

IORG #: **IORG0003504**
Institution: **Instituto Nacional de Infectologia Evandro Chagas - INI**
Expires: **09/10/2028**

OMB No. 0990-0279
Approved for use through June 30, 2025

**U.S. Department of Health and Human Services (HHS)
Registration of an Institutional Review Board (IRB)**

This form is used by institutions or organizations operating IRBs that review:

- a) Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or**
- b) Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services**

This form is to be used for the following purposes:

Fields with an * are required for OHRP IRBs and FDA IRBs

Fields with an ♦ are required for OHRP IRBs but are optional for FDA IRBs

Fields with an ‡ are required for FDA IRBs but are optional for OHRP IRBs

Fields with no symbol are optional for both OHRP IRBs and FDA IRBs

- 1. *Has your institution or organization previously registered an IRB with the Office for Human Research Protections (OHRP)?**

[X] Yes, proceed to section 2 [] No, proceed to section 3

- 2. *What is your institution or organization (IORG) number? IORG0003504**

This number was provided by OHRP the first time your institution or organization registered an IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777.

- 3. Name of Institution or Organization Operating the IRB(s)**

*Name of Institution or Organization: **Instituto Nacional de Infectologia Evandro Chagas - INI**

*Mailing Address: **Av. Brasil, 4365**
Manguinhos - Rio de Janeiro - RJ - Brazil
Zip/Postal Code: 21040-900

*Street Address (if different from the Mailing Address above):

*City: **Rio De Janeiro** *State/Province: *Zip/Postal Code:
*Country (if outside the U.S.): **BRAZIL**

4. Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities Performed by the IRB(s)

*First Name: **Sandra Wagner** Middle Initial: *Last Name: **Cardoso**
Earned Degree(s): **MD, PhD** Title or Position: **IRB Coordinator**

*Mailing Address (if different from the Mailing Address in section 3):

Av. Brasil, 4365
Manguinhos - Rio de Janeiro, RJ, BRAZIL
Zip/Postal Code: 21040-900

*City: **Rio de Janeiro** *State/Province: *Zip/Postal Code:
*Country (if outside the U.S.): **BRAZIL**
*Phone: **+ 55** *FAX: **+ 55 21-3865-9585** *E-Mail: **cep@ini.fiocruz.br**
21-3865-9585

5. Contact Person Providing this Registration Information

*First Name: **Fabio** Middle Initial: *Last Name: **Marques**
Earned Degree(s): Title or Position: **Secretary**

Name of Institution or Organization (if different from the Name in section 3):

Instituto Nacional de Infectologia Evandro Chagas - INI

*Mailing Address (if different from the Mailing Address in section 3):

Av. Brasil, 4365
Manguinhos, Rio de Janeiro - RJ - Brazil
Zip/Postal Code: 21040-900

*City: **Rio De Janeiro** *State/Province: *Zip/Postal Code:
*Country (if outside the **BRAZIL**
*Phone: **55 21 3865-9585** *FAX: **55 21 3865-9585** *E-Mail: **cep@ini.fiocruz.br**

6. IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

[X] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00004170**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

[] No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Comite - CEP IPEC

C. Location of the IRB

*Mailing Address (if different from the Mailing Address in section 3):

**Av. Brasil, 4365
Manguinhos, Rio de Janeiro - RJ - Brazil
Zip/Postal Code: 21040-900**

*Street Address of the IRB (if different from the Mailing Address of the IRB):

*City: **Rio de Janeiro**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **BRAZIL**

*Phone: **+ 55 21 38659585** *FAX: **+ 55 21 38659585** *E-Mail: **cep@ini.fiocruz.br**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities:

2

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

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F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

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G. For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

i) Approximate number of active protocols involving FDA-regulated products:

ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

human drugs	food additives
medical devices	color additives
biological	other
	Specify

H. IRB Chairperson

*First Name: **Sandra** Middle Initial: *Last Name: **Cardoso**

Earned Degree(s): **Ph.D.** Title or Position:

Mailing Address (if different from the Mailing Address in section 3):

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Manguinhos, Rio de Janeiro - RJ - Brazil

Zip/Postal Code: 21040-900

City: **Rio de Janeiro** State/Province: Zip/Postal Code:

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I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Cardoso, Sandra	F	MD, Ph.D.	S	Infectious and Parasitary Diseases	Y	
Cardozo, Marcos Maurício Braga	M	N/A	N	Patient Representative	N	
Carneiro, Mauro Brandão	M	MD, PhD	S	Bioethics	Y	
Brito, Patrícia Dias de	F	PhD	S	Nutritionist	Y	
Silva, Sonia Maria Fonseca	F	N/A	N	Patient Representative	N	
Lima, Eric Henrique Roma de	M	PhD	S	Biologist	Y	
Pimentel, Maria Inês Fernandes	F	MD, PhD	S	Medicine (Dermatology)	Y	
Siqueira, Andre Machado de	M	MD PhD	S	infectious and parasitary diseases	Y	
Schmaltz, Carolina Arana	F	MD PhD	S	infectious and parasitary diseases	Y	
Freitas, Dayvison Francis	M	MD PhD	S	dermatologist	Y	
Milhomem, Eunes de Castro	F	MSc	S	psychologist	Y	
Leal, Edylene Pereira	F	BS	S	Lawyer	Y	
Almeida, Maria da Gloria	F	PhD	S	Biologist	Y	
Moreira, Ronaldo Ismério	M	PhD	S	statistical and physicist	Y	
Oliveira, Rosely Maria Zancope	F	PhD	S	Biomedicine	Y	
Gutierrez Galhardo, Maria Clara	F	MD, PhD	S	Dermatology	Y	
da Costa, Ananda Dutra	F	Ph.D.	S	speech therapist	Y	
Pereira Vaz, Beatriz de Jesus	F	MD, PhD	S	Medicine	Y	
dos Santos, Francisca Maria	F	N/A	N	Patient Representative	N	
Bressan, Clarisse da Silveira	F	Ph.D.	S	Infectious and Parasitary Diseases	Y	
Andrade, Hugo Boechat	M	Ph.D.	S	Infectious and Parasitary Diseases	Y	
Leite, Iúri da Costa	M	Ph.D.	S	statistical	Y	
Facchinetti, Livia Dummont	F	Ph.D.	S	Physiotherapist	Y	
Domingos, Mara Lucia Araujo	F	high school	N	Patient Representative	N	

Nogueira, Mariana Machay Pinto	F	M.D.	S	Nursing	Y
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Alternative Members

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person’s immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

