Aviso: Esta é uma versão do documento original destinada a consulta, trata-se de tradução de documento público relacionado à condução de estudos clínicos no Brasil.

Disclaimer: This is a version of the original document intended for consultation, it is a translation of a public document related to the conduction of clinical trials in Brazil.

RESOLUTION No. 674, OF MAY 6TH, 2022.

Provides for research classification and the processing of research protocols in the EC/Conep System.

The President of the National Health Council (CNS), by the regulatory powers and duties granted by the CNS Internal Regulation and ensured by Law No. 8,080, of September 19th, 1990; by Law No. 8,142, of December 28th, 1990; by the Complementary Law No. 141, of January 13th, 2012; by Decree No. 5,839, of July 11th, 2006; complying with the provisions of the Constitution of the Federative Republic of Brazil of 1988 and related Brazilian legislation; and

Considering the affirmation of the Brazilian Unified Health System (SUS) as a model of universal health system established by the Citizen Constitution of 1988, which is the right of all and duty of the State, in its principles and guidelines that guarantee universality, integrality, and equity of access to public health actions and services, including decentralized, hierarchical, regionalized management with community participation;

Considering that the CNS Board is responsible for approving standards on ethics in studies involving human beings and other issues in the field of bioethics and for monitoring their implementation, as provided for in Art. 11, XIV, of the CNS Internal Regulation;

Considering CNS Resolution No. 446, of August 11th, 2011, which provides for the powers of the Brazilian National Committee for Ethics in Research (CONEP/CNS/MS); and

Considering that the President of the National Health Council is responsible for deciding, *ad referendum*, on emergency matters, when it is impossible to consult the Board, submitting his act for resolution by the Board at a subsequent meeting (Art. 13, item VI of the CNS Internal Regulation, approved by CNS Resolution No. 407, of September 12th, 2008).

Decides ad referendum of the Board of the National Health Council

To approve the following guidelines regarding the research classification and the processing of research protocols in the EC/Conep System.

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Chapter I PRELIMINARY PROVISIONS

Art. 1 This Resolution establishes the processing of scientific research protocols involving human beings, in the EC/Conep System, according to the classification of the research and the modulation factors, as defined by this Resolution.

Chapter II TERMS AND DEFINITIONS

Art. 2 For the purposes of this Resolution, the following terms and definitions are adopted:

I - Collection: an organized set of documents, in physical or electronic format, which can serve as a source for collecting information for the constitution of a database for scientific research purposes;

II - Anonymization: use of reasonable technical means available at the time of processing, through which data loses the possibility of association, directly or indirectly, with an individual;

III - Directed data collection: activity with face-to-face interaction or in a virtual environment to generate or collect data that will be analyzed in the research, including interviews, administration of questionnaires and scales, filling out forms, carrying out activities with a focus group, among others;

IV - Accredited Ethics Committee: EC that, in addition to being accredited in the EC/Conep System, is certified by Conep for the analysis of protocols that are processed in the special collegiate board modality;

V - Certified Ethics Committee: EC that meets the operating conditions established in the EC/Conep system guidelines, is registered by Conep and can act as an EC of a proposing, participating or co-participating institution;

VI - Personal data: information relating to an identified or identifiable natural person;

VII - Study design: method adopted to achieve the study objectives;

VIII - Healthcare device: equipment, apparel, material, article or system applicable in the health area that does not use the pharmacological, immunological or metabolic means to perform its main function, and may, however, be assisted in its functions by such means;

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IX - Interview: face-to-face or virtual interaction, individual or in groups, in which data collection and generation are based on a previously prepared script or a triggering question;

 $X\,$ - Drug: chemical substance that is the active ingredient of the medicinal product;

XI - Modulation factors: characteristics of the consent process, confidentiality and/or study methods that may modify the type of protocol processing in the EC/Conep System;

XII - Public access information: data that can be used in the production of study and in the transmission of knowledge and that are available, without restriction to the access of investigators and citizens in general, not subject to limitations related to privacy, security or access control. This information may or may not be processed and contained in any medium, support and format, produced or managed by public or private bodies;

XIII - Public domain information: data, documents or works that are not protected by copyright;

XIV - Aggregated information or data: represent data or information from a group of people or a population and do not allow their detailing at the individual level;

XV - Intervention in the body: study procedure performed on the human body, in its physical dimension, invasive or not;

XVI - Human biological material: specimens, samples and aliquots of original biological material and its fractionated components;

XVII - Medicinal product: pharmaceutical product with prophylactic, diagnostic or therapeutic purposes;

XVIII - Observation: study procedure in which the actions of everyday life are observed by the investigator, with or without interaction with the participant;

XIX - Participant observation: study procedure characteristic of the Humanities and Social Sciences, in which the investigator has direct contact (face-toface or virtual) with the participant, sharing, as far as circumstances permit, the activities, occasions, interests, and affections of a group of people or a community for obtaining information about social reality in its own context;

XX - Genetically modified organism: organism whose genetic material has been modified by any genetic modification technique;

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XXI - Organism that represents a high risk to the community: organism with a high risk of producing harm to human and animal health and that has a high risk of dissemination and of causing adverse effects to the flora, the environment, and the community;

XXII - Consolidated opinion: opinion of ethical assessment of a study protocol, issued after the simplified, collegiate board or special collegiate board processing;

XXIII - Summary opinion: opinion resulting from the submission of a study protocol, evaluated via the express processing in the EC/Conep System;

XXIV - Action study: study in which all stages are planned and carried out with the different agents involved in common agreement;

XV - Market survey: collection of information from the consumer, competitor or supplier to guide decision-making or solve marketing problems;

XVI - Poll: verbal or written consultation of a punctual nature, carried out using a specific methodology, through which the participant is invited to express their preference, evaluation or the meaning they attribute to themes, actions of people and organizations, or to products and services; without the possibility of identifying the participant;

XVII - Research of strategic interest to the SUS: protocols that contribute to public health, justice, reduction of social inequalities and technological dependence, as well as emergencies in public health, forwarded to Conep's assessment by request of the Secretariat of Science, Technology, Innovation, and Strategic Inputs to Health of the Ministry of Health (SCTIE/MS);

XVIII - Covert research: research conducted without the participant being informed about its objectives and procedures, and without obtaining consent before or during the research. Covert research is only justified in circumstances in which information on objectives and procedures would change the target behavior of the research, or when the use of this method is presented as the only way to conduct the research, and the procedure to be adopted by the investigator with the participant must be explained to the EC, with regard to risks, communication to the participant and use of the collected data, in addition to the commitment, or not, to confidentiality. Whenever it proves to be feasible, the participant's consent should be sought afterwards;

XIX - Privacy: right of the research participants to maintain control over their personal choices and information and to protect their private life, their image, and their personal data, as a guarantee that these life choices will not suffer undue invasion, by public control, state or non-state, and by social disapproval, based on the characteristics or the results of the research;

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XXX - Research procedure: process carried out specifically as a result of the study, previously outlined in the study methods based on its epistemological bases, involving the adequate and justified presentation of the techniques and operative instruments that must be used to achieve the defined objectives. The procedure may or may not involve intervention in the human body and may or may not be invasive;

XXXI - Invasive procedure in the physical dimension: study procedure that crosses the natural physical barriers of the human body, with or without discontinuity of them, or enters its cavities through natural orifices;

XXXII - Biological product: corresponds to a biological medicinal product (allergens, antibodies, biologics, blood products, probiotics, and vaccines), an advanced therapy product (cell therapy, gene therapy, and tissue engineering therapy) and the like;

XXXIII - Protagonism: right of the participant to assume an active role in the knowledge production process, not as an informant, nor as an interlocutor of the study, being able to identify himself/herself, if they so wished, and even include their co-authorship, if that is the case;

XXXIV - Registration of consent or assent: document produced in any medium, format or media, such as paper, audio, film, electronic and digital media, that records the granting of informed consent or assent, and the form of registration is chosen based on the individual, social, linguistic, economic, and cultural characteristics of the study participant and due to the methodological approaches applied;

XXXV - Informed consent form: document in which the participant's and/or legal guardian's informed consent is expressed in writing, and must include all the necessary information, in clear and objective language, easy to understand, for the most complete clarification about the study in which they propose to participate;

XXXVI - Assent form: document prepared in accessible language for minors or the legally incapable, through which, after the research participants are duly informed, they will express their consent to participate in the study, without prejudice to the consent of their legal guardians;

XXXVII - Study classification: process by which the type of research is defined, based on the study design and research procedures;

XXXVIII - Ad referendum processing: processing of the protocol, in the EC/Conep System, which does not require a resolution by the collegiate board, but the opinion must be recorded and communicated at the next meeting of the EC and/or Conep;

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XXXIX - Protocol processing: refers to the form and steps by which the study protocol is processed in the EC/Conep System.

Chapter III STUDY DESIGN

Art. 3 Research involving human being can be classified according to the study design, divided into two types, according to their objectives:

I - Studies that aim to describe or understand phenomena that happened or happen in the daily life of the study participant;

II - Studies that aim to verify the effect of an investigational product or technique, deliberately administered to the participant as a result of the research, prospectively, with or without a control group.

Chapter IV RESEARCH PROCEDURE

Art. 4 Research involving human beings can be classified according to their procedure, divided into two types:

I - Studies involving intervention in the human body;

II - Studies not involving intervention in the human body.

Art. 5 The research procedure that involves intervention in the human body may or may not be invasive in the physical dimension.

Chapter V RESEARCH CLASSIFICATION

Art. 6 Research is classified, according to their design and procedure, into three types: A, B, and C, as provided in Annex I of this Resolution.

Art. 7 Type A research aim to describe or understand phenomena that happened or happen in everyday life, with no intervention in the human body. They are divided into the following subtypes:

I - A1: when carried out exclusively from a collection of preexisting data, in physical or electronic media, which are not publicly accessible;

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II - A2: when performed with observation or participant observation;

III - A3: when an interview, administration of questionnaires, focus group or other forms of directed data collection were carried out (face-to-face or not/virtually/electronically/by telephone);

IV - A4: when performed with biological material stored in a biobank or biorepository, or exclusively with cultures of already established human cells.

Art. 8 Type B research aim to describe or understand phenomena that occur in everyday life, with physical intervention in the human body. They are divided into the following subtypes:

I - B1: when none of the research procedures is invasive in the physical dimension;

II - B2: when any of the research procedures is invasive in the physical dimension.

Art. 9 Type C research aim to verify the effect of an investigational product or technique, deliberately administered to the participant as a result of the research, prospectively, with or without a control group. They are divided into the following subtypes:

I - C1: when the object of investigation is not a medicinal product, drug, biological product or healthcare device;

II - C2: when the object of investigation is a medicinal product, drug, biological product or healthcare device.

Chapter VI MODULATION FACTORS

Art. 10 The modulation factors modify the way in which the research protocol is processed, as provided in Annex II of this Resolution. They are defined according to:

I - Characteristics of the consent and confidentiality process:

a) the research provides for the request to waive the participants' consent for the use of their biological material previously stored in a biobank or biorepository;

b) the research provides for the request to waive consent for access to a collection that has personal identifying data of the participant;

c) the confidentiality of the participant's data or that of third parties is not guaranteed by the circumstances of the study;

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d) it is not possible to obtain the Informed Consent Form/Registration or Assent Form;

e) covert research or in which consent will be obtained a posteriori;

f) the research involves situations that may limit the participant's autonomy, generated by hierarchical, authority or dependency relationships;

g) research carried out in communities whose culture recognizes the authority of the leader or the collective over the individual.

II - Characteristics of the research methods:

a) the research provides for irreversible anonymization of the data;

b) research with genetic manipulation of gametes or the use of embryonic stem, pre-embryo, embryo or fetal cells;

c) research involves the interaction of research participants or the community with genetically modified organisms or organisms at collective high risk;

d) research that involves forwarding human biological material abroad;

e) the research aims to: evaluate a drug, medicinal product, biological product, equipment or therapeutic device already registered with Anvisa; carry out a bioequivalence research;

f) research performs food, enteral nutrition, and parenteral nutrition assessment or analysis; personal hygiene products, cosmetics, and perfumes; sensory analysis of food and materials;

g) studies aimed exclusively at evaluating the teaching-learning process;

h) action research or research involving participant protagonism; invitation to participants to analyze the data.

Art. 11 Modulation factors do not change the type of research, but the modality of the protocol's processing.

Art. 12 The characteristics of the research participant in themselves do not constitute a modulation factor.

Chapter VII PROCESSING OF PROTOCOLS

Art. 13 There are four modalities for processing protocols in the EC/Conep System: express, simplified, collegiate board, and special collegiate board.

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§1 The processing foreseen for the types of research protocols are:

a) express processing: types A1 and A2;

b) simplified processing: types A3, A4, and B1;

c) collegiate board processing: types B2 and C1;

d) special collegiate board processing: type C2.

§2 Modulation factors may change this processing, according to Annex II of this Resolution.

§3 At the initiative of the rapporteur or the coordinator of the EC, with justification, the protocol may have its processing modified, according to the type of research and the applicable modulation factors.

Art. 14 The express processing provides for the issuance of a Summary Opinion and, in the other modalities, a Consolidated Opinion.

§1 The opinions are issued to the investigator by the EC coordinator.

§2 The summary and consolidated opinions follow the forms established in Plataforma Brasil.

Art. 15 In the express processing, the ethical analysis is based, above all, on the rapporteur checking the type of research, the modulation factors filled in by the investigator in Plataforma Brasil, and the documents submitted.

§1 The rapporteur must approve the protocol when it meets all of the following conditions:

a) be type A1 or A2 research;

b) there is no modulation factor that changes the processing (Annex II).

c) there are no ethical obstacles.

§2 In the case of approval of the protocol by the rapporteur, the opinion is forwarded to the coordinator for issuance of the Summary Opinion. The analysis by the collegiate board is waived, and the deliberation must be recorded and communicated at the next collegiate board meeting.

§3 If ethical obstacles are identified, the protocol must be processed in the simplified or collegiate board modality, as indicated by the rapporteur.

Art. 16 In the simplified processing, the ethical analysis is based, above all, on the rapporteur checking the type of research, the modulation factors filled in by the investigator in Plataforma Brasil, and the documents submitted.

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§1 The rapporteur, after ethical assessment, must approve the protocol when it meets all of the following conditions:

a) be type A3, A4, and B1 research;

b) there is no modulation factor that changes the processing (Annex II);

c) there are no ethical obstacles.

§2 In the case of approval of the protocol by the rapporteur, the opinion is forwarded to the coordinator for issuance of the Consolidated Opinion. The analysis by the collegiate board is waived, and the deliberation must be recorded and communicated at the next collegiate board meeting.

§3 If there are ethical issues that do not allow the approval provided for in paragraph 1, the assessment of the report of the rapporteur by the collegiate board will be necessary when:

I - Initial opinion is of non-approval;

II - Opinion of pending response is of non-approval;

III- Appeal analysis.

§4 In other situations of pending issue analysis, the *ad referendum* processing is possible. In this case, the decision must be communicated at the next meeting of the collegiate board.

Art. 17 In the collegiate board processing, the ethical analysis is based, above all, on checking the type of research, the modulation factors filled in by the investigator in Plataforma Brasil, the documents submitted, and the assessment of the EC collegiate board.

§1 The rapporteur, after ethical assessment, must approve the protocol when it meets all of the following conditions:

a) be type B2 and C1 research;

b) there is no modulation factor that changes the processing (Annex II);

c) there are no ethical obstacles.

§2 In the case of approval of the project by the rapporteur, the assessment of the opinion must be carried out by the collegiate board before the issuance of the Consolidated Opinion by the coordinator, in cases of:

I - Initial analysis of protocol or amendment, regardless of the opinion;

II - Initial analysis of notification with an opinion of non-approval;

III - Analysis of response with an opinion pending or non-approval;

IV - Appeal analysis.

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§3 In cases of analysis of responses with an opinion of approval, the *ad referendum* processing is possible. In this case, the decision must be communicated at the next meeting of the collegiate board.

Art. 18 In the special collegiate board processing, the ethical analysis is based, above all, on checking the type of research, the modulation factors filled in by the investigator in Plataforma Brasil, the documents submitted, and the assessment by the collegiate board of the accredited EC or Conep.

§1 The rapporteur, after ethical assessment, must approve the protocol when it meets all of the following conditions:

a) be type C2 research;

b) there is no modulation factor that changes the processing (Annex II);

c) there are no ethical obstacles.

§2 In the case of approval of the protocol by the rapporteur, the assessment of the opinion must be carried out by the collegiate board of the accredited EC before the issuance of the Consolidated Opinion by the coordinator, in cases of:

I - Initial analysis of protocol or amendment, regardless of the opinion;

II - Initial analysis of notification with an opinion of non-approval;

III - Analysis of response with an opinion pending or non-approval;

IV - Appeal analysis.

§3 In cases of analysis of responses with an opinion of approval, the *ad referendum* processing is possible. In this case, the decision must be communicated at the next meeting of the collegiate board.

§4 The special collegiate board processing follows the proceeding provided for in Chapter VII of CNS Resolution No. 506, of February 3rd, 2016.

Art. 19 In case of doubts about the classification of the research or the associated modulation factors, the EC coordinator must forward the report of the rapporteur for assessment by the collegiate board.

Art. 20 In the case of a multicenter research, the initial processing takes place at the EC of the coordinating center or accredited EC, when applicable, and is subsequently forwarded for analysis by the ECs of the other centers and/or co-participating institutions, after approval.

Chapter VIII DEADLINES FOR PROCESSING PROTOCOLS

Art. 21 The deadline for document checking is up to seven (7) days.

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Art. 22 The deadline for issuing the opinion, after the documentary check, is up to fifteen (15) days for the express processing; up to twenty-one (21) days for the simplified processing; up to thirty (30) days for the collegiate board processing; and up to forty-five (45) days for the special collegiate board processing.

Sole paragraph. If there is a change in the form of processing, as assessed by the EC, the deadline will start with the new method of processing.

Art. 23 The investigator has a period of up to thirty (30) days, extendable upon justification, to respond to a pending opinion from the EC, on Plataforma Brasil.

Art. 24 The first instance of appeal is the EC in which the research protocol is not approved, with Conep being the next and last instance of appeal in the EC/Conep System.

Sole paragraph. The appeal request period is up to thirty (30) days for each instance.

Art. 25 The submission, by the investigator, of a response to a pending opinion or an appeal to a non-approval opinion restarts the counting of the processing deadlines.

Chapter IX STUDIES EXEMPT FROM REGISTRATION ON PLATAFORMA BRASIL

Art. 26 Studies that fall exclusively into the following situations are exempt from consideration by the EC/Conep System:

I - Poll with unidentifiable participants;

II - Research that uses publicly accessible information, pursuant to Law No. 12,527, of November 18th, 2011;

III - Research that uses information in the public domain;

IV - Census survey carried out by government agencies;

V - Research carried out exclusively with information or data already available in aggregate form, without the possibility of individual identification;

VI - Research carried out exclusively with scientific texts to review the scientific literature;

VII - Research that aims at the theoretical deepening of situations that emerge spontaneously and contingently in professional practice, provided that they do not reveal data that can identify the individual;

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VIII - Activity carried out with the exclusive purpose of education, teaching, extension or training, without the purpose of scientific research, of undergraduate students, technical courses students, or of professionals in specialization.

a) Undergraduate Final Papers, Master's Dissertations, Doctoral Theses, Monographs, and the like do not fall under the preceding item, and in these cases, the research protocol must be submitted to the EC/Conep System;

b) if, during the planning or execution of the education, teaching, extension or training activity, the intention to incorporate the results of these activities into a research project arises, the research protocol must be submitted to the EC/Conep System.

IX - Market surveys;

X - Scientific studies carried out with cells, tissues, organs, and organisms of non-human origin, including their biological products, provided that there is no interaction with research participants or imply the collection or use of human biological material to obtain them;

XI - Activity for describing or analyzing the production or administrative process for the sole purpose of organizational development.

Chapter X FINAL PROVISIONS

Art. 27 Studies considered to be of strategic interest to the SUS will be forwarded to Conep for assessment and will have a special processing within ten (10) days.

Art. 28 In studies in which the Ministry of Health is the proposing institution, Conep will be the EC responsible for the analysis, following the type of research and the type of processing under the terms of this Resolution.

Art. 29 Conep is solely responsible for registering biobank development protocols, and the concept of research typification and modulation factors is not applicable.

Art. 30 In CNS Resolution No. 466, of December 12th, 2012, CNS Resolution No. 506, of February 3rd, 2016, and CNS Resolution No. 510, of April 7th, 2016, where it reads "definition and gradation of risk", it is understood as "research classification"; where it reads "risk levels" or "minimum, low, moderate or high risk", it is understood as "research classification and processing modality", under the terms of this Resolution.

Art. 31 The processing deadlines defined in items 2.2 and 2.3 of CNS Operational Standard No. 001, of September 30th, 2013, are void.

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Art. 32 Research protocols in the thematic areas provided for in item IX.4, sub-items 1 to 8, of CNS Resolution No. 466, of December 12th, 2012, must follow the research classification and processing modality, under the terms of this Resolution.

Sole paragraph. The EC may submit a research protocol with due justification for assessment by Conep, at its discretion.

Art. 33 This Resolution will enter into force upon implementation of adjustments to the Plataforma Brasil for its operation.

FERNANDO ZASSO PIGATTO President of the National Health Council

I ratify CNS Resolution No. 674, of May 6th, 2022, pursuant to Law No. 8,142, of December 28th, 1990.

MARCELO ANTÔNIO CARTAXO QUEIROGA LOPES State Minister of Health

Ministry of Health / National Health Council



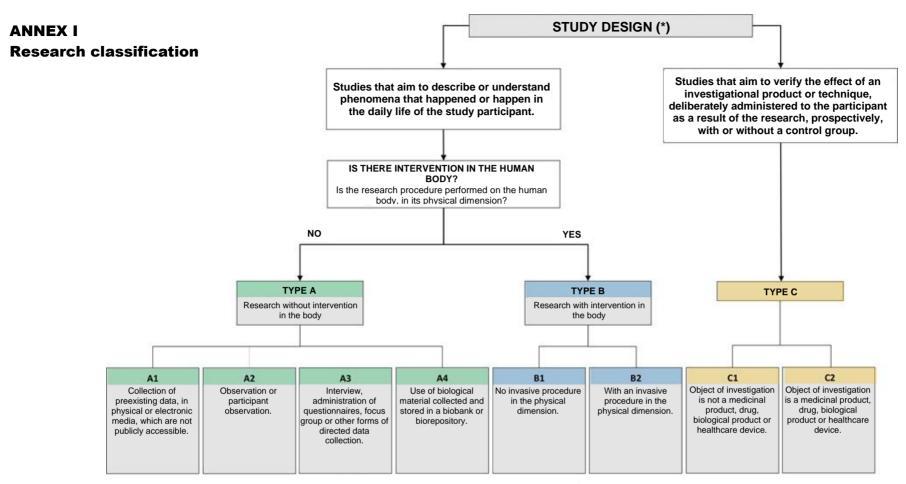
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(*) If the research procedure involves more than one subtype, the more complex processing prevails.



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ANNEX II – Processing of protocols in the EC/Conep System according to classification and modulation factors.

	RESEARCH TYPE								
MODULATION FACTORS	A1	A2	A3	A4	B1	B2	C1	C2	
	Express processing	Express processing	Simplified processing	Simplified processing	Simplified processing	Collegiate board processing	Collegiate board processing	Special collegiate board processing	
I. CHARACTERISTICS OF THE CONSENT AND CONFIDENTIALITY PROCESS									
 a. The research provides for the request to waive the participants' consent for the use of their biological material previously stored in a biobank or biorepository, for research purposes. 				Collegiate Board					
b. The research provides for the request to waive consent for access to a collection that has personal identifying data of the participant.	Collegiate Board	Collegiate Board	Collegiate Board	Collegiate Board	Collegiate Board				
c. The confidentiality of the participant's data or that of third parties is not guaranteed by the circumstances of the research.	Collegiate	Collegiate Board	Collegiate Board	Collegiate Board	Collegiate Board				
d. It is not possible to obtain the Informed Consent Form/Registration or Assent Form.	Collegiate	Collegiate Board	Collegiate Board	Collegiate Board	Collegiate Board				
e. Covert research or in which consent will be obtained <i>a</i> <i>posteriori</i> .		Collegiate Board	Collegiate Board		Collegiate Board				



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 f. The research involves situations that may limit the participant's autonomy, generated by hierarchical, authority or dependency relationships. 		Simplified	Collegiate Board		Collegiate Board			
g. Research carried out in communities whose culture recognizes the authority of the leader or the collective over the individual.	Collegiate	Collegiate Board	Collegiate Board	Collegiate Board	Collegiate Board			
II. CHARACTERISTICS OF THE RE	SEARCH MET	HODS						
 h. The research provides for irreversible anonymization of the data 				Collegiate Board	Collegiate Board			
i. Research with genetic manipulation of gametes or the use of embryonic stem, pre- embryo, embryo or fetal cells.				Special Collegiate Board	Special Collegiate Board	Special Collegiate Board	Special Collegiate Board	
j. Research involves the interaction of research participants with genetically modified organisms or organisms at collective high risk.				Special Collegiate Board	Special Collegiate Board	Special Collegiate Board	Special Collegiate Board	
 k. Research that involves forwarding human biological material abroad. 				Collegiate Board	Collegiate Board			
 The research aims to: evaluate a drug, medicinal product, biological product, equipment or therapeutic device already registered with Anvisa; carry out a bioequivalence research. 								Collegiate Board



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m. Research performs food, enteral nutrition, and parenteral nutrition assessment or analysis; personal hygiene products, cosmetics, and perfumes; sensory analysis of food and materials.					Collegiate Board
 n. Studies aimed exclusively at evaluating the teaching-learning process. 	Express			Simplified	Collegiate Board
o. Action research or research involving: participant protagonism; invitation to participants to analyze the data.	Express				



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