

# OFFICIAL DIARY OF THE UNION

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135 **Body: Ministry of Health/National Health Council**

## RESOLUTION No. 647, OF OCTOBER 12, 2020

Provides for the rules regarding the regulation of the process of appointment and performance of CEP members appointed by social control entities.

THE PRESIDENT OF THE NATIONAL HEALTH COUNCIL (CNS), in the use of his regimental powers and attributions conferred by the Internal Regulations of the CNS and guaranteed by Law No. 8,080, of September 19, 1990; by Law No. 8,142, of December 28, 1990; by Complementary Law No. 141, of January 13, 2012; by Decree No. 5,839, of July 11, 2006; complying with the provisions of the 1988 Constitution of the Federative Republic of Brazil and related Brazilian legislation; and

Considering that the Federal Constitution of 1988 establishes "health as a right of all and a duty of the State, guaranteed through social and economic policies aimed at reducing the risk of disease and other aggravations and at universal and equal access to actions and services for its promotion, protection and recovery";

Considering that according to Art. 33 of Law No. 9,784, of January 29, 1999, "administrative bodies and entities, in relevant matters, may establish other means of participation by the managed, directly or through legally recognized organizations and associations";

Considering that the CNS is responsible for "following up the process of scientific and technological development and incorporation in the health area, aiming at the observation of ethical standards compatible with the sociocultural development of the Country", as foreseen in its Internal Regulation, approved through the CNS Resolution No. 407, of September 12, 2008;

Considering the relevance of redefining norms and procedures related to the members of Ethics Committees in Research with Human Beings (CEP) appointed by social control entities;

Considering the protagonism and relevance of social control for the exercise of ethics in the research evaluated by the CEP/Conep System;

Considering the need to regulate and promote the performance of representatives of the social control in the protection of research participants in the CEP/Conep System;

Considering the provisions of CNS Resolution No. 466, of December 12, 2012, in its items XIII.1 and XIII.2, and in CNS Resolution No. 510, of April 7, 2016, and considering the need to update CNS Resolution No. 240, of June 5, 1997, and Operational Standard No. 001 of 2013 as it applies to the representation of users; and

Considering that it is the attribution of the President of the National Health Council, to decide, ad referendum, on emergency matters, when it is impossible to consult the Plenary, submitting its act to the Plenary's deliberation at a subsequent meeting (Art. 13, item VI of the Rules of Procedure Internal of the CNS, approved by CNS Resolution No. 407, of September 12, 2008), resolves:

Ad referendum of the Plenary of the National Health Council:

Art. 1st Approve the following rules regarding the regulation of the appointment process and performance of CEP members appointed by social control entities.

### CHAPTER I

of the preliminary provisions

Art. 2 This Resolution promotes the replacement, within the scope of the CEP/Conep System, of the term User Representative (RU) by the term Research Participant Representative (RPP), to name the member indicated to the CEP by an entity of social control.

## CHAPTER II

### Of terms and definitions

Art. 3 For the purposes of this Resolution, the following terms and definitions are adopted:

I - Social Control: process through which the population participates directly, or through representatives, in consultative, deliberative and decision-making bodies, in the definition, execution and monitoring of public policies;

II - Entity indicating the Representative of Research Participants: it is the organization or social movement, preferably public policy council, responsible for appointing the Representative of Research Participants to the CEP/Conep System; and

III - Research Participants Representative: member of the CEP/Conep System, member of the social control, which represents the interests of research participants.

## CHAPTER III

### The profile and performance of the representative of research participants

Art. 4th The RPP must have a history of participation in social and/or community movements.

Single paragraph. The history of participation in the RPP is not limited to the health area, and may encompass all segments of action of social movements.

Art. 5 The RPP must be at least 18 (eighteen) years old.

Art. 6 The RPP must be able to express the points of view and interests of individuals and/or groups of research participants, in order to represent the collective interests of different audiences in the CEP/Conep System.

Art. 7 The role of the RPP includes, but is not limited to:

§1 To attend meetings, training and events organized by the CEP/Conep System;

§2 To promote, in collaboration with the other members of the CEP/Conep System, issues specifics related to the interests and rights of research participants; and

§3 Contribute to the ethical evaluation developed by the CEP, being able to carry out the reporting of research protocols, when so designated by the CEP coordination.

Art. 8 The CEP must explicitly establish in its internal regulations the maximum number of reappointments of its RPP member, as well as the number of justified absences, which must be equal to that of the other CEP members.

Art. 9th The RPP can be a member of, at most, two CEPs simultaneously in the same period.

Art. 10 It is the obligation of the RPP to maintain confidentiality of any and all confidential information obtained in the exercising its activity as a member of the CEP/Conep System.

Art. 11 The term of office of the RPP in the CEP is 3 (three) years, counting from the date of its appointment.

## CHAPTER IV

### Indication of the representative of research participants

Art. 12 The nomination must be formalized in a dated letter, duly signed by the legal representative of the nominating entity and addressed to the CEP coordination.

Single paragraph. When the person indicated is the legal representative of the entity nominee, a copy of the minutes of the meeting at which the decision for the nomination was made must be attached.

Art. 13 The RPP nomination letter sent to the CEP must include:

§1 Description of the nominating entity and the actions carried out by it in the 12 (twelve) months prior to the date of nomination;

§2 Description of the history of social and/or community participation of the indicated RPP;

§3 The means of contact of the indicated RPP.

Art. 14 The indication of the RPP should preferably be carried out by a policy council public in any segment.

§1 When the indication of the RPP is carried out by the Health Council, the nominee must be preferably member of the users segment;

§2 When the nominating entity of the RPP is not the Health Council, the CEP must communicate formally to the corresponding Municipal Health Council of your locality the name and entity of the RPP indicated;

§3 When the appointment is not made by a public policy council, it must be carried out by a collegiate body with action focused on social control.

Art. 15 The CEP is responsible for refusing the indication of the RPP only when it is identified that the indication does not fit the norms established in this or other resolutions and norms of the National Health Council.

Art. 16 In its composition, the CEP must have at least two RPP members.

Single paragraph. For CEP with more than 14 (fourteen) members, the proportionality of 1 (one) RPP member for each (seven) CEP members.

Art. 17 All RPP nominations to a CEP do not need to be carried out by the same nominating entity, and it is up to the CEP to decide whether to request the indication of its RPP to the same entity or to multiple entities.

Art. 18 The CEP must submit the RPP indications received for validation by Conep.

## CHAPTER V

The competences of the research ethics committee and its sponsoring institution in relation to

performance of the representative of research participants

Art. 19 The CEP must provide a Permanent Training Plan for its members, and must include content targeted and accessible to RPPs.

Art. 20 It is the responsibility of the CEP to encourage the role of RPPs, respecting their individual characteristics.

Single paragraph. Encouraging protagonism includes, but is not limited to:

I - Involve and insert the RPP in the regular activities of analysis and ethical debates of the CEP;

II - Ensuring the registration and linking of the RPP profile to the CEP on the Brazil Platform; and

III - Integrate the RPP into the training of members.

Art. 21 Whenever necessary, the RPP must be guaranteed by the institution that maintains the CEP its travel, food and other possible expenses related to the performance of its function as a member of the CEP.

Single paragraph. The guarantee of participation includes, but is not limited to, the following activities:

I - Capacity building and training promoted by the CEP/Conep System;

II - Ordinary meetings of the CEP; and

III - Extraordinary meetings of the CEP.

## CHAPTER VI

The competences of the entity indicating the representative of the research participants

Art. 22 Whenever deemed necessary, the nominating entity can consult the RPP and the CEP to which it was nominated to obtain information related to its performance in the activities of the ethics committee.

Single paragraph. Respecting the caput, the RPP is not allowed to disclose confidential information related to research protocols and ethical deliberations, even if requested by the nominating entity.

Art. 23 It is the prerogative of the nominating entity, during the term of office of the RPP, to carry out the replacement of the individual indicated by her to the CEP.

Art. 24 The nominating entity may withdraw from the nomination made to the CEP before the end of the three-year term of office of the RPP.

## CHAPTER VII

### Of the final provisions

Art. 25 This Resolution establishes, within the scope of Conep, a specific consultative instance focused on the discussion, appreciation and collection of data and information on issues related to the indication and performance of RPP in the CEP/Conep System, as well as for the proposition of training projects and capacity building in the area.

Single paragraph. The instance must be coordinated by an RPP.

Art. 26 In order to support the CEP/Conep System, the Executive Secretariat of Conep must maintain a database containing contact information for the entities that indicated the RPP to the CEPs.

Art. 27 Cases not covered by this Resolution will be resolved by the National Research Ethics Committee of the National Health Council.

Art. 28 CNS Resolution No. 240, of June 5, 1997, and item B.1 "Nomination of user members" of topic "2.2. Operational aspects of the CEP", of CNS Operational Standard No. 001/2013, are hereby revoked.

Art. 29 The research ethics committees that make up the CEP/Conep System must adapt to the changes promoted by this Resolution within a period of up to 12 months, after the date of its publication.

Art. 30 This Resolution will come into effect from the date of its publication.

**FERNANDO ZASSO PIGATTO**

President of the National Health Council

I ratify CNS Resolution No. 647, October 12, 2020, pursuant to the Decree of Delegation of Competence of November 12, 1991.

**MARCELO ANTÔNIO CARTAXO QUEIROGA LOPES**

Minister of State for Health

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