# **Regional research management Platform within Ethics Committees and Local Health Trusts of the Regional Health Service of Emilia-Romagna (SIRER)**

# **Platform Terms and Conditions of Use & Privacy Policy**

Local Health Trusts and Scientific Institutes for Research, Hospitalization and Healthcare (IRCCS) of the Regional Health Service of Emilia-Romagna require the electronic transmission of applications for authorisation to conduct studies, as applications also need to be approved by the Ethic Committee of the related *Area Vasta*.

The Platform, aimed for sharing documents and communications related to studies assessment, is protected and access is restricted to registered Users.

The registration of the Promoter, or the CRO registration delegated by the Promoter himself (hereafter “Applicants”), is needed in order to submit the application for an opinion.

Direct access to the SIRER Research Platform will allow Applicants to both collaborate in the Application filling in and in being informed in respect of trial assessment process, until the study completion.

In addition, the Promoter and the CRO (as a delegate) will be able to consult all relevant documentation, information and communications at any time.

**Platform Terms of Use**

The Platform is owned by the Emilia-Romagna Region. The Region reserves the right to modify the Platform Terms and Condition of Use and to further implement the Platform itself.

By accessing the Platform, the Applicant accepts the following:

* the Platform, or part of it, may be temporarily unavailable because of malfunction and/or connection flaws or events beyond the Emilia-Romagna Region control;
* the Emilia-Romagna Region does not have any control over instruments the Applicant is using to log on the Database, neither over the way he is consulting the Database through such instruments;
* the Emilia-Romagna Region does not hold the responsibility for the conduct of the Users while consulting the Database;
* when consulting the Platform, the Applicant agrees for itself and for its own Users for not to duplicate the Platform, neither in whole nor in part. Any full or partial data re-use or mining of the Database – even if minimal – is forbidden;
* it is forbidden to use the Platform for any purpose that is unlawful or to divulge or disseminate in any way materials or contents to commit an act of unlawful interference
* it is forbidden to damage or make the Platform less efficient, both in part or in whole.

**Authorisation of Users**

For the purpose of accessing the Platform, each User delegate by the Applicant should therefore individually request the activation submitting the needed documentation to the e-mail [assistenza.sirer@lepida.it](mailto:assistenza.sirer@lepida.it), as indicted in the registration form.

**The system will be accessed through the Public System of Digital ID (*Sistema Pubblico di Identità Digitale*, SPID) to which each User should be registered**.

The Applicant will be responsible for any prejudice caused to the Emilia-Romagna Region or to third parties consequences of any failure to comply with the conditions of use.

Any violation of conditions of use will lead to the access authorisation revoke of the User responsible for the violation itself.

The Applicant undertakes to promptly inform the Emilia-Romagna Region (by writing to the mail address [assistenza.sirer@lepida.it](mailto:assistenza.sirer@lepida.it)) for any possible loss of the required qualification to access the Platform from one or more internal Users (as an example because of the ending of User collaboration with the Applicant), in order to allow the Region to disable the access permissions.

**Per acceptance**

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| --- | --- |
| The Applicant:  [signature]  Name:  Title:  Date and place: | The User:  [signature]  Name:  Title:  Date and place: |

**Privacy Policy**

Information note pursuant to Article 13 of the Regulation (UE) 2016/679

The following privacy policy, also to be intended as information note pursuant to Article 12 of the Regulation UE n. 2016/679 (hereafter “Regulation”), describes the processing of personal data of SIRER Users, accessible through the following address: <https://sirer.progetto-sole.it/>.

**Data Controller**

Data Controllers are the legal representatives of Local Health Trusts and Scientific Institutes for Research, Hospitalization and Healthcare (IRCCS) of the Region.

Please, refer to Health Trusts/IRCCS websites for contact details.

System administrators are responsible for data processing. Health Trusts/IRCCS professionals and members of Ethics Committees and their Secretariat, who are involved in various respects in the system use, are authorised to process data.

**Data Protection Officer**

Contact details of Data Protection Officers (DPOs) are to be found in the above-mentioned websites.

Kind of processed data and purposes of processing

Navigation data

The computer systems and software procedures used to operate the site acquire, during normal operation, some personal data whose transmission is implicit in the use of Internet communication protocols.

In this category of data includes IP addresses, computer domain names used by the Users, the Uniform Resource Identifier/Locator addresses of the required resources, the method used in submitting the request to the server, the size of the file obtained in response, the numerical code indicating the status of the response given by the server (successful, error, etc.) and other parameters relating to the operating system and the user’s computer environment.

These data, necessary for the use of web services, are also processed for the purpose of:

* obtaining anonymous statistical information on the use of the services (most visited pages, number of visitors per hour or day, geographical areas of origin, etc.);
* checking the correct functioning of the offered services.

Data provided by the User

The processing of data provided by the user by filling in the forms on the Platform, it is done in compliance with the regulations in force.

*Cookies and tracking systems*

No cookies are used for user profiling and no other tracking methods are used. Session cookies (non-persistent) are used strictly limited to what is necessary for the safe and efficient navigation of the sites. The storage of session cookies in terminals or browsers is under the user’s control, whereas on the servers, at the end of HTTP sessions, information relating to cookies remains recorded in the service logs.

Legal basis and purposes of processing

The processing of your personal data is carried out for the performance of institutional functions (Regional Law 29/2004) related to the processes of studies approval and authorization.

Period of personal data storage

Data provided by the User are processed for the time necessary to perform the requested services, except for a longer period of retention, where required by law, regulation, or if the processing proves necessary to meet legal purposes. The processing shall be carried out exclusively by authorised and adequately trained employees and collaborators, as well as, for the performance of specific activities, by external, public and/or private entities, previously designated, by specific agreement pursuant to Article 28 of the Directive 95/46/EC (General Data Protection Regulation), as data processors. Data will not be transferred outside the European Union.

The rights of data subjects

The subjects have the right to obtain, in the cases provided for by current legislation, access to personal data and the rectification or cancellation or the limitation of the processing data referring to them or to object the processing (Articles 15 et seq. of the Regulation). The appropriate request is made by contacting the Data Controller or the Data Protection Officer.

Complaint right

Data subjects who consider the processing of their personal data has been carried out in breach of the provisions of the Regulation, have the right to lodge a complaint with the Data Protection Supervisor (pursuant to Article 77 of the Regulation) or to submit it to the competent judicial authorities (pursuant to Article 79 of the Regulation).

Processing place

Personal data processed by the Owner are stored within the European Union.

**Further information about data processing**

**Defence (before the courts)**

The User’s personal data may be used by the Data Controller, in court or in the preparatory stages for its possible establishment. The User is aware that the Data Controller may communicate the User’s personal data to the Public Authorities if expressly requested to do so.

Amendments to these regulations

The Data Controller reserves the right to make changes to this information notice, recommending that the Applicant use the most up-to-date version of this form, taking as a reference the date of the last change indicated at the end of the text. In the event of non-acceptance of the changes made to this statement, the User may request the Data Controller to remove her/his personal data. Unless otherwise specified, the previous privacy policy will continue to apply to personal data collected up to that moment.

Having seen the consent hereby authorizes the processing of personal data

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| --- | --- |
| Applicant:  [signature]  Name:  Title:  Date and place: | User:  [signature]  Name:  Title:  Date and place: |