exercise of rights of their holders referring to the collection, production, organization,

² http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12527.htm

utilization, and treatment of personal data, as well as those of children and adolescents, and civilly incapable person.

iv. Data related to natural persons are duly anonymized, with no possibility of direct or indirect association to an individual, considering the use of technologies available at the time of the deposit.

v. The reversion of data anonymization is impossible or very unlikely to be achieved, even if submitted to cross-section with other sets of known or public access personal data.

vi. In the case of research involving cohort studies, personal data are pseudonymized according to the Law, without possibility of direct or indirect association to an individual, whose additional data (or key code) are organized separately and, therefore, they should be kept in a controlled and secure environment with the Depositor User or the Data Manager, according to the Depositor User's indication.

vii. Deposited data that are pseudonymized will only be made available for replicability or reproductibility of the research, without the additional data (key code) that enable the reversion of the pseudonymization process, in compliance with ethical and legal criteria for their reuse.

h) In the case of research or technological development involving access to the Brazilian genetic patrimony and/or associated traditional knowledge, its registration shall be made on the self-declarative SisGen system, with the indication of the dataset deposited in this Repository.

i. The Depositor User declares to know and commits to comply with the obligations imposed by [Law nº 13,123, of May 20, 2015](#)³, as well as its regulations, and assumes the commitment to maintain and provide all information required by the public authorities for the traceability of activities resulting from the access to genetic patrimony or associated traditional knowledge, indicating, when there is, the occurrence of and fundamentals for the obligation of legal confidentiality of these data and information.

ii. Only after the issuance of the certificate of regularity of access by the competent authority, which shall be part of the dataset to be deposited, shall the data be made available, as long as there is no legal hypothesis of confidentiality.

iii. The Depositor User is responsible for the control over the access to deposited data referring to research or scientific development performed on the Brazilian genetic patrimony. At the discretion of the Depositor User, this data may have public access, as long as no legal confidentiality falls upon them.

iv. Referring to associated traditional knowledge, the registers relative to the previous informed consent according to uses, costumes, tradition, or community protocols shall be part of the deposited dataset.

³ http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13123.htm

3.3 ON THE ACCESS TO RESEARCH DATA

At the discretion of the Depositor User and/or the Data Curator, specific rules and access control may be applied to data defined as PUBLIC (UNRESTRICTED) or RESTRICTED (BLOCKED). In the case of PUBLIC access, the Depositor User and/or the Data Curator may define questionnaires and Terms of Access for the access to Research Data. .

In the case of RESTRICTED access, the Depositor User and/or the Data Curator may restrict part of or all the archives that compose the set of Research Data, and may establish the specific archives that must be protected, by technical criteria and prioritizing the protection of sensible data, especially related to business secrecy/strategy, ongoing scientific research, and/or documents protected by means of confidentiality agreements signed with third parties.

Data under confidentiality in accordance with the Access to Information Act or other specific legislation should not be deposited on the Institutional Repository ARCA DADOS, as well as Research Data with potential to generate new products, services, or that are potentially protected by intellectual property offices in Brazil and worldwide.

In case the access criterion is defined differently from PUBLIC, the Depositor User commits to promote a periodical analysis of the deposited dataset, every 2 (two) years at the most, if data are maintained for a longer period, with the purpose of verifying if the reasons or conditions that have determined the access criterion also remain. If they no longer remain, a less restrictive access criterion shall be attributed to the dataset.

In case the access criterion is defined differently from PUBLIC, the Depositor User, together with the Data Curator, shall be responsible for:

- a) Authorizing the access and its permissions and defining the terms and conditions for the use, availability and sharing of Research Data;
- b) Periodically reviewing the lists of access authorization and revoking permissions when no longer necessary;
- c) The guard and maintenance of the key code (access key) to the dataset, object of the deposit;
- d) For the outcomes resulting from the management of data access;
- e) Verifying the possibility of publication of the metadata, or elements of identification of the dataset, without compromising the confidentiality attributed to the data.

4 ON ALTERATIONS, MODIFICATIONS AND EXTINCTION OF THE PRESENT TERM

Fiocruz reserves the right to, at any time, modify this Term, by including, removing or altering any of its clauses (“Update”). The Update will have immediate effect, and will be published on the Repository, and the continuity of the use of the Repository will be considered as the unequivocal acceptance of and agreement with the modified Term.

In case the User does not agree with the Update, he/she shall immediately cease the use, access and deposit of data on the Repository, since any new use or activity performed after the alteration will be regulated by means of the new Term.

5 ON GARANTEE EXEMPTION AND LIABILITY LIMITATIONS

The Repository is provided “in the state in which it is”. To the maximum extent permitted by law, Fiocruz provides no guarantees and/or express or implicit conditions over the Research Data, including, without limitation, any guarantees; or on the ownership and non-violation of third-parties’ intellectual property regarding the Repository; or the on Research Data and any of their components; or on the delivery, or not, of support services to the USER.

Except for what is established in this Term, there are no other distinct guarantees or conditions of use in relation to the access of the Depositor User to the Repository, either express or implicit. In effect, all possible guarantees, conditions and/or attributions established in this Term may be excluded or altered in accordance with what is permitted by law, without prejudice to Fiocruz and its collaborators.

Fiocruz does not guarantee, declare or ensure that the use of the Repository will be uninterrupted or free of errors, nor ensures that it is free of loss, interruption, attack, virus, interference, piracy, or other security invasion, and is exempt of any responsibility in relation to these issues, or from use by third parties not foreseen in this Term.

At the discretion of Fiocruz, the Repository may, at any time, be modified, updated or discontinued, temporarily or permanently, and may be distributed and managed in the way that is most convenient for Fiocruz, and there is no responsibility or obligation by Fiocruz to indemnify for any modification, updates, suspensions or discontinuity of the Repository.

6 ON INTELLECTUAL PROPERTY

It is forbidden to use any names, marks, registered or not, logos, symbols, or other designations of Fiocruz or its employees and collaborators, especially, but

not limited to, in any propaganda, press information, or publicity, without the previous written approval from Fiocruz.

The Depositor User, by means of the present Term, transfers free of charge to Fiocruz all and any rights on improvements, feedbacks and/or comments provided to Fiocruz about the Repository (“Improvements”), as well as commits to keep confidentiality about the information on Improvements, not revealing them to third parties.

7 GENERAL PROVISIONS

The Depositor User agrees to exempt and indemnify Fiocruz of all responsibilities, demands, damages, expenses and losses arising in relation to Research Data deposited or made available on the Repository.

The Depositor User commits to inform the Managers of the Repository, at any time, about problems or inconsistencies with ownership, intellectual property or its violation, violation of third parties’ rights, privacy or confidentiality, when related to Research Data.

If any provision in this Term is considered invalid or unenforceable, this provision will be null, without affecting the legitimacy and validity of the remaining provisions.

The Depositor User legally commits to provide all and any additional information, necessary to the compliance with legal norms or order emanating from competent public authority that may be demanded in the course of custody of the deposited data and that until this point has not been provided or registered.

The forum elected is the Federal Court, Court Division of Rio de Janeiro State, to settle any litigation arising from this instrument, provided in Item I, Article 109 of the Federal Constitution.