



**International Clinical Trials
Registry Platform**

ICTRP Registry Profile

Registro Peruano de Ensayos Clínicos (REPEC)

Peruvian Clinical Trial Registry (REPEC in Spanish)



Basic Information

I. Name of person completing this form	Leda Yamilée Hurtado Roca
II. Role of the person completing this form (that is, the role of this person in the registry making this application)	Head Officer General Office for Research and Technological Transfer
III. Date this form was completed	13 / 02 / 2023 <i>dd mm yyyy</i>
IV. Signature of person completing this form	
V. Official Name of Registry (list abbreviation used, if relevant) Eg Australian and New Zealand Clinical Trials Registry (ANZCTR)	Registro Peruano de Ensayos Clínicos (REPEC) Peruvian Clinical Trial Registry (REPEC in Spanish)
VI. Registry postal address	Av. Defensores del Morro 2268 (Ex Huaylas) - Chorrillos, Lima –Perú Postal code: 15054
VII. Registry street address (if different to postal address)	Av. Defensores del Morro 2268 (Ex Huaylas) - Chorrillos, Lima –Perú Postal code: 15054
VIII. Registry URL (Registry's web site address)	https://ensayosclnicos-repec.ins.gob.pe/
IX. Registration URL (Web site where users go to register a trial)	https://repec.ins.gob.pe/
X. Application type	Application for Primary Registry status <input checked="" type="checkbox"/> Application for Partner Registry status <input type="checkbox"/>
XI. What is the name of the agency (or agencies) that funds the registry?	National Institute of Health (Peru)
XII. What is the name of the agency that manages the registry?	National Institute of Health (Peru)



<p>XIII. Does the registry have an Advisory Board? *</p>	<p>Yes No <input type="checkbox"/> <input checked="" type="checkbox"/></p>
<p>XIV. If the registry has an Advisory Board, please describe its terms of reference, which organizations are represented on the Board, and how often it meets. If necessary, please attach this information to the application as a separate document.</p>	<p>Not applicable</p>
<p>XV. Is registration of a clinical trial a legal requirement in the country (or countries) covered by the registry? *</p> <p>If yes, please provide the title of the relevant law and information on how a copy of the law can be obtained (including the relevant web address)</p>	<p>Yes No <input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>XV. Is registration of a clinical trial a legal requirement in the country (or countries) covered by the registry? *</p> <p>If yes, please provide the title of the relevant law and information on how a copy of the law can be obtained (including the relevant web address)</p> <p>The Clinical Trials Regulation rules the execution of Clinical Trials in Peru that has been established by the Supreme Decree No. 021-2017-SA. Based on this regulation, the registration is mandatory for clinical trials which intervention include pharmaceutical products (such as: medicines, biological products including vaccines, herbal medicinal products and dietetic products and sweeteners) and medical devices.</p> <p>Available from:</p> <p>https://ensayosclnicos-repec.ins.gob.pe/regulacion/normatividad-vigente/205-reglamento-de-ensayos-clinicos</p> <p>Likewise, The Law No. 30287, Law on Prevention and Control of Tuberculosis in Peru established that the registration of experimental research in tuberculosis is mandatory and public. This applies to all types of interventions</p> <p>This Law is available here:</p> <p>https://ensayosclnicos-repec.ins.gob.pe/regulacion/normatividad-vigente/205-reglamento-de-ensayos-clinicos</p>
<p>XVI. Is registration of a clinical trial a requirement to obtain ethics approval in the country (or countries) covered by the registry? *</p> <p>If yes, please provide the title of the relevant document describing this requirement</p>	<p>Yes No <input type="checkbox"/> <input checked="" type="checkbox"/></p> <p>The ethical approval of the clinical trial is obtained prior to its submission to regulatory authority, which is the National Institute of Health in Peru. This is because the ethical approval is a compulsory requirement prior to the registration of any clinical trial.</p>



International Clinical Trials Registry Platform

and information on how this document can be obtained (including the relevant web address)	
XVII. Is the registry currently accepting clinical trials for registration?	Yes No <input checked="" type="checkbox"/> <input type="checkbox"/>
XVIII. How many trials are on your database? On 31 / 01 / 2023, one thousand nine hundred and eighty (1986) clinical trials <i>dd</i> <i>mm</i> <i>yyyy</i> have been registered. <small><u>Note:</u> The ICTRP cannot consider a registry for Primary Registry status until it contains at least 10 trials submitted directly by Responsible Registrants. It is not acceptable for a registry to only include trial information that has been downloaded and imported from another registry.</small>	
XIX. Does the registry agree in principle to comply with the International Standards for Clinical Trial Registries?	Yes No <input checked="" type="checkbox"/> <input type="checkbox"/>



Content

1.1. The Registry will accept prospective registration of interventional clinical trials submitted by Responsible Registrants

1.1.1. Does the Registry register trials before the first participant has been recruited?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry query submissions where registration is being sought after the first participant has been recruited?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry make it clear to Responsible Registrants that prospective registration means that a trial must complete the registration process, and have a trial registration number issued, before the recruitment of the first participant.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
1.1.2. Does the Registry register trials that have already recruited the first participant? (Also referred to as retrospective registration)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
1.1.3. Does the Registry register other types of studies, including observational studies	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
1.1.4. Does the Registry register all trials submitted by Responsible Registrants	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry accept trials submitted by Responsible Registrants?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry ask the person submitting a trial for registration to verify that they meet the terms and conditions for being a Responsible Registrant before being able to proceed to trial registration?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry use the contact details provided by the Responsible Registrant to verify that those details are correct?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) As a minimum, Registries must send an email to the address given and receive a reply from that same address. When possible, the telephone number and/or surface mail address will also be verified in a similar fashion.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Does the Registry ensure that all Responsible Registrants are associated with an institution or organization	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
f) Does the Registry obtain institutional contact details for the Responsible Registrant, including name and telephone number of the institution?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
1.1.5. Does the Registry accept studies for registration when the data is submitted as an electronic data file (eg as an xml file)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Note: This is not a requirement and is being asked for information only.



1.2. The registry will be open to all prospective registrants (either internationally or within one or more specific countries) (ICMJE requirement)

<p>a) Which types of study does the Registry accept for registration? (tick all that apply)</p> <p><input checked="" type="checkbox"/> Interventional studies</p> <p><input type="checkbox"/> Observational studies</p>
<p>b) If registration is restricted in some way (eg only accepts trials from a particular sponsor, or in a particular health care condition (eg cancer) or intervention) please specify how it is restricted:</p> <p>It is not.</p>
<p>c) From which countries does the Registry accept trials for registration:</p> <p>There is no restriction for any country.</p>

1.3. The Registry will be able to collect and publicly display the WHO Trial Registration Data Set (TRDS) (ICMJE requirement).

a) Does the Registry collect and display, on a publicly accessible web site, all of the items in the WHO Trial Registration Data Set	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have quality control procedures in place to ensure all items in the TRDS contain meaningful data?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry collect the optional TRDS data items? If yes, please specify:	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

1.4. The Registry will make an effort to keep registered information up-to-date.

a) Does the Registry permit Responsible Registrants to update information about their trial?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>b) Does the Registry have a reminder system to facilitate the submission of updated information by the Responsible Registrant.</p> <p>If yes, please state how often the Registry reminds Responsible Registrants to update their data (eg once every 6 months; once every year):</p> <p>Data is updated once a year.</p> <p><u>Note:</u> This is not a requirement and is being asked for information only.</p>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>c) Does the Registry display the date the trial record was last updated?</p> <p><u>Note:</u> This is not a requirement and is being asked for information only.</p>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>d) Does the Registry request updates from Responsible Registrants at least annually until the Registrant has recorded meaningful information about the publication of the trial results (e.g. has listed a citation in a "Publications" field)</p> <p><u>Note:</u> This is not a requirement and is being asked for information only.</p>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>



1.5. The Registry will never remove a trial once it has been registered.

a) Does the Registry ever delete a trial record from their database, or remove it from public view, once a registration number has been issued? If yes, please explain the circumstances under which a record would be deleted:	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
b) Does the Registry inform Responsible Registrants at the time of registration that a trial cannot be deleted once it has been registered?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry have clear and transparent processes for dealing with requests to remove a trial record from public view, and have these processes been documented in the SOPs?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

2. Quality and Validity

2.1. The Registry will have processes in place to make sure that registered data is complete and accurate.

a) Do Registry staff routinely check all data submitted about a trial for completeness and meaningfulness to ensure that all TRDS fields are populated and comply with the minimum standards?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) If one or more items in the TRDS submitted for registration are incomplete or not meaningful, do Registry staff contact the Responsible Registrant and attempt to obtain complete and meaningful data?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry's database system apply automated checking procedures (e.g. range checks, logic rules) to data items to facilitate validity checking?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the Registry have processes in place for deciding whether to register trials where the Responsible Registrant remains non-compliant with requests to provide complete and meaningful data?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Does the Registry undertake regular internal quality control audits to assess the level of completeness and accuracy of the data collected?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

2.2. The Registry will have documented Standard Operating Procedures (SOPs). These SOPs will be aligned with the International Standards for Clinical Trial Registries.

a) Does the Registry have written standards for all procedures and processes employed by the registry? o <i>These written standards are known as Standard Operating Procedures (SOPs)</i>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry use these SOPs to train all staff processing trial registrations to ensure that common standards for ensuring data completeness and meaningfulness are adhered to?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Are the internal registry-specific SOPs aligned with the WHO International Clinical Trial Registry Platform International Standards for Clinical Trial Registration?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



2.3. The Registry will have processes in place to make sure that people and trials exist

2.3.1. Does the Registry make sure that the person registering the trial exists <i>and that they are the appropriate Responsible Registrant</i> ?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
2.3.2. Does the Registry make sure that the trial exists? If yes, please briefly describe what the registry does to make sure that the trial exists. It is undertaken through the fulfillment of the following requirements including the Ethics Committee approval, and the Research Institution approval where the clinical trial will be conducted.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry obtain written third-party confirmation that a trial exists? If yes, please specify the method of confirmation: It is undertaken through the fulfillment of the following requirements including the Ethics Committee approval, and the Research Institution approval where the clinical trial will be conducted.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry display in the trial record: a. if the registry has obtained written third party confirmation of the trial's existence, and b. the name of the third party from whom confirmation was received (eg the name of the ethics committee)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

2.4. The Registry will have a publicly accessible audit trail so that changes made to the [WHO TRDS](#) for an individual trial can be tracked.

a) Does the Registry allow Responsible Registrants to update their registered trial records?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry make available a publicly accessible audit trail of any changes to any TRDS items?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the have quality control procedures in place to ensure any updated information continues to fulfil the standards for each TRDS item.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the Registry use the most up-to-date information as the default display?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Can the TRDS, as originally registered, be accessed at all times?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

2.5. The Registry agrees to comply with the International Standards for Clinical Trial Registries (ISCTR).

a) Does the Registry Administrator have a thorough working knowledge of the operational aspects of their registry?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Is the Registry Administrator committed to ensuring that all Registry staff are familiar with the standards described in the ISCTR?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Are all Registry staff familiar with the contents of the ISCTR?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



3. Accessibility

3.1. The Registry will make the [WHO TRDS](#) for all registered trials accessible to the public at no charge (ICMJE requirement).

a) Does the Registry make the WHO TRDS items for all studies in their register (ie the registry database) accessible online at no charge to the end user?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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3.2. The Registry will make it possible for the [WHO TRDS](#) for all registered trials to be searched electronically (ICMJE requirement).

a) Is it possible to search the Registry online using electronic searches of text words and phrases via a simple, single search box?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the online search allow users to search in at least the condition field and the intervention field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) When the results of a trial identified by a search are displayed, are all items in the WHO TRDS visible?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the online search have an advanced search option?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Note: This is not a requirement and is being asked for information only.

3.3. The Registry will allow Responsible Registrants to submit a trial for registration at any time of day on any day of the week (24 hours a day, seven days a week).

a) Is it possible to submit a trial to the registry 24 hours a day, seven (7) days a week?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) If the Registry is planning downtime, does it publish advance notice of downtime at least one (1) week beforehand?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

3.4. The Registry will allow their register database to be searched at any time of day on any day of the week (24 hours a day, seven days a week).

a) Is it possible to search the register online 24 hours a day, 7 days a week?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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International Clinical Trials Registry Platform

3.5. It is desirable that Registries in the WHO Registry Network also make the [WHO TRDS](#) available in the language(s) of the country or countries served by the registry.

<p>a) Does the Registry accept and/or display trial information in languages others than English?</p> <p>If yes, please specify the languages used:</p> <p>The information from the Registry is available in both languages, Spanish and English.</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>Only answer the remaining questions in this section if the answer to the above question is yes.</p>	
<p>b) Does the Registry have quality control procedures in place to ensure that all translations are accurate?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>c) Are all TRDS items for all records also available in English?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>d) Are all trial records translated into English by the Responsible Registrant checked by registry staff against the non-English submission before being accepted for registration?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>e) Are all trial records translated by Registry staff checked by at least one other staff member?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>f) If there is a discrepancy in a translation, is the translation checked by a third person?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>g) Does the Registry make users of the Registry aware of who performed the translation (the Responsible Registrant or Registry staff) of a registered record?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>h) If a trial is registered in more than one language then will the Registry submit the "Scientific Title", and a language identifier, to the ICTRP Search Portal for each language used?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>



4. Unambiguous Identification

4.1. The Registry will have in place processes to prevent the registration of a single trial more than once on their database.

a) Does the Registry make sure that a trial that has been submitted for registration is not already been included in their register by first searching and checking their own database?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have policies and procedures in place to deal with inadvertent duplicate registration of the same trial within their own register?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

4.2 The Registry will facilitate the retrospective linking (or bridging) on the WHO Search Portal of a single trial registered with more than one registry by entering secondary identifiers. This includes the UTN, and the unique identifiers allocated by other registries in the WHO Registry Network.

a) Does the Registry require responsible Registrants to make an entry in the <i>Secondary Identifiers</i> field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) If there are no known secondary identifiers, does the Registry require Responsible Registrants to enter 'Nil known' in the <i>Secondary Identifiers</i> field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry require Responsible Registrants to enter a UTN? a. <i>The UTN may be entered into either the Secondary Identifiers field or a field designated specifically for collection of the UTN</i>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Note: This is not a requirement and is being asked for information only.

4.3. It is desirable that Primary Registries will search the ICTRP Search Portal and attempt to determine if the trial has already been registered by another Primary Registry in the WHO Registry Network or an ICMJE approved registry.

a) Does the Registry attempt to determine whether a submitted trial has been registered in another Primary Registry or an ICMJE approved registry before registration?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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Note: This is not a requirement and is being asked for information only.



5. Technical Capacity

5.1. The Registry will submit the [WHO TRDS](#) for all records on their register, in English, to the WHO ICTRP Central Repository.

a) Will (or does) the Registry submit the WHO TRDS items for all records on their register, in English, to the WHO ICTRP Central Repository? <ul style="list-style-type: none"> Note: If a registry accepts study types other than interventional trials (i.e. observational studies) these must be provided as well. 	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Will (or does) the Registry submit records in the format requested by the WHO ICTRP (e.g. xml file) at least once per month?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Will (or does) the Registry, after the initial data transfer of all records, only submit new or updated records each time (rather than the entire data set every time)?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

5.2. The Registry will have access to a database that is used to store and manage the submitted data.

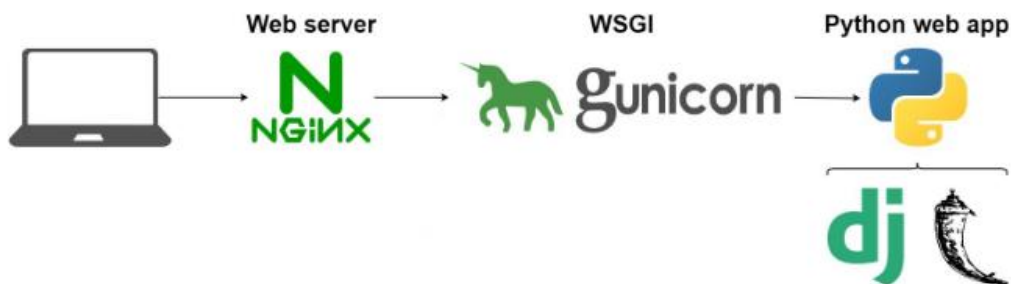
a) Does the Registry have access to a database that is used to store and manage the submitted data?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry use database software and hardware that guarantees reliable access to registered data and data safety at all times?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

5.3. The Registry will have access to adequate information technology support.

a) Does the Registry have access to reliable information technology support? The General Office of Information Systems (Oficina General de Información y Sistemas , in Spanish) from National Institute of Health of Peru, provides assistance and support to the Registry.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have access to all of the following? a. reliable application, database, backup and mail servers The descriptions are shown as follows; 1. Application server : Processor : Intel Xeon Gold 6142 (4 VCPUs) Memory : 16GB 2. Database server: Processor : Intel Xeon Gold 6142 (4 VCPUs) Memory : 16GB Management Server: POSTGRES SQL 13.5 3. Mail server: not available b. good internet connectivity speed Internet speed of 312.96 MB	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



<p>c. sound operating systems</p> <p>The server use the operating system Linux Centos 8</p> <p>d. appropriate software for servers, desktops and laptops</p> <p>The Server application Linux centos 8 and management POSTGRES SQL</p> <p>e. database and web development and maintenance personnel</p> <p>One Database Administrator who is responsible for maintaining the system database. One Web Administrator who is responsible for managing the web application. One Network Administrator who is responsible for maintaining the network system, the network system security and its further upgrade.</p> <p>f. other skilled information technology personnel to support these systems, as required</p> <p>.....</p>	
<p>c) Please briefly describe the Registry's information technology infrastructure. (A separate document may be submitted separately if necessary)</p> <p>The system of the Peruvian Clinical Trial Registry (REPEC) is a web application developed in Python with framework DJANGO language with a POSTGRES SQL. This system enables recording information in relation to the clinical trial regulatory process in Peru, which includes the evaluation of its authorization, amendments and monitoring, and others by using the assigned username and password.</p> <p>The Peruvian Clinical Trial Registry displays both authorized and unauthorized clinical trial information.</p> <p>The following information is the description of the technological infrastructure of the REPEC:</p> <p>1 Application server :</p> <p>Processor : Intel Xeon Gold 6142 (4 CPUs) Memory : 16GB Operative system : Linux Centos 8</p> <p>2 Database server:</p> <p>Processor : Intel Xeon Gold 6142 (4 CPUs) Memory : 16GB Operative system : Linux Centos 8 Management server: POSTGRES SQL</p>	



The workstation elements for the users are:

- CPU with the following minimum requirements: Memory 2 GB Ram and Pentium IV.
- Operative system with Windows platform (XP and higher).
- Web Browser: Google chrome, Internet Explorer (version 8 and higher).

5.4. The Registry will have adequate security and other provisions against data corruption and loss.

<p>a) Does the Registry have documented procedures for ensuring adequate data security and other provisions to prevent data corruption and loss?</p> <p>The document is "The Storage and Backup Information - PRA-OGIS-001" Ed.02 approved by the 002-2021-DG-OGIS-OPE/INS Directorial Resolution on December 14th 2021.</p>	<table> <tr> <td>Yes</td><td>No</td></tr> <tr> <td><input checked="" type="checkbox"/></td><td><input type="checkbox"/></td></tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>b) Does the Registry issue alerts in advance of website downtime?</p> <p>If yes, please briefly describe how these alerts are circulated and who is responsible for circulating them.</p> <p>The system allows publishing advance notice of downtime to the users if the Registry is planning downtime.</p> <p>Responsible for the activity General Information and Systems Office</p>	<table> <tr> <td>Yes</td><td>No</td></tr> <tr> <td><input checked="" type="checkbox"/></td><td><input type="checkbox"/></td></tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				



6. Administration and Governance

6.1. The Registry will have at least a national remit, and the support of government within the country (or region) to act as the Primary Registry for that country or region (defined as a group of countries and not a group of states within a country).

a) Does the Registry have at least a national remit?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have a letter of support, or other appropriate documentation, from the Ministry of Health or other relevant national or regional agencies? The Clinical Trials Regulation assign the responsibility of REPEC to INS. This regulation was approved with a Supreme Decree (No. 021-2017-SA) sign by The President of Peru and the Health Minister. Supreme Decree No. 021-2017-SA is available here (Articles 102° and 103°) <u>Note:</u> The letters of support must be submitted to the ICTRP Secretariat as part of the application	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) From which country (or countries) does the Registry have the remit to act as the national (or regional) clinical trial registry? Peru		
d) Please specify the name of the national agencies that have given their support to the Registry: Peruvian National Institute of Health		

6.2. The Registry will publicly disclose ownership, governance structure and not-for-profit status.

a) Is the Registry managed by a not-for-profit agency?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry publicly disclose its ownership, governance structures and not-for-profit status in a prominent place on the registry's website?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) What is the web address for the page where the ownership, governance and not-for-profit information is displayed? http://www.ins.gob.pe/portal/home		
d) Will the Registry inform the ICTRP immediately if their ownership, governance structures or not-for-profit status change in any way?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

6.3. The Registry agrees that, should it cease to function, at least the [WHO TRDS](#) (original and updated) for all trial records will be transferred to a Primary Registry in the WHO Registry Network.

a) Will the Registry transfer at least the WHO TRDS (original and updated) for all trial records to another Primary Registry in the WHO Registry Network if it ceases to function?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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6.4. The Registry will have a strategy in place ensure the medium to long term sustainability of the registry

a) Does the Registry have a documented business plan?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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b) Does the Registry's business plan include strategies to ensure its medium to long term sustainability?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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7. The Trial Registration Data Set (TRDS)

7.1. The Registry will collect and publicly display all items in the WHO Trial Registration Data Set (TRDS)

	Item/Label	Does the registry collect this data item?		Does the registry publicly display this data item?	
1	Primary Registry and Trial Identifying Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
2	Date of Registration in Primary Registry	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
3	Secondary Identifying Numbers	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
4	Source(s) of Monetary or Material Support	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
5	Primary Sponsor	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
6	Secondary Sponsor(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
7	Contact for public queries	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
8	Contact for scientific queries	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
9	Public title	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
10	Scientific title	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
11	Countries of Recruitment	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
12	Health condition(s) or problem(s) studied	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
13	Interventions	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
14	Key Inclusion and Exclusion Criteria	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
15	Study type	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
16	Date of first enrolment	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
17	Target sample size	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
18	Recruitment status	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



	Item/Label	Does the registry collect this data item?		Does the registry publicly display this data item?	
19	Primary Outcome(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
20	Key Secondary Outcome(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

7.2. The Registry may choose to collect and publicly display other data items. It is recommended that registries consider the following optional, additional data items:

	Item/Label	Does the registry collect this data item?		Does the registry publicly display this data item?	
21	Lay Summary / Synopsis	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
22	Approvals Comite de ética	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
23	Results links	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>



8. Partner Registries

8.1. Primary Registries in the WHO Registry Network will have the capacity to partner with other Registries.

a) Is the Registry willing and able to form partnerships with other Registries that do not themselves fulfil the criteria for a Primary Registry in the WHO Registry Network?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry currently have any Partner Registries? If yes, please provide the name(s) of these partners:	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
c) If the registry has partners, are they listed on the proposed Primary Registry's web site? If yes, please provide the address of this web page:	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Note: A completed Registry Profile form is required for all Partner Registries. This profile will be published on the ICTRP's web site.		

8.2. Primary Registries in the WHO Registry Network will ensure that potential Partner Registries meet WHO minimum standards requirements.

a) Does the proposed Primary Registry agree that, before agreeing to accept a Partner Registry and their trial registration records, they will make sure that the Partner Registry meets all the WHO minimum standards listed in the International Standards for Clinical Trial Registries?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Has a Registry Profile form been completed and submitted for all of the Registry's Partner Registries? The Registry currently does not have any Partner Registries.	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

8.3. Primary Registries will have procedures in place to enable exchange of data with Partner Registries.

a) Is the Registry able to accept data (that is, as electronic data files) from Partner Registries or other appropriate data providers?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry agree to establish a Memorandum Of Understanding (MOU) or other such agreement with each Partner Registry or other data providers, as per the requirement described in the International Standards for Clinical Trial Registries?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Primary Registry agree the area of coverage/responsibility of their Partner Registries or other data providers (such as geographical location, health condition, intervention type, etc) and incorporate this into their SOPs and instructions to Registrants to avoid any confusion or unintentional duplicate registration?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the Primary Registry record the identification number and date of registration in the Partner Registry within the trial record on the Primary Registry?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Does the Primary Registry identify records that have been sourced from Partner Registries or other data providers so users are aware of the data source?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
f) Before announcing Partner Registries, Primary Registries must have successfully imported data into the Primary Registry?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



Contact Information

Administrator

The Administrator is the person employed to manage the Registry and will be the primary point of contact between the Registry and the ICTRP Secretariat.

Title (<i>Dr/Prof/Mr/Mrs/Ms/Miss</i>)	Miss
Given Name	Jenny
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Secondary Contact

The Secondary Contact must not be the same as the Administrator. Secondary contact details are requested for circumstances when the Administrator is unavailable.

Title (<i>Dr/Prof/Mr/Mrs/Ms/Miss</i>)	Mrs
Given Name	Jeniffer
Family Name	Sandy Torres
Telephone number	051-1- 748 1111 (Extension 2187)
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Email	jsandy@ins.gob.pe

Information Technology Officer

The Information Technology Officer should be the person who will be responsible for submitting the data for inclusion on the ICTRP Central Repository. They should have a good understanding of all of the IT issues relevant to the registry.

Title (<i>Dr/Prof/Mr/Mrs/Ms/Miss</i>)	Mrs
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**Agency that manages the registry
Contact Information**

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General Office for Research and Technology Transfer
Peruvian National Institute of Health

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Clinical Trials Evaluation Area –
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General Office for Research and Technology Transfer
Peruvian National Institute of Health

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