User manual

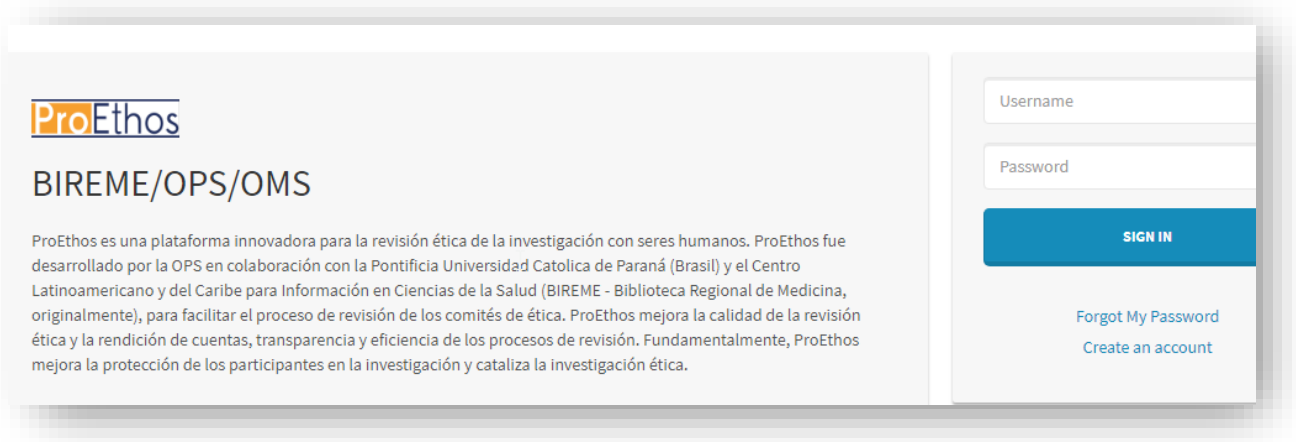
Table of contents

OVERVIEW

Welcome to ProEthos! ProEthos is a web-based platform that facilitates the presentation of electronic research proposals involving human subjects for ethics review. The goal is to help Members of an Ethics Review Committee (ERC) eliminate paperwork, so their time is well spent conducting rigorous analyses of a research protocol's ethical and methodological aspects. ProEthos facilitates the input of accurate research data. It also supports the assignation of protocols to Members and External Reviewers; the creation and distribution of final research decisions; and the ongoing monitoring of projects.

To adopt ProEthos for your ERC, the first step is to install it on your institution's local server. A list of its basic requirements and instructions about how to install ProEthos can be found on our GitHub page: https://github.com/bireme/proethos. Installation of the system on a server Ubuntu 14.04 LTS is highly recommended; it can also be installed in a server running on a Windows-based operating system.

- Once ProEthos has been successfully installed in a server connected to your institution, the main screen should appear like the image below:



- The installer should set one admin account with which to assign access to all the other users
- Users should then create accounts in the system. The developer in charge of ProEthos at your institution should be able to approve user access and assign corresponding roles for the core group of users.

ProEthos has 5 unique user roles

1. **Investigator**	**Presents a protocol for Ethics review**. Fills in all the information that the system asks for: 7 tabs based on the 20 fields for the registry of clinical trials (OMS / ICTRP) and attaches additional archives, such as informed consent and assent documentation, questionnaires, budgets and other documentation.
2. **Secretary**	**Operations manager of the committee**. Performs administrative functions; the Secretary may or may not participate in the Ethics review of protocols beyond the initial screening process. Secretary assigns protocol to Committee Members and Ad-hoc Members. Provides follow-up to the protocol throughout all its phases of review.
3. **Member**	**Participates in the ethical review of protocols**. Member receives messages from the Secretary to login to the system to analyze protocols before in-person meetings. Members write their analyses on the protocols to share with other members of the Committee and the Secretary.
4. **Ad hoc**	**External reviewer**. They only have privileges to enter and conduct a review of a protocol that is specifically assigned to them.
5. **Administrator**	**Administers the system**. They have privileges to configure the system or make edits.

To approve new user accounts:

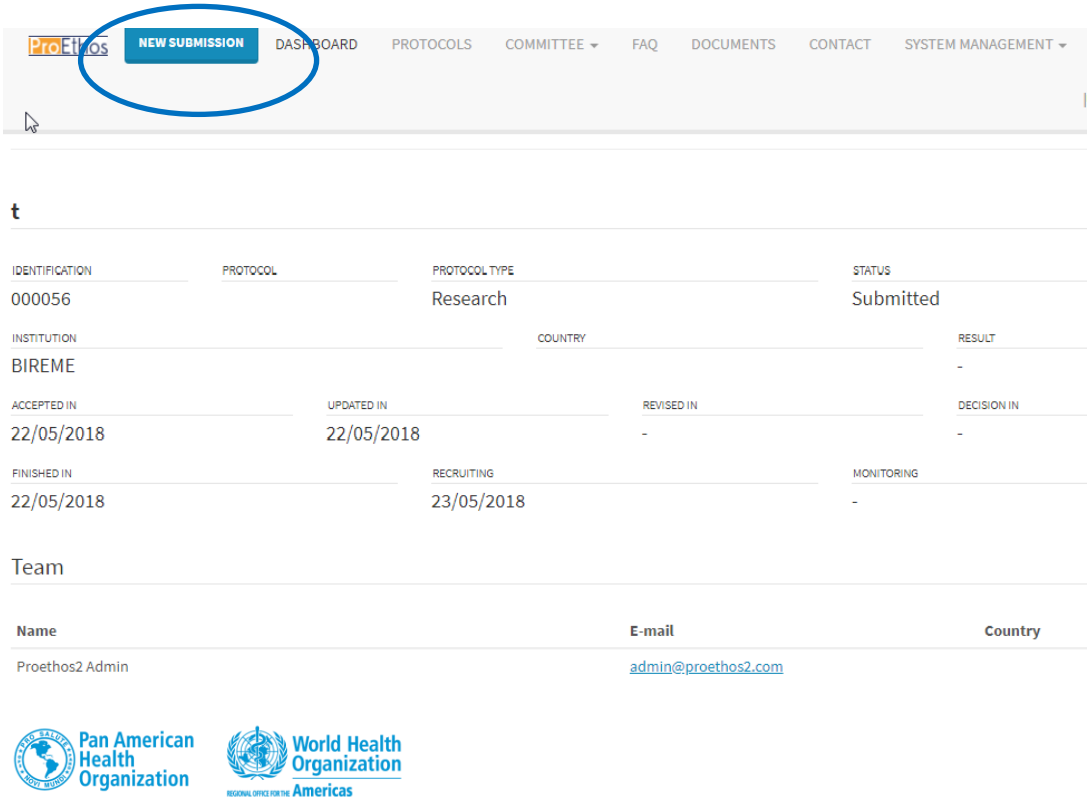
- Login as the administrator
- Go to **Committee** > **Users** and find the user you wish to approve
- 1. Click the **Edit roles [head]** icon under the **Actions** menu and check the box for all of the roles this particular user should have. Save. 2. Then click on the **Update user [pencil]** icon to the right of the previous one and click the box that

asks **Active?**

- Clicking Active should send the user a confirmation email letting them know their account is ready to use

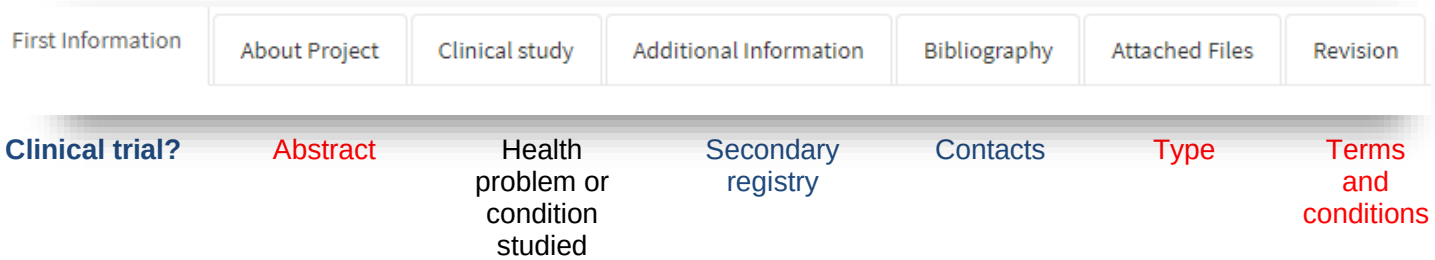
1. Investigator: presents a research protocol for ethics review

- The Investigator's role includes: the presentation of their protocol and upload of documents that support the research.
- Below is Dashboard view for Investigators.



- Clicking on **New submission** initiates the data entry for a new protocol.
- **New submission** activates the 7 tabs that the system asks for to complete the input of a new protocol (based on the 20 fields of the clinical trials registry (OMS / ICTRP). You can keep track of which tab you are in because it appears a bit more elevated than the other 6 tabs.
- If the **Clinical trials** box is selected additional data entry fields will be enabled.

- The table below shows all the tabs containing the “standardized” information that the system asks Investigators to complete. This information comes preprogramed in the platform’s code and is visible upon finalizing the download of the platform from GitHub
- Each entity that downloads the system has the right to modify the following information: logos, obligatory fields, etc. according to each committee’s needs and preferences.
- All text written in a blue font in the table below represents fields that accept plain text. **Bold text** represents fields that bring up new windows that ask Investigators for additional information. Red text represents drop-down or calendar-style fields or lists that populate using numbers.

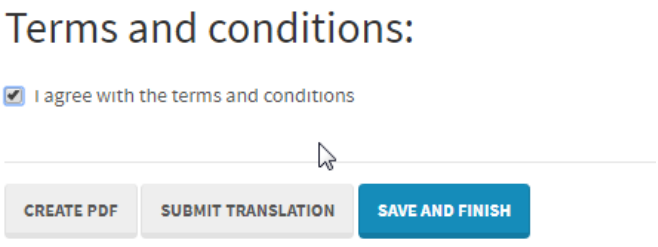


Scientific title	Key words	Gender	**New cost**	Prior ethical approval?	**Document** (select Word, PDF, .jpg)
Public title	Introduction	Sample size	Funding source		
Acronym	Justify	Minimum age:	Primary sponsor		
	Objectives	Maximum age:	Secondary sponsor		
		Inclusion criteria	Program:		
		Exclusion criteria:	**New task**		
		Estimated recruitment date			

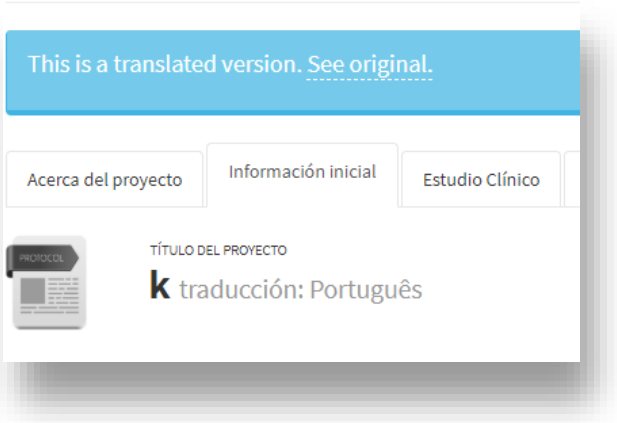
Documents to upload

- Investigators can upload any document they believe will help them receive an expedient approval. We recommend making the following documents mandatory, at a minimum: protocol, informed consent, questionnaire.

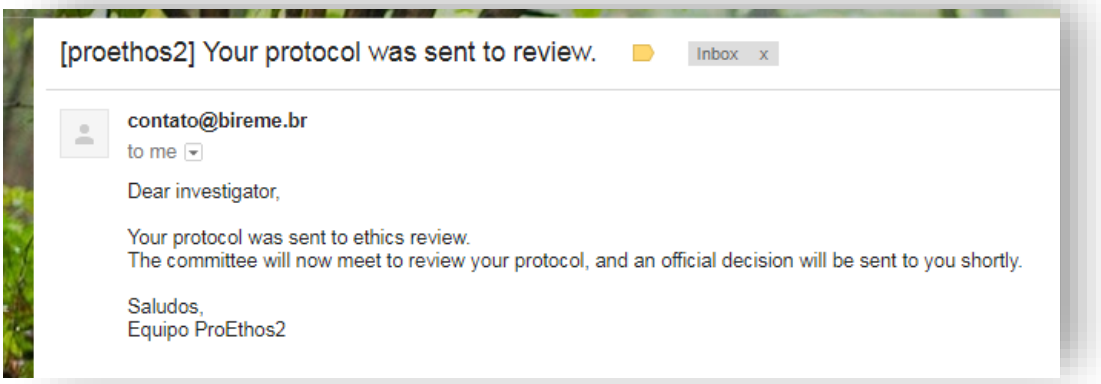
- After filling out all the fields that the system asks for, the Investigator can review their input data before submitting
- At the end of the upload, Investigators are given the following options: **Create a PDF**, **Translate the information**, and **Save and close**
- **Create PDF** is a recommended action, so that Investigators may save a version of their protocol to their computer



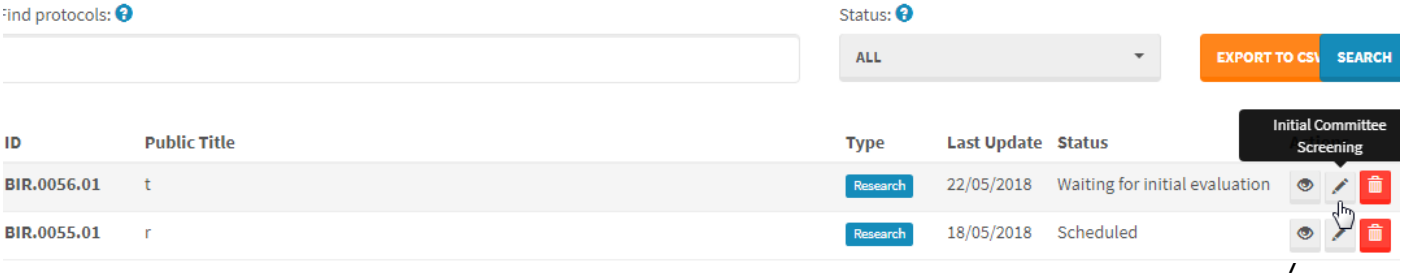
- Clicking on **Translate the information** takes the Investigator to the start of the input to fill the fields again in another language (English, Portuguese, French, Spanish)



- After finishing the input of the protocol and selecting **Save and finalize** the investigator should receive a confirmation email (shown below)



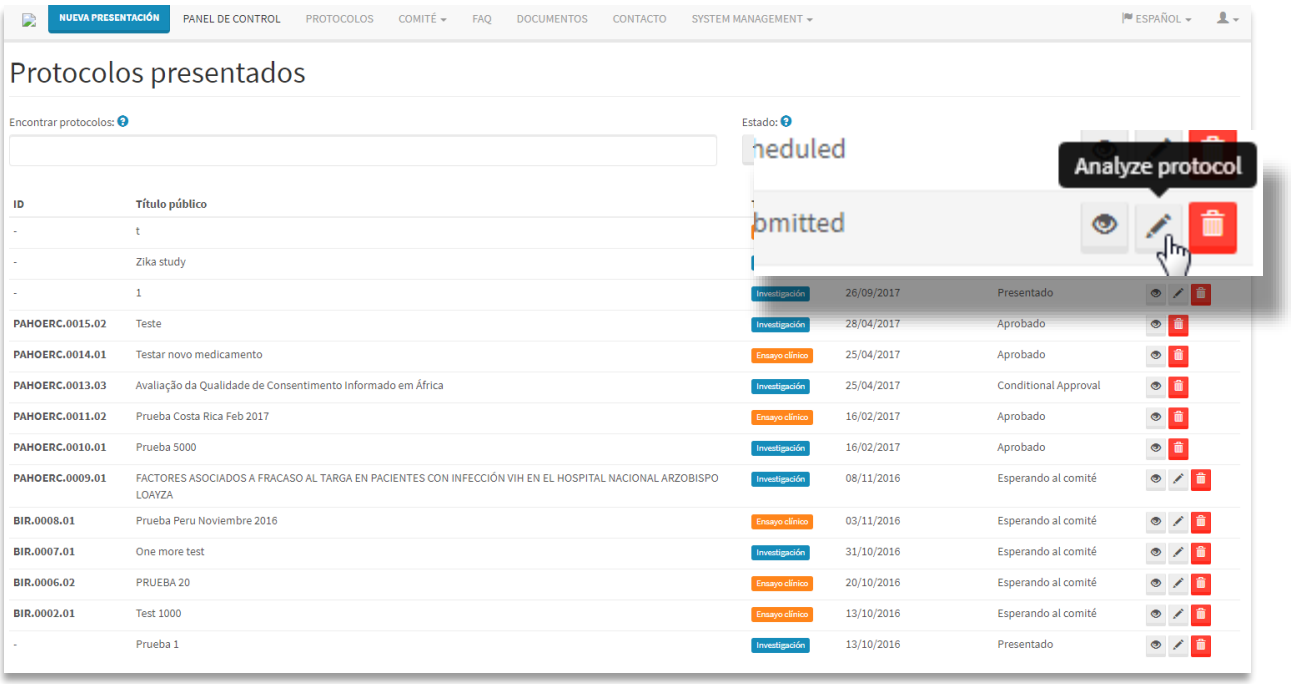
- Investigators can see all the information about their submitted protocols under their own **Control Panel**
- Investigators can login to their accounts in any moment to view the status of their protocols
- The **Actions** button (on the right-hand side of the screen) allows Investigators to view or edit their submissions (for example to add new documents such an informed consent document)



- The system takes note of each action or upload the Investigator completes and keeps a detailed history of interactions.
- Investigators then wait to receive notification from the committee about their protocol's status.

2. Committee Secretary: carries out the initial review of the protocol, assigns protocols, schedules meetings

- The person fulfilling the role of the Committee's Secretary has the same rights as any Committee Member with additional privileges that allow them to screen and track protocols through the ethics review process cycle, to assign to members and plan the committee's work



- This is the primary view of the Secretary's Dashboard
- The Secretary is the role that manages the initial administration of protocols, the steps in the process, and the people involved in the platform
- His/her role begins with a screening of a new protocol, before it is presented to the whole Committee

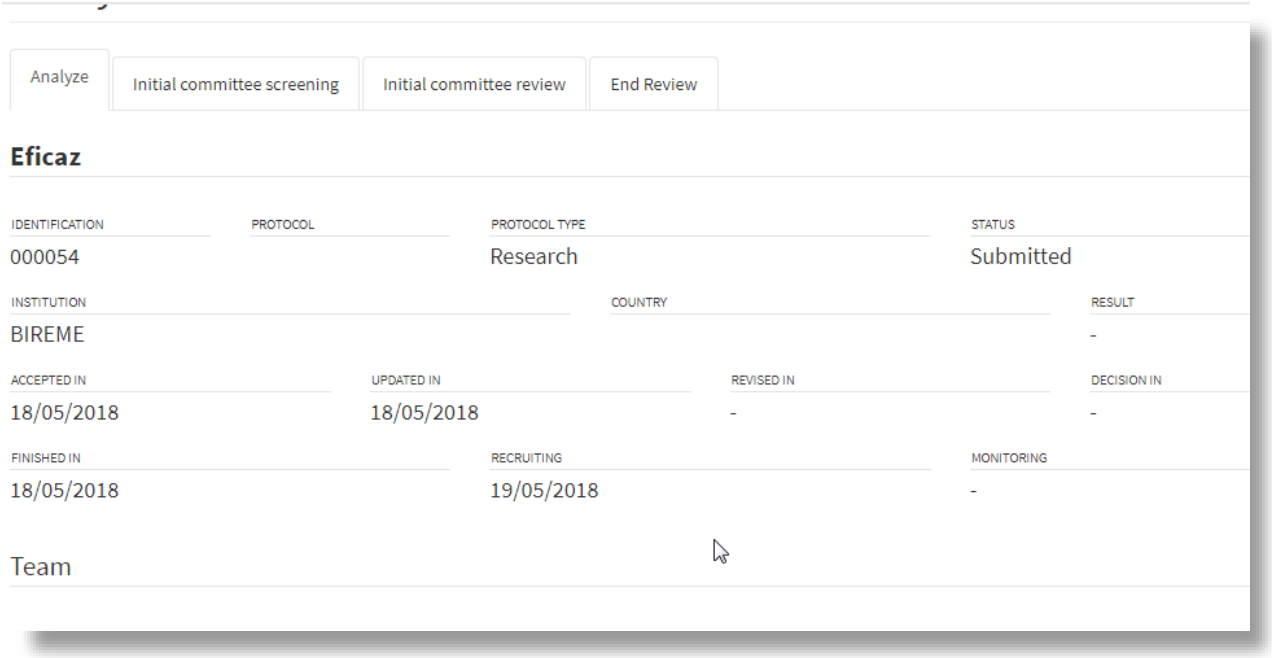
Analyze protocol

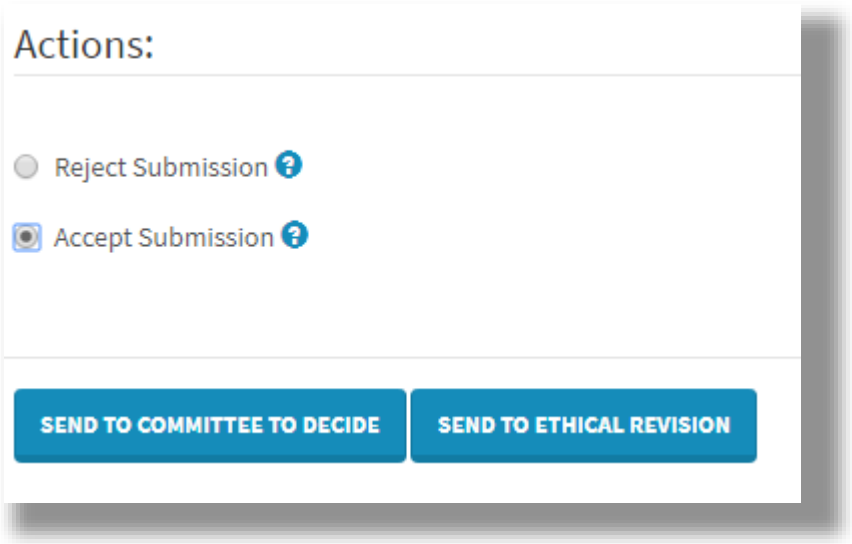
During this first step of ethical review, the Secretary screens the protocol to ensure that it is complete, correct, and that is worth sending to the committee for review.

- The Secretary receives a notification email after an investigator submits a protocol for review
- The email brings the Secretary to the Committee's protocol portal to see the specific protocol (the Secretary can also login to the system at any point to see if there are new submissions). This screen is the same as the

Committee Member's screen and but offers additional administrative privileges

- The Secretary can **view** or **analyze** (edit) all the protocols that are in the State of "Presented"
- To initiate a preliminary review of a protocol, the Secretary should click on the pencil icon under **Actions.** This opens the "Analyze the protocol" action
- Clicking on **Analyze the protocol** brings up four tabs; unlike the 7 tabs it brings up for an investigator role these 4 tabs do not represent thematic input fields but specific steps that a committee should take during its ethics review process



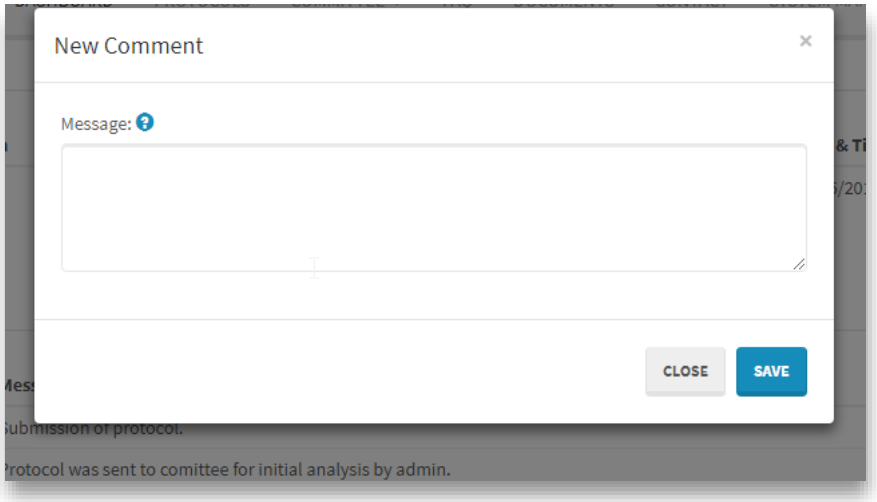


- **Analyzing the protocol** summarizes the presentation of the study and allows the Secretary to view the attached files. The Secretary should analyze the submission and decide at the end of the page which status to apply to the protocol: **Reject the submission** or **Accept the submission**
    - *Reject submission* – sends the submission back to the investigator. A window will pop up for the Secretary to add a reason that will be visible to the investigator. ProEthos will then send an email back to the investigator letting them know that the submission needs something else to be completed, and the submission will reopen for investigators.

- When accepting the presentation of the protocol the Secretary is given the option to **Send to the committee for a decision** or **To send to ethics review**

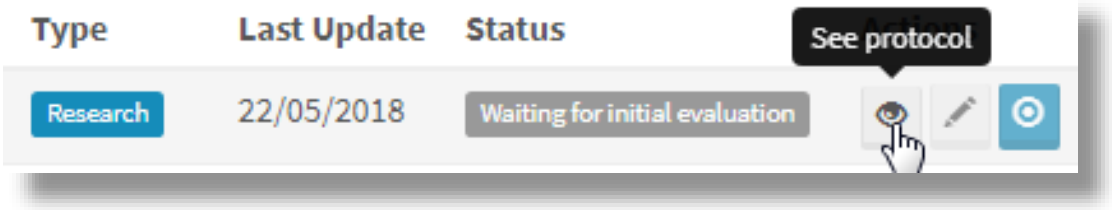
Show protocol

- The Secretary should click on the **New comment** button to add a comment that introduces the protocol to the committee
- Once the comment is saved the protocol can be assigned to specific member of



the committee or to Ad-hoc members

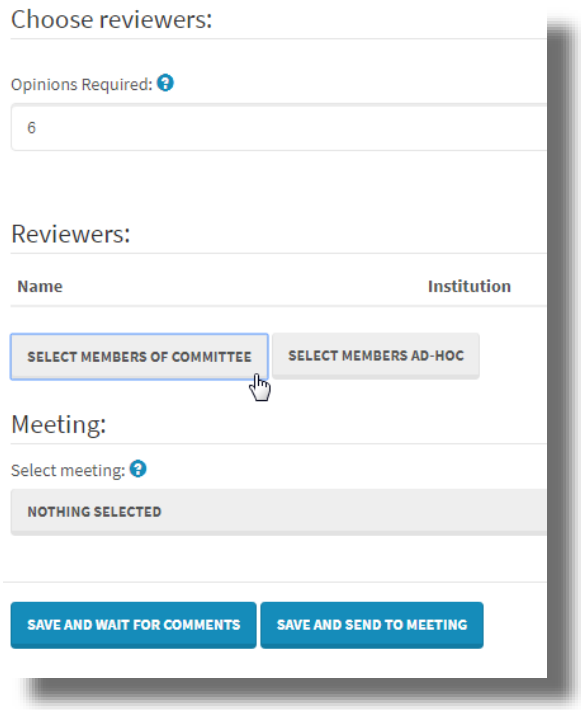
- An ID is assigned to the protocol once it is initially accepted by the Secretary. For Investigators and Committee Members, the status looks like this:



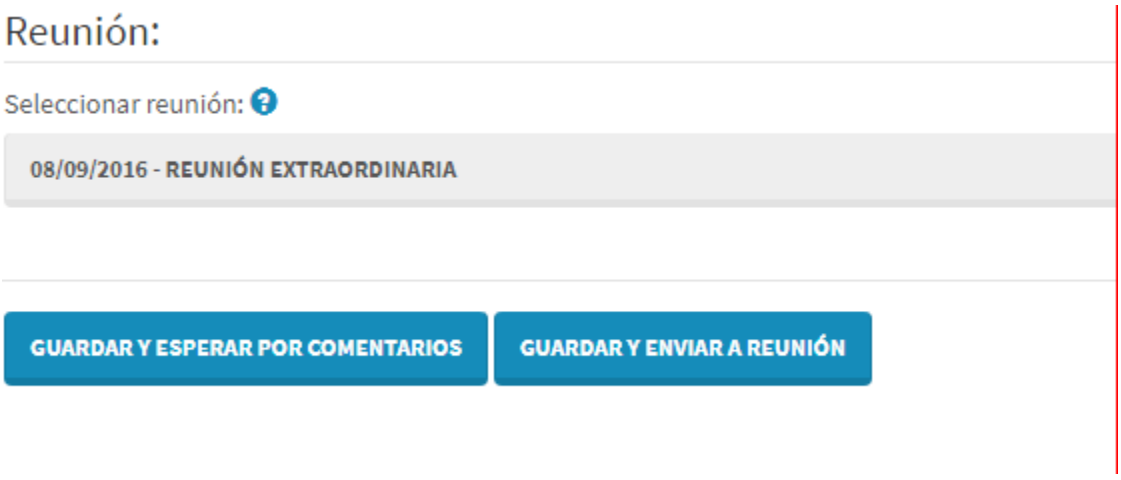
- The next step for the Secretary is to assign the protocol to Members or Ad-hoc Members

Initial Committee Review

- The next step for the Secretary is to assign the protocol to Members or Ad-hoc Members, first choosing the number of opinions that will be required for a decision to be made

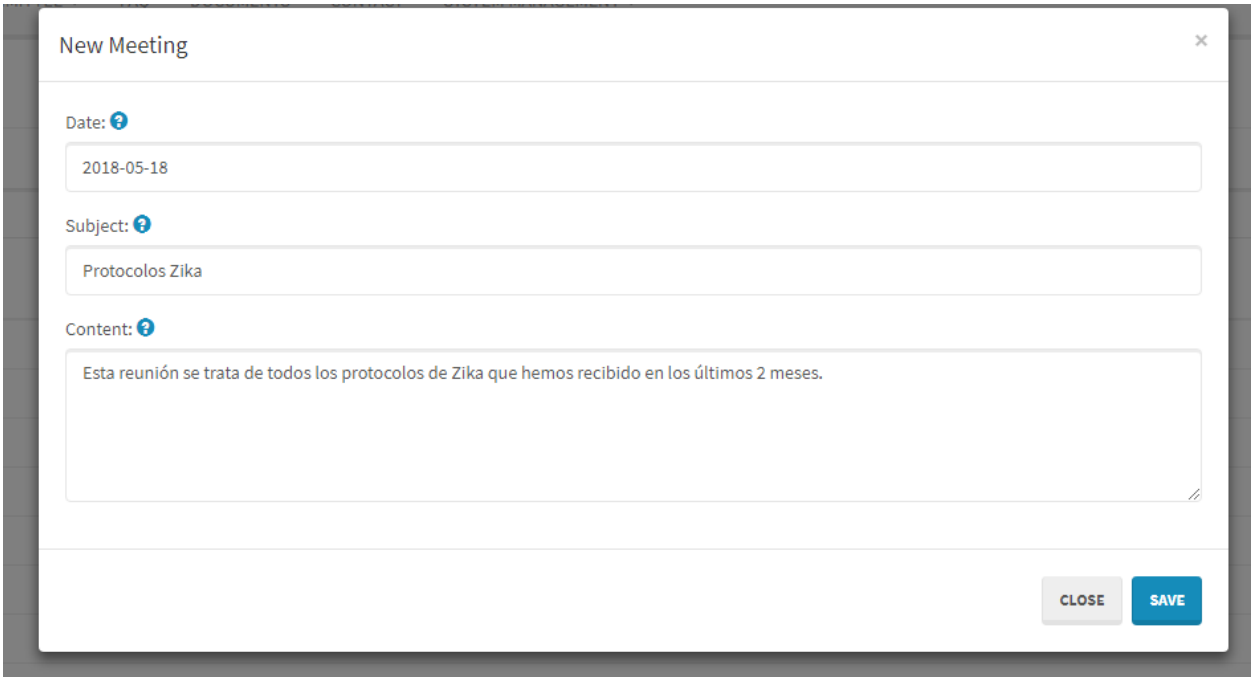


- The Committee Member list is populated with the users who are assigned the Member role. Ad-Hoc Members can be any external people who create accounts in the system. Ad-hoc Members should be notified before they appear in the list for assignment in the specific protocols
- In in this same screen a meeting can be selected **Save and send** to meeting in the protocol or **Save and wait for commentary**. If there is no meeting on the agenda, the best option is to save it and wait until one is scheduled.

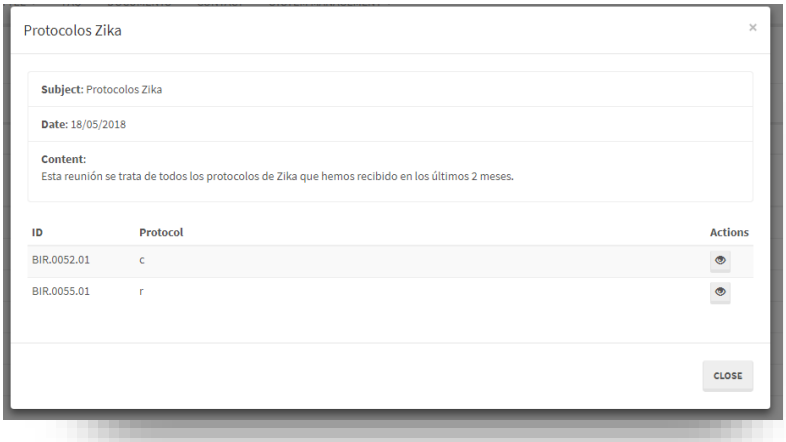


Create a new meeting

- A new meeting can be created under the label **Committee** > **New meeting**

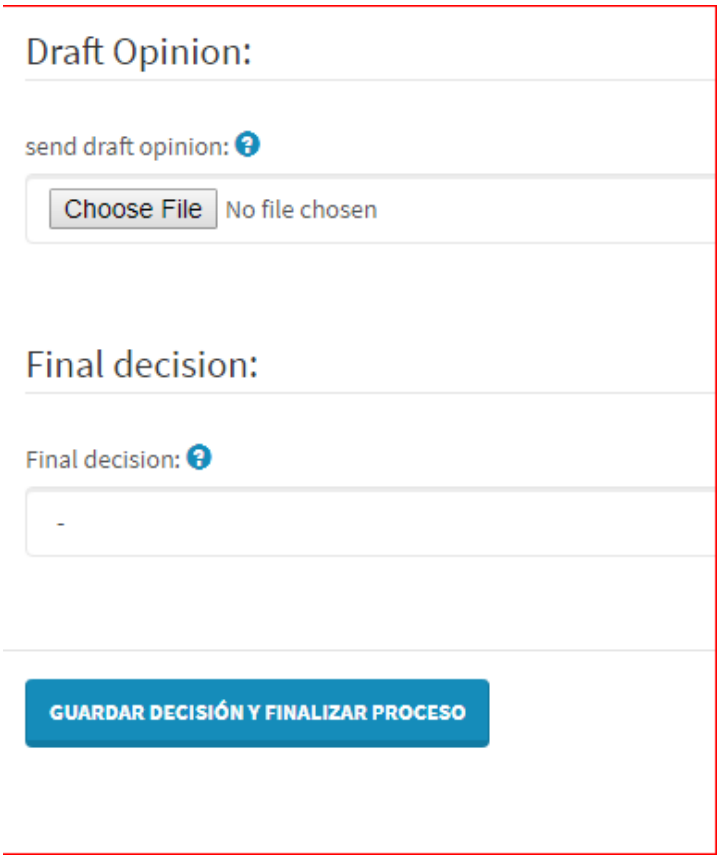


- After adding a name, data, time and topic for the **new meeting**, save to create it. It will then appear in the list of potential meetings that can be drawn from in the protocol review function
- The Secretary can go to **Committee** > **Protocols** and take Actions to assign protocols to a meeting.
- Once created, the system generates an agenda of the protocols that have been assigned to a specific named, scheduled meeting.



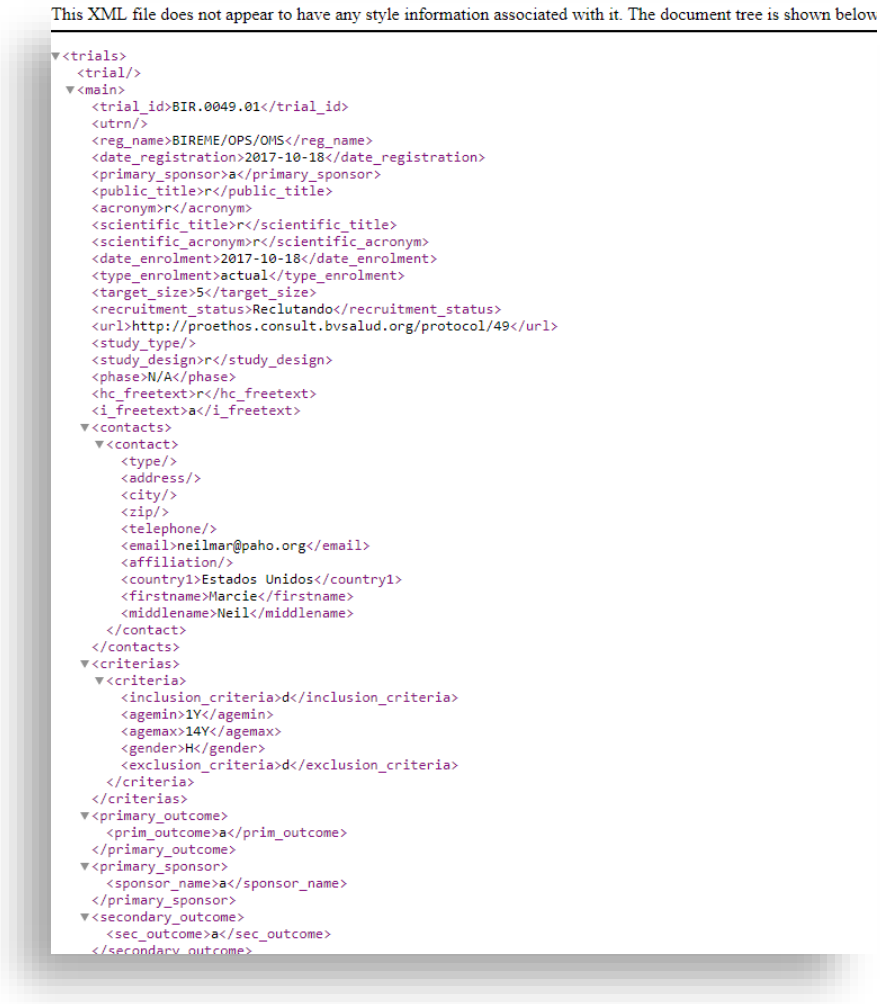
Issue a decision

- The following action that the system will enable from the Committee's Dashboard is **Finalize review**. After a protocol is assigned to a meeting, the directive appears automatically above the pencil icon, under **Actions** in the **Protocol** section
- In this section an Observation, such as a word file generated by the Committee, can be uploaded to be easily sent to investigators
- One of the final decisions can be selected and sent: Approved, not Approved, conditionally approved, Expedited approval, or exempt from review.



- **Save Decision** and **Finalize the Process** is the last step in the process of review
- After confirming your decision, one can choose a period monitoring period and the system will send an email to the PI (at 6, 9 or 12 months)
- A future monitoring action can also be added to the **Protocols** section in any moment

- Finally, complete protocol can be exported to an XML ICTRP/WHO-compatible format to facilitate its integration with another system (for example, an institutional registry for research projects or clinical trial registries)

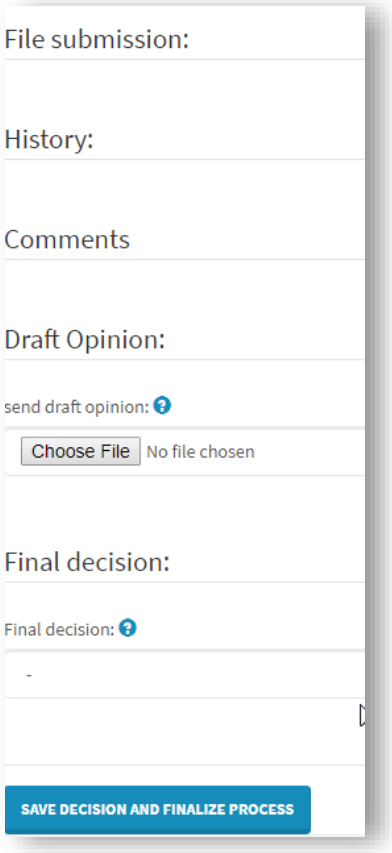


- Finally, the Secretary can see all a timeline of the communication history between the PI and Members, as well as the monitoring actions and steps and documents added throughout the process. This can be useful in the case of a dispute about the timeline of events or in case of communication breakdown.

3. Committee Member: Participates in protocol review

- Above is the *Dashboard view, which falls below the tab* COMTTIEE> Protocols
- Committee Members can:

    - Search for protocols in the search bar (by state of review, accepted, in process, etc.);
    - Export the list of protocols to an Excel Spreadsheet
    - View the protocol and add a comment
    - Analyze each protocol in detail
- The Comité Member receives an automatic email with the follow-up action to take when the Secretary assigns it to them:
- They can also login to the system at any time in order to review the status of their assigned protocols and provide comment



Analyze | Initial committee screening | Initial committee review | End Review

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IDENTIFICATION	PROTOCOL	PROTOCOL TYPE	STATUS
000056	BIR.0056.01	Research	Waiting for initial evaluation

INSTITUTION	COUNTRY	RESULT
BIREME		-

ACCEPTED IN	UPDATED IN	REVISED IN	DECISION IN
22/05/2018	22/05/2018	-	-

FINISHED IN	RECRUITING	MONITORING
22/05/2018	23/05/2018	-

Team

File submission:

History:

Elegir revisores:

Opiniones requeridas:

3

Revisores:

Nombre

SELECCIONAR MIEMBROS DEL COMITÉ | SELECCIONAR MIEMBROS AD-HOC

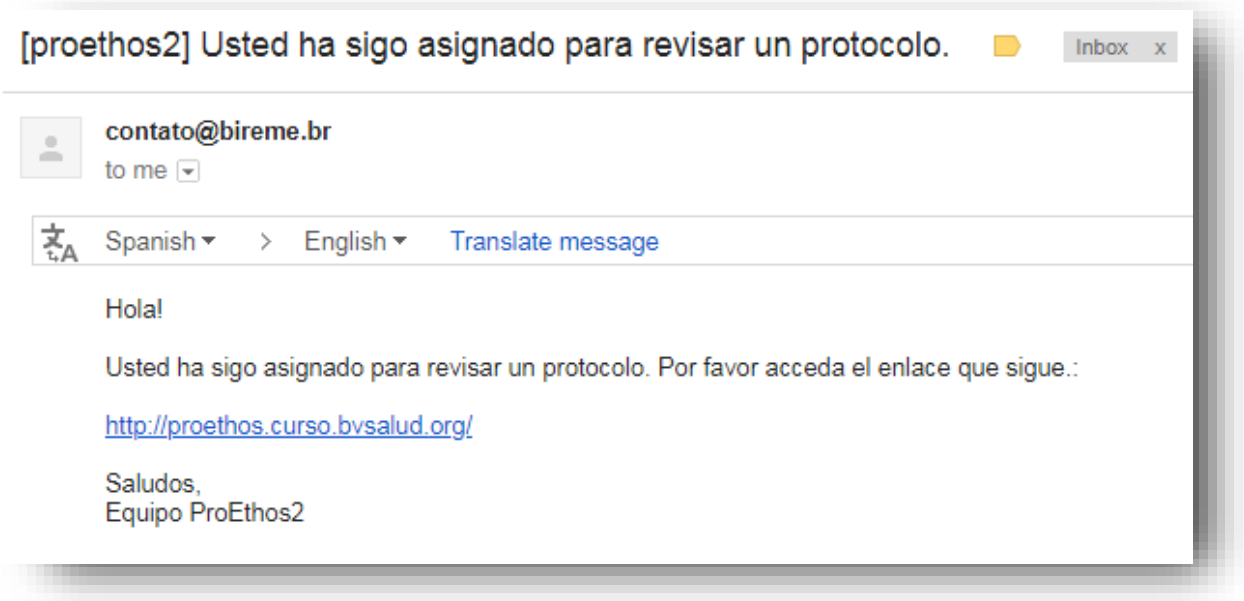
Pan American Health Organization

World Health Organization
Regional Office for the Americas

4. Ad-hoc Member: Participates in review of specific protocols

The person who fulfills the Secretary role notifies the external reviewer that they should create an account in ProEthos

- The Secretary should then assign them a protocol through the system and send him/her an email with an active link that will direct them to the portal to fill out the



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- The Ad-hoc Member should analyze the protocol and leave a comment in the system
- Once they have completed their review, ProEthos again notifies the Secretary that it has been completed

5. Administrator: Configures the administration of the system on the front-end (Distinct from a programmer)

- While the programmer is the person who should make changes and updates to the system the administrator can also make minor changes to the front-end that aid the practical day-to-day usage of the system
- The administrator role can be added to any other system role (it is best if this administrative role is not given to anyone outside the committee, such as an Ad-hoc member or PI)
- Some of the site aspects that could be changed easily are:
    - Help messages
        - Definitions and other descriptive information should be included that helps the investigators to input in data fields for the specific context of the committee
    - Translations –
        - ProEthos uses the embedded program JMI translations in order to make adjustments. Users with the admin role can access this function.
    - Controlled lists:
        - Types of upload
        - Types of extentions that can be uploaded (.tiff, .jpg. etc.)
        - State of recruitment (recruiting, finished)
        - Monitoring actions (month intervals)
        - Names of clinical trial registries
        - Gender(s)
    - The administration of user accounts
    - Configurations – such as the contact information for the committee, the logo, description, etc.