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Ministry of Health
Executive Secretariat of the National Health Council
National Research Ethics Commission

CIRCULAR LETTER No. 34/2021/CONEP/SECNS/MS

Brasília, December 9, 2021.

To the

Research Ethics Committees

Subject: Guidelines for new processing of biobank development protocols for research purposes through the current version of Plataforma Brasil.

Dear coordinators of the Research Ethics Committees (CEP) and those responsible by Biobanks,

1. The Brazil Platform, when it was created and implemented, was intended only to process research protocols. The creation of biobanks for research purposes, defined in accordance with Resolution of the National Health Council (CNS) No. 441 of 2011 and Ordinance of the Ministry of Health (MS) No. 2201 of 2011, has so far been processed outside this electronic system, initially on paper and in recent years, in digital media.

2. Seeking to implement a new procedure, we are incorporating the processing of biobank development protocols for research purposes into the Brazil Platform. In this sense, the National Research Ethics Commission (Conep) requests that the Research Ethics Committees and those responsible for biobanks proceed with the gradual insertion of protocols for establishing biobanks in the Brazil Platform, as indicated below:

2.1. When it comes to inserting a biobank development protocol already approved by the CEP/Conep System, it will be up to the person responsible for the biobank to insert the documents analyzed and approved in the Brazil Platform for documentary validation by the CEP of the supporting institution (or by the CEP indicated by Conep) and by Conep through the functionality <to register projects approved prior to Plataforma Brasil,> [see attachment 1]. It should be noted that the submission of amendments and notifications will only be processed by Plataforma Brasil after approval of documentary validation by CEP and Conep. If an amendment or activity report is processed in the CEP/Conep System, it must remain outside the Plataforma Brasil until the end.

2.2. When it comes to inserting a protocol for the development of biobanks from institutions that aim to establish them for research purposes, from the effective date of this document, it will be up to the person responsible for the biobank (designated by the legal responsible of the institution) to follow the guidelines in the annex 2, and must insert the biobank development protocol documents, using the <register a new project> functionality available on Plataforma Brasil.

3. The document comes into force from the date of publication. Therefore, Conep counts on the collaboration of everyone involved and thanks you in advance for your efforts. If you have any questions, send an email to <conep.biobancos@saude.gov.br>. With no other objective at the moment, we subscribe to

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us.

Annex I – Guidelines for those responsible for biobanks for inserting documents on development protocols already approved by CEP and Conep on a date prior to the publication of this document to continue with document validation on the Brazil Platform:

a) It is up to the person responsible for the biobank – which must be the one mentioned in the last opinion issued by Conep – to submit the documents of the already approved development protocol for documentary validation on Plataforma Brasil as the responsible researcher.

b) After accessing Plataforma Brasil, in the *researcher tab,* the person responsible for the biobank must click on the <Previous Project> button (located at the top of the right side) referring to the item <to register approved projects prior to Plataforma Brasil, click here>.

c) The message <*in this option will be used to register a survey that was approved prior to the implementation of Plataforma Brasil. Therefore, it will be necessary to include the digitalization of Opinions received, both from CEP and CONEP, the latter in the case of Projects referring to a special thematic area. Do you confirm the inclusion of an approved research prior to Plataforma Brasil? >,* the person responsible for the biobank must click on the <yes> option, being directed to screen 1 – preliminary information.

1. Instructions for filling out the first screen <preliminary information>

1.1. In the item <does the research involve human beings, as research participants, individually or collectively, directly or indirectly, in its entirety or parts of it, including the handling of information or materials? For more information, see resolution 466, resolution 510>, select the option <yes>.

1.2. In the item <enter the model you want to fill out (the complete model is not yet available to the public. Use the simplified model) > click on the <simplified> option.

1.3. In the item <main researcher>, the fields will appear filled with the data entered when registering the *responsible researcher* on Plataforma Brasil (in this case, understand as responsible for the biobank). The fields <Social Name>, <Telephone> and <Email> can be edited and updated, if necessary.

1.4. In the item <do you want to delegate authorization to complete this project to other people already registered in the system? >, the person responsible for the biobank must click on the desired option <yes> or <no>. If the person responsible for the biobank chooses <yes>, the <assistants> and <research team> pop-up window will open to fill in the data of the assistants and/or the biobank team. The data to be filled in is <nationality>, <CPF/document>, <name>, click search. After entering the data, click <close>.

1.5. In the item <proposing institution>, the institution maintaining the biobank must be selected.
It should be noted that the options available for selection will be those institutions linked to the researcher's profile (in this case, the profile of the person responsible for the biobank), when registering on Plataforma Brasil. In this item, the option <without proponent> should not be selected.

1.6. In item <is it an international study? >, select the option <no>, even if there are biobank partner institutions outside the country.

1.7. Click on the <next> button at the end of the page, on the right side, to be directed to the second screen <study area>. If the person responsible for the biobank chooses to suspend the filling, the fields already completed must be saved. To do this, click <save>. The following message will appear in the pop-up window <attention: do you want to save the search information? >, and the person responsible for the biobank must click on the <confirm> option.

2. Instructions for filling out the second screen <study area>

2.1. The person responsible for the biobank should not indicate any of the thematic areas presented on the second screen of Plataforma Brasil. The fields must remain blank and/or empty:

2.2. The sub-item “Major Area 9. Others” referring to the item <Major Areas of Knowledge (CNPq) (Select up to three) > must be marked.

2.3. A field will open which must be filled in with the word <Biobanco>.

2.4. The item <Main Purpose of the Study (OMS)> should not be filled in (no available options will appear).

2.5. In the item <Public Title of the Research>, the title of the biobank must be inserted, as explained below: **“Biobank Development Protocol: *insertion of the title described in the opinion of the biobank approved by Conep.”***

2.6. In the item <Main Research Title>, the title of the biobank must be inserted, as explained below: **“Biobank Development Protocol: *insertion of the title described in the biobank opinion approved by Conep.”***

2.7. The items <Public Title Acronym> and <Public Acronym Expansion> will remain unavailable for completion. Therefore, the mentioned fields must remain blank.
“The item <MULTIPLE SECONDARY AIDS> should not be filled in and should remain blank.

2.8. In the item <public contact>, the question <will you be the main researcher? > should be interpreted as “will be responsible for the biobank”, the option <yes> should be selected. When clicking <yes>, the CPF fields will appear; social name; telephone and email of the person responsible for the biobank. If you click on the <no> option, there will be the option to <add contact>.

2.9. In the item <Scientific Contact>, the name of the person responsible for the biobank will already appear in the system.

2.10. If the person responsible for the biobank chooses to suspend the filling, the fields already completed must be saved. To do this, click <save>. The following message will appear in the pop-up window <attention: do you want to save the research information?>, and the person responsible for the biobank must click on the <confirm> option.

2.11. To proceed with filling out, you must click on the <next> button at the end of the page, on the right side. A pop-up window will open with the following message <you are submitting a previous research project to the brazil platform, but you did not enter the CAAE /SISNEP number (secondary id). Confirm? >, and the person responsible for the biobank must click on the option <yes>, automatically redirecting to the third screen <study design/financial support>.

3. Instructions for completing the third screen <study design/financial support>

3.1. The fields enabled for editing on the third screen are <drawing>; <funding> and <keyword>. Below are the instructions for entering information in the mentioned fields.

3.2. In the <drawing> field, the ways in which the samples were collected must be described, that is, how the samples were granted for storage in the biobank, whether during assistance or through a pathology laboratory, among others), as already approved by the CEP System/ Conep.

3.3. In the item <financing>, when clicking on <add financing>, three possibilities will appear, and the person responsible for the biobank must choose and insert the type of financing that best suits the biobank in question.

3.4. In the <keyword> field, the types of biological materials foreseen in the already approved biobank development protocol must be described. To do this, click on <add keyword>, write the type of biological material and click on add. Repeat this process until all expected sample types are properly added.

3.5. Click on the <next> button at the bottom of the page, on the right side, and the person responsible for the biobank will be directed to the fourth screen <study details>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>.
The pop-up message <ATTENTION: Do you want to save the search information? >, and the person responsible for the biobank must click on the <confirm> option.

4. Instructions for filling out the fourth screen <study details>

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4.1. The <Summary> field must be filled in according to the information below:

The biobank was initially approved by the CEP on [dd/ mm/ yyyy], through opinion [nº], and by Conep on [dd/ mm/ yyyy], through opinion [nº].

OR

The biobank was initially approved by the CEP on [dd/ mm/ yyyy], through opinion [nº].
Subsequently, the biobank was approved with a recommendation by Conep in [dd/ mm/ yyyy], through opinion [nº], and received final approval by the CEP in [dd/ mm/ yyyy], through opinion [nº] [see note below].

Note: If Conep has issued an approved opinion with recommendations to the CEP for the development protocol, the person responsible for the biobank must also insert the date of final approval by the CEP, issued after the approved opinion with recommendation by Conep.

4.1.1. If there are amendments or activity reports already approved by the CEP/Conep System, the relevant information must also be inserted, such as:

Amendment 1 – Amendment 1 to the biobank was approved by the CEP on [dd/ mm/ yyyy], through opinion [nº], and by Conep on [dd/ mm/ yyyy], through opinion [nº], and so on for amendments 2, 3 etc. [see note below].

Note: If Conep has issued an approved opinion with recommendations to the CEP for the development protocol, the person responsible for the biobank must also insert the date of final approval by the CEP, issued after the approved opinion with recommendation by Conep.

4.1.2. Activity report – The biobank activity report for the period [insert period of activities] was approved by the CEP on [dd/ mm/ yyyy], through opinion [nº], and by Conep on [dd/ mm/ yyyy]], through opinion [nº] [see note below].

Note: If Conep has issued an approved opinion with recommendations to the CEP for the development protocol, the person responsible for the biobank must also insert the date of final approval by the CEP, issued after the approved opinion with recommendation by Conep.

4.2. The <Introduction> field must be filled in with the information below, namely:

4.2.1. Regarding the composition of the team responsible for the biobank: *[insert the names and institutional positions of all members who make up the team responsible for the Biobank].*

4.2.2. Regarding the roles of each member of the team responsible for the biobank: *[insert the roles in the biobank of all team members].*

4.2.3. Regarding the location of the biobank: *[insert the name of the department/ sector and the Institution [insert the name of the institution].*

4.2.4. Regarding the types of biological materials: *[insert the types, number of samples already stored and the year in which the types of samples began to be stored].*

4.3 - The <hypothesis> field must include <not applicable>.

4.4 - The field <primary objective> must contain the following information: <constitute a biobank for storing human biological samples and associated information for research purposes>.

4.5 - The <secondary objective> field must include <not applicable>.

4.6 - The field <proposed methodology> must contain information relating to the items mentioned, already planned and approved, as follows:

4.6.1. Regarding potential biobank participants (grantors or consenters): *[insert information regarding potential biobank participants, including age, sex and any particularities].*

4.6.2. Regarding the consent and/or assent process and the collection of samples from biobank participants: *[insert information regarding the time, condition and location in which the*

clarification will be made, considering, for this purpose, the peculiarities of the person invited to participate in the biobank and their privacy].

4.6.3. Regarding the biobank's secure system guaranteeing secrecy, respect for confidentiality and data recovery of biobank participants: *[insert information relating to the biobank's data security system].*

4.6.4. Regarding standard operating procedures relating to the stages of collection, processing, storage, distribution and disposal of samples: *[insert information relating to pre-defined operational procedures, under institutional responsibility and management applicable to stored human biological material].*

4.6.5. Description of the policies for the use of stored human biological material, in order to guarantee the preservation of the collection, favor its social and scientific use and avoid unnecessary depletion of samples: *[insert description of the policies for the use of stored human biological material, in order to guarantee the preservation of the collection, prioritize its social and scientific use and avoid unnecessary depletion of samples].*

4.6.6. Regarding the storage and sharing of samples between partner institutions (if any): *[insert information about the agreement between the participating institutions covering the operationalization, sharing, use of human biological material stored in Biobank, including the possibility of dissolution of future of the partnership and the consequent sharing and destination of stored data and materials (CNS Resolution 441/2011, item 13; Ordinance MS 2.201/11, Chapter IV, Section III, Article 31). 4.7* - In the field <inclusion criteria> select < does not apply>.

4.8. In the <exclusion criteria> field, select <not applicable>.

4.9. In the <risks> field, potential risks to biobank participants must be described, such as breach of confidentiality, loss of biological samples, among others.

4.10. In the <benefits> field, the potential benefits to biobank participants should be described.

4.11. The field <data analysis methodology> must include <not applicable>.

4.12. The <primary outcome> field must include <not applicable>.

4.13. The <secondary outcome> field must include <not applicable>.

4.14. In the <sample size in Brazil> field, the expected total number of biological samples to be stored by the biobank for research purposes must be entered, considering the capacity allowed by the physical structure. The maximum total value that Plataforma Brasil allows is <9,999,999,999>. When entering the sample size in Brazil, the number will be automatically updated by the system in “number of research participants” and country “Brazil” in the item <recruitment countries>.

4.15. Regarding <date of first recruitment>, tick <not applicable>.

4.16. In the item “recruitment countries” and in the “country of origin” field, the person responsible for the biobank must indicate Brazil as the country of origin. It should be noted that no other countries should be added.

4.17. Click on the <next> button at the bottom of the page, on the right side, and you will be directed to the fifth screen <other information>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>. The pop-up message <Attention: Do you want to save the search information? > and the person responsible for the biobank must click on the <confirm> option.

5. Instructions for filling out the fifth screen<other information>

5.1. In the field <will there be use of secondary data sources (medical records, demographic data, etc.)? the person responsible for the biobank must select the option <yes> and specify the secondary data sources in the field to be enabled for editing <Details>.

5.2. In the item <enter the number of individuals personally approached, recruited, or who will undergo some type of intervention in this research center> the same number informed in the

step 4.14.

5.3. In the item <Groups into which research participants in this center will be divided>, you must click on <Add Group>. When opening the pop-up window, the person responsible for the biobank must enter a type of biological sample stored in the biobank in the <Group Identification> field. It should be noted that groups must be inserted depending on the types of biological materials stored in the approved biobank. In the <Nº of Individuals> field, the number expected to be collected for the collection of the mentioned material and a brief description of the interventions to be carried out with the mentioned sample must be inserted.

5.4. In the item <is the study multicenter in Brazil? > the option <no> must be selected.

5.5. Even if there are partner institutions of the biobank, the item <co-participating institution> should not include a co-participating institution.

5.6. In the field <proposes exemption from ICF> you must select the option <no>.

5.7. In the item <will samples be retained for storage in a bank?>, the option <yes> must be selected and the field <justification> must contain the following text <Storage of biological samples in a biobank for research purposes>.

5.8. In the item <execution schedule>, click on <Add Schedule> and enter expected dates (start date and end date) to send the next biobank activity report.

5.9. In the item <financial budget>, the person responsible for the biobank must click on <add expense>, insert two types of materials: (1) permanent materials and (2) consumable materials, and must inform the type and respective values expected for maintenance of the biobank.

5.10. In the item <other information, justifications or considerations at the discretion of the Researcher>, the person responsible for the biobank may insert any information they deem important.

5.11. In the item <Bibliography>, the references used to prepare the biobank development protocol must be inserted, including the National Health Council regulations on material banks, among others.

5.12. To continue filling, click the <Next> button and a pop-up window <project files> will open. Before uploading documents to Plataforma Brasil, make sure that the file name does not contain special characters or blank spaces. To link words in the file name, use *underscore* (_) such as “institutional_responsibility_term”. All files will be automatically scanned by the system itself. If the file names are not in the mentioned format, the system will not *upload* the document.

5.13. Regarding the item <attach cover page>, step 1 <print cover page> does not need to be carried out as there is no document for biobank development protocols.

5.14. In the item <step 2: after signing the cover page, scan it and attach it here>, the person responsible for the biobank must click on <attach cover page> and attach the Institutional Responsibility Term (TRI).

5.15. In the item <include files>, subitem <Document Type>, select the option <previous opinion> to <attach> each opinion issued by CEP and Conep. Repeat the operation as many times as necessary, depending on the number of opinions issued (pending, unapproved and approved by CEP and Conep) when analyzing the already approved biobank development protocol.

5.16. Select <Detailed Project / Investigator Brochure> to <attach> the internal regulations of the already approved initial development protocol.

5.17. Select <biological material / biorepository / biobank handling declaration>” to <attach> the standard operating procedures relating to the sample collection, processing, storage, distribution and disposal steps.

5.18. Select <TCLE / Terms of Assent / Justification of Absence> to <attach> the version of the TCLE or Term of Assent (TA) approved when approving the biobank development protocol. Repeat the operation as many times as necessary, depending on the number of documents approved.

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5.19. In the item <others> the other necessary documents must be attached. In the case of amendments approved before submission on Plataforma Brasil, the same procedures must be followed. However, it should be noted that the file name must contain the letter “E” and the amendment number, for example, “E1_Regimento_interno_v.2_2020”.

5.20. Click on the <next> button at the bottom of the page on the right and you will be directed to the sixth screen titled <finish>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>. The pop-up message <Attention: Do you want to save the search information? >, and the person responsible for the biobank must click on the <confirm> option.

6. Instructions for filling out the sixth screen <finish>:

6.1. In the item <maintain confidentiality of the entire research project? > it will be up to the person responsible for the biobank to choose <yes> or <no>. By clicking on the option <yes>, the item <deadline> can be edited, and it is up to the person responsible for the biobank to select the period to maintain confidentiality of the entire research project for 6 months, 1 year, 2 years, 3 years, 4 years, 5 years or until publication of results. If you choose <no>, the <deadline> item cannot be edited.

6.2. The terms described on screen 6 refer to <General Commitment>, <Financing and Budgeting Commitments>, <Indemnity Commitment>, <Methodological Commitment> and <Documentation Commitment>. The person responsible for the biobank, after reading and agreeing to these commitments, must click <accept terms above>.

6.3. Finally, you must click on the <send project to CEP> button, located at the bottom of the screen, so that the development protocol follows the document validation process in the CEP/Conep System.

Annex 1.1. – Guidelines for research ethics committees to analyze biobank development protocols for research purposes already approved by the CEP/Conep System.

1. The protocol for establishing biobanks must follow the usual procedure in the CEP, and must be ethically analyzed and with a duly justified opinion issued, in accordance with CNS Operational Standard no.
001/2013. A pending opinion or non-approval opinion (if applicable) may be issued by the CEP and/or Conep, if the biobank team posts incorrect documents or does not comply with previously approved documents.

2. After deliberation by the collegiate body to approve the biobank, the person responsible for the CEP biobank must OBLIGATORY enter <approved> in the field <Status of the Opinion> and in the item <does it require Conep's assessment?> the option <yes> must be selected.

3. Only after approval of the biobank development protocol by Conep will the aforementioned bank be able to collect and transfer human biological samples for research.

4. The biobank development protocol, when validated and approved, will have its status changed to <Project prior to the Platform Accepted>.

Annex II – Guidelines for those responsible for biobanks for the initial submission of biobank development protocols for institutions that aim to establish biobanks for research purposes.

a) It is the responsibility of the person responsible for the biobank designated by the person responsible for the maintaining institution to submit the documents on Plataforma Brasil;

b) After accessing the Brazil Platform, *researcher tab,* the person responsible for the biobank must click on the button <New Submission> referring to the request **“To register a new project, click here”;**

c) The person responsible for the biobank will be directed to screen 1 – <preliminary information>.

1. Instructions for filling out the first screen <preliminary information>

1.1. In the item <does the research involve human beings, as research participants, individually or collectively, directly or indirectly, in its entirety or parts of it, including the handling of information or materials? For more information, see resolution 466, resolution 510>, select the option <yes>.

1.2. In the item <enter the model you want to fill out (the complete model is not yet available to the public. Use the simplified model)>, click on the <simplified> option.

1.3. In the item <main researcher>, the fields will appear filled with the data entered when registering the *responsible researcher* on Plataforma Brasil (in this case, understand as responsible for the biobank). The fields <Social Name>, <Telephone> and <E-mail> can be edited and updated, if necessary.

1.4. In the item <do you want to delegate authorization to complete this project to other people already registered in the system? >, the person responsible for the biobank must click on the desired option <yes> or <no>. If the person responsible for the biobank chooses <yes>, the <assistants> and <research team> pop-up window will open to fill in the data of the assistants and/or the biobank team. The data to be filled in is <nationality>, <CPF/document>, <name>, click search. After entering the data, click <close>.

1.5. In the item <proposing institution> the institution maintaining the biobank must be selected.
It should be noted that the options available for selection will be those institutions linked to the researcher's profile (in this case, the profile of the person responsible for the biobank), when registering on Plataforma Brasil. In this item, the option <without proponent> should not be selected.

1.6. In the item <is it an international study?>, select the option <no>, even if there are biobank partner institutions outside the country.

1.7. Click on the <next> button at the end of the page, on the right side, to be directed to the second screen <study area>. If the person responsible for the biobank chooses to suspend the filling, the fields already completed must be saved. To do this, click <save>. The following message will appear in the pop-up window <attention: do you want to save the research information?>, and the person responsible for the biobank must click on the <confirm> option.

2.Instructions for filling out the second screen <study area>

2.1. The person responsible for the biobank should not indicate any of the thematic areas presented on the second screen of Plataforma Brasil. The fields must remain blank and/or empty.

2.2. The subitem “Major Area 9. Others” must be marked referring to the item <Major Areas of Knowledge (CNPq) (Select up to three)>.

2.3. A field will open which must be filled in with the word <Biobanco>.

2.4. The item <Main Purpose of the Study (OMS)> should not be filled in (no available options will appear).

2.5. In the item <Public Title of the Research>, the title of the biobank must be inserted, as explained below: **“Biobank Development Protocol: *insert the proposed title.”.***

2.6. In the item <Main Research Title>, the title of the biobank must be inserted, as explained below: **“Biobank Development Protocol: *insert the proposed title.”.***

2.7. The items <Public Title Acronym> and <Public Acronym Expansion> will remain unavailable for completion. Therefore, the mentioned fields must remain blank.
“The item <MULTIPLE SECONDARY ID'S> should not be filled in and should remain blank.

2.8. In the item <public contact>, the question <will you be the main researcher?> should be interpreted as “will you be responsible for the biobank” and the option <yes> must be selected. When clicking <yes>, the CPF fields will appear; social name; telephone and email of the person responsible for the biobank. If you click on the <no> option, there will be the option to <add contact>.

2.9. In the item <Scientific Contact> the name of the person responsible for the biobank will already appear in the system.

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2.10. If the person responsible for the biobank chooses to suspend the filling, the fields already completed must be saved. To do this, click <save>. The following message will appear in the pop-up window <attention: do you want to save the research information? >, and the person responsible for the biobank must click on the <confirm> option.

2.11. To proceed with filling out, you must click on the <next> button, at the end of the page, on the right side. A pop-up window will open with the following message <you are submitting a previous research project to the brazil platform, but you did not enter the CAAE /SISNEP number (secondary id). Confirm? >, and the person responsible for the biobank must click on the option <yes>, automatically redirecting to the third screen <study design/financial support>.

3.Instructions for completing the third screen <study design/financial support>

3.1. The fields enabled for editing on the third screen are <drawing>; <funding> and <keyword>. Below are the instructions for entering information in the mentioned fields.

3.2. In the <drawing> field, the ways in which the samples were collected should be described, that is, how the samples were granted for storage in the biobank: whether during assistance or through a pathology laboratory, among others).

3.3. In the item <financing>, when clicking on <add financing>, three possibilities will appear, and the person responsible for the biobank must choose and insert the type of financing that best suits the biobank in question.

3.4. In the <keyword> field, the types of biological materials foreseen in the biobank development protocol must be described. To do this, click on <add keyword>, write the type of biological material and click on add. Repeat this process until all expected sample types are properly added.

3.5. Click on the <next> button at the bottom of the page, on the right side, and the person responsible for the biobank will be directed to the fourth screen <study details>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>.
The pop-up message <ATTENTION: Do you want to save the search information? > and the person responsible for the biobank must click on the <confirm> option.

4. Instructions for filling out the fourth screen <study details>

4.1. The <Summary:> field must be filled in with the development protocol information in summary form.

4.2. The <Introduction> field must be filled in with the information below, namely:

4.2.1. Regarding the composition of the team responsible for the biobank: *[insert the names and institutional positions of all members who make up the team responsible for the Biobank].*

4.2.2. Regarding the roles of each member of the team responsible for the biobank: *[insert the roles in the biobank of all team members].*

4.2.3. Regarding the location of the biobank: *[insert the name of the department/ sector and the Institution [insert the name of the institution].*

4.2.4. Regarding the types of biological materials: *[insert the types, number of samples already stored and the year in which the types of samples began to be stored].*

4.3. The <hypothesis> field must include <not applicable>.

4.4. The field <primary objective> must contain the following information: <constitute a biobank for storing human biological samples and associated information for research purposes>.

4.5. The <secondary objective> field must contain <not applicable>.

4.6. The field <proposed methodology> must contain information relating to the items mentioned, as follows:

4.6.1. Regarding potential biobank participants (grantors or consenters): *[insert information regarding potential biobank participants, including age, sex and any*

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particularities].

4.6.2. Regarding the consent and/or assent process and the collection of samples from biobank participants: *[insert information regarding the time, condition and place in which the clarification will be carried out, considering, for this purpose, the peculiarities of the person invited to participate in the biobank and your privacy].*

4.6.3. Regarding the biobank's secure system guaranteeing secrecy, respect for confidentiality and data recovery of biobank participants: *[insert information regarding the biobank's data security system].*

4.6.4. Regarding standard operating procedures relating to the stages of collection, processing, storage, distribution and disposal of samples: *[insert information relating to pre-defined operational procedures, under institutional responsibility and management applicable to stored human biological material].*

4.6.5. Description of the policies for the use of stored human biological material, in order to guarantee the preservation of the collection, favor its social and scientific use and avoid unnecessary depletion of samples: *[insert description of the policies for the use of stored human biological material, in order to guarantee the preservation of the collection, prioritize its social and scientific use and avoid unnecessary depletion of samples].*

4.6.6. Regarding the storage and sharing of samples between partner institutions (if any): *[insert information about the agreement between the participating institutions covering the operationalization, sharing, use of human biological material stored in Biobank, including the possibility of future dissolution of the partnership and the consequent sharing and destination of stored data and materials (CNS Resolution 441/2011, item 13; Ordinance MS 2,201/11, Chapter IV, Section III, Article 31].*

4.7. In the <inclusion criteria> field, select <not applicable>.

4.8. In the <exclusion criteria> field, select <not applicable>.

4.9 - In the <risks> field, potential risks to biobank participants must be described, such as breach of confidentiality, loss of biological samples, among others.

4.10. In the <benefits> field, the potential benefits to biobank participants should be described.

4.11. The field <data analysis methodology> must include <not applicable>.

4.12. The <primary outcome> field must include <not applicable>.

4.13. The <secondary outcome> field must include <not applicable>.

4.14. In the <sample size in Brazil> field, the expected total number of biological samples to be stored by the biobank for research purposes must be entered, considering the capacity allowed by the physical structure. The maximum total value that Plataforma Brasil allows is <9,999,999,999>. When entering the sample size in Brazil, the number will be automatically updated by the system in “number of research participants” and country “Brazil” in the item <recruitment countries>.

4.15. Regarding <date of first recruitment>, tick <not applicable>.

4.16. In the item “recruitment countries”, in the “country of origin” field, the person responsible for the biobank must indicate Brazil as the country of origin. It should be noted that no other countries should be added.

4.17. Click on the <next> button at the bottom of the page, on the right side, and you will be directed to the fifth screen <other information>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>. The pop-up message <Attention: Do you want to save the search information? > and the person responsible for the biobank must click on the <confirm> option.

5. Instructions for filling out the fifth screen <other information>

5.1. In the field <will there be use of secondary data sources (medical records, demographic data, etc.?), the person responsible for the biobank must select the option <yes> and specify the secondary data sources in the field to be enabled for editing <Details>.

5.2. In the item <enter the number of individuals personally approached, recruited, or who will undergo some type of intervention in this research center> the same number informed in step 4.14 must be described.

5.3. In the item <Groups into which research participants in this center will be divided>, you must click on <Add Group>. When opening the pop-up window, the person responsible for the biobank must enter a type of biological sample stored in the <Group Identification> field. It should be noted that groups must be inserted depending on the types of biological materials to be stored provided for in the biobank development protocol. In the <Number of Individuals> field, the number planned for collecting the mentioned material and a brief description of the interventions to be carried out with the mentioned sample must be inserted.

5.4. In the item <is the study multicenter in Brazil? > the option <no> must be selected.

5.5. Even if there are partner institutions of the biobank, the item <co-participating institution> should not include a co-participating institution.

5.6. In the field <proposes exemption from ICF> you must select the option <no>.

5.7. In item <will samples be retained for bank storage? > the option <yes> must be selected and the field <justification> must contain the following text: <Storage of biological samples in a biobank for research purposes>.

5.8. In the item <execution schedule>, click on <Add Schedule> and enter expected dates (start date and end date) to send the next biobank activity report.

5.9. In the item <financial budget>, the person responsible for the biobank must click on <add expense>, insert two types of materials: (1) permanent materials and (2) consumable materials, and must inform the type and respective values expected for the maintenance of the biobank.

5.10. In the item <other information, justifications or considerations at the discretion of the Researcher>, the person responsible for the biobank may insert any information they deem important.

5.11. In the item <Bibliography>, the references used to prepare the biobank development protocol must be inserted, including the National Health Council regulations on material banks, among others.

5.12. To continue filling, click the <Next> button and a pop-up window <project files> will open. Before uploading documents to Plataforma Brasil, make sure that the file name does not contain special characters or blank spaces. To link words in the file name, use *underscore* (_) such as “institutional_responsibility_term”. All files will be automatically scanned by the system itself. If the file names are not in the mentioned format, the system will not *upload* the document.

5.13. Regarding the item <attach cover sheet>, step 1 <print cover sheet> does not need to be performed as there is no cover sheet for biobank development protocols.

5.14. In the item <step 2: after signing the cover page, scan it and attach it here>, the person responsible for the biobank must click on <attach cover page> and attach the Institutional Responsibility Term (TRI).

5.15. Select <Detailed Project / Investigator Brochure> to <attach> the internal regulations of the development protocol.

5.16. Select <biological material / biorepository / biobank handling declaration>” to <attach> the standard operating procedures relating to the sample collection, processing, storage, distribution and disposal steps.

5.17. Select <TCLE / Terms of Assent / Justification of Absence> to <attach> the version of the TCLE and Term of Assent.

5.18. Click on the <next> button at the end of the page, on the right side, and you will be directed to the sixth screen titled <finish>. If the person responsible for the biobank chooses to suspend filling, the fields already completed must be saved. To do this, click <save>. The pop-up message <Attention: Do you want to save the search information? > and the person responsible for the biobank must click on the <confirm> option.

6. Instructions for filling out the sixth screen <finish>

6.1 - In the item <maintain confidentiality of the entire research project?> it will be up to the person responsible for the biobank to choose <yes> or <no>. By clicking on the option <yes>, the item <deadline> can be edited, leaving the person responsible for the biobank to select the period to maintain confidentiality of the entire research project for 6 months, 1 year, 2 years, 3 years, 4 years, 5 years or until the results are published. If you choose <no>, the <deadline> item cannot be edited.

6.2 - The terms described on screen 6 refer to the <General Commitment>, <Financing and Budgeting Commitments>, <Indemnity Commitment>, <Methodological Commitment> and <Documentation Commitment>. The person responsible for the biobank, after reading and agreeing to these commitments, must click <accept terms above>.

6.3 - Finally, you must click on the button <send project to CEP> located at the bottom of the screen so that the development protocol follows the process for document validation in the CEP/Conep System.

Annex II.1. – Guidelines for research ethics committees for ethical analysis of biobank development protocols for research purposes

1. It should be noted that the biobank development protocol must first be analyzed by the institutional CEP or by the CEP indicated by Conep, with the issuance of a duly justified opinion, in accordance with CNS Operational Standard No. 001/2013. There may or may not be pending opinions issued. approved (if applicable). When approved, it must necessarily be evaluated by Conep (CNS Resolution nº 441, of May 12, 2011). After the collegiate deliberation on the approval of the biobank, the CEP coordinator must enter <approved> in the field <Status of the Opinion>, and in the item <needs Conep's assessment?> select the option <yes>.

2. Only after approval of the biobank development protocol by Conep will the aforementioned bank be able to collect and transfer human biological samples to carry out research.

Yours sincerely,

CRISTIANE ALARCÃO FULGENTIO
Executive Secretary of the National Research Ethics Commission

Accordingly,

JORGE ALVES DE ALMEIDA VENANCIO
Coordinator of the National Research Ethics Commission

Document signed electronically by **Jorge Venâncio, Administrator,** on 12/13/2021, at 10:12 pm, according to official Brasília time, based on § 3 of art. 4th, of Decree No. 10,543, of November 13, 2020; and art. 8th, of Ordinance No. 900 of March 31, 2017.

Document signed electronically by **Cristiane Alarcão Fulgencio, Executive Secretary of the National Research Ethics Commission,** on 12/16/2021, at 8:07 pm, according to official Brasília time, based on § 3 of art. 4th, of Decree No. 10,543, of November 13, 2020; and art. 8th, of Ordinance No. 900 of March 31, 2017.

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Reference: Process nº 25000.180199/2021-12 SEI nº 0024285625

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