RESOLUTION No. 674, OF MAY 06, 2022.

Provides for the typification of research and the processing of research protocols in the CEP/ Conep System.

The President of the National Health Council (CNS), in the use of his statutory powers and attributions conferred by the CNS Internal Regulations and guaranteed by Law No. 8080, 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; It is

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

Whereas it is incumbent upon the CNS Plenary to approve norms on ethics in research involving human beings and other issues in the field of bioethics and monitor their implementation, as provided for in Art. 11, XIV of the CNS Internal Regulations;

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

Considering that it is the responsibility of the President of the National Health Council to decide, *ad referendum,* on emergency matters, when it is impossible to consult the Plenary, submitting his act to the deliberation of the Plenary in a subsequent meeting (Art. 13, item VI of the Internal Regulations of the CNS, approved by CNS Resolution nº 407, of September 12, 2008).

Resolves *ad referendum* of the Plenary of the National Health Council

Approve the following guidelines regarding the typification of the research and the processing of research protocols in the CEP/Conep System.

Single Section

Chapter I
PRELIMINARY PROVISIONS

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

Chapter II
TERMS AND DEFINITIONS

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

I - Collection: 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 the purpose of scientific research;

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

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

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

V - Accredited Research Ethics Committee: CEP that meets the operating conditions established in the System guidelines
CEP/Conep, has its registration granted by Conep and can act as CEP of proposing, participating or co-participating institution;

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

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

VIII - Device in the health area: equipment, device, material, article or system applicable in the health area that does not use the medium

pharmacological, immunological or metabolic to carry out its main function, being able, however, to be assisted, in its functions, by such means;

IX - Interview: face-to-face or virtual interaction, individual or group, 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 principle of the medicine;

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

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

XIII - Information in the public domain: data, documents or works that are not copyrighted;

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

XV - Intervention in the body: research procedure carried out in the body human, in its physical dimension, which may or may not be invasive;

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

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

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

XIX - Participant observation: research procedure characteristic of the area of Human and Social Sciences, in which the researcher has direct contact (face-to-face or virtual) with the participant, sharing, as circumstances allow, activities, occasions, events interests and affections of a group of people or a community, with the aim of obtaining information about social reality in its own context;

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

XXI - Organism that represents a high risk to the community: organism with a high risk of causing damage 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 - Consubstantiated opinion: ethical assessment opinion of a research protocol, issued after the simplified, collegiate or special collegiate procedure;

XXIII - Summary opinion: opinion resulting from the submission of protocol research, evaluated via express procedure in the CEP/Conep System;

XXIV - Action research: research in which all stages are planned and executed with the different actors involved in common agreement;

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

XVI - Public opinion survey: verbal or written consultation of a specific nature, carried out through specific methodology, through which the participant is invited to express his preference, evaluation or the meaning he attributes to themes, actions of people and organizations, or to products and services; no possibility of identifying the participant;

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

XVIII - Covert research: research conducted without the participant being informed about the objectives and procedures of the study, and without prior consent being obtained or during the research. Covert research is only justified in circumstances in which information about objectives and procedures would change the target behavior of the study, or when the use of this method is the only way to conduct the study, and the procedure to be adopted must be made explicit to the CEP. by the researcher with the participant, with regard to risks, communication to the participant and use of the data collected, in addition to the commitment, or not, with confidentiality. Whenever feasible, the participant's consent should be sought later;

XIX - Privacy: research participant's right to maintain control over their choices and personal information and to safeguard their privacy, their image and their personal data, being a guarantee that these life choices will not suffer undue invasions, by public control,

state or non-state, and by social disapproval, based on the characteristics or results of the research;

XXX - Research procedure: process carried out specifically due to the study, previously outlined in research methods based on their epistemological bases, involving the adequate and justified presentation of the techniques and operative instruments that must be used to reach 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: research 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 medicine (allergens, antibodies, biomedicines, 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 process of knowledge production, not as an informant, nor as a research interlocutor, being able to identify himself, if he so wishes, and even record his co-authorship, if this is the case the case;

XXXIV - Record of consent or assent: document produced in any medium, format or media, such as paper, audio, filming, electronic and digital media, which records the granting of consent or free and informed assent, being the chosen form of record from the individual, social, linguistic, economic and cultural characteristics of the research participant and due to the applied methodological approaches;

XXXV - Free and informed consent form: document in which the free and informed consent of the participant and/or their legal guardian is explained, in writing, and must contain all the necessary information, in clear and objective language, easy to understand, for the most complete explanation about the research in which you intend to participate;

XXXVI - Term of assent: document prepared in accessible language for minors or for the legally incapable, through which, after the research participants are duly clarified, they will explain their consent to participate in the research, without prejudice to the consent of their legal guardians ;

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

XXXVIII - Processing *ad referendum:* processing of the protocol, in the CEP/Conep system, which dispenses with deliberation by the collegiate, and must, in the

However, the opinion must be recorded and communicated at the next CEP and/or Conep meeting;

XXXIX - Processing of protocol: refers to the form and steps by which which the research protocol is processed in the CEP/Conep System.

Chapter III
STUDY DESIGN

Art. 3rd Research involving human beings can be typified according to the design of the study, 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 research participant;

II - Studies that aim to verify the effect of the product or technique under investigation, deliberately applied to the participant due to the research, prospectively, with or without a control group.

Chapter IV
RESEARCH PROCEDURE

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

I - Studies involving intervention in the human body;

II - Studies that do not involve 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.

Capítulo V
RESEARCH TYPIFICATION

Art. 6th Researches are classified, according to the design and procedure of the study, into three types: A, B and C, as provided in Annex I of this Resolution.

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

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

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

III - A3: when conducting an interview, application of questionnaires, focus group or other forms of directed data collection (in person or not in person/ virtual/electronic/telephone);

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

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

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

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

Art. 9° Type C surveys aim to verify the effect of the product or technique under investigation, deliberately applied to the participant as a result of the survey, prospectively, with or without a control group. They are divided into subtypes:

I - C1: when the object of investigation is not a drug, drug, biological product or device in the health area;

II - C2: when the object of investigation is a medicine, drug, biological product or device in the health area.

Chapter VI
MODULATION FACTORS

Art. 10 The modulation factors modify the way 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 foresees the request for waiver of the participant's consent for the use of their biological material previously stored in a biobank or biorepository;

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

c) the confidentiality of the data of the participant or third parties is not ensured by the circumstances of the research;

d) it is not feasible to obtain the Registration/Consent Term Free and Clarified or Term of Assent;

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

f) the research involves situations that can 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 foresees the irreversible anonymization of the data;

b) research with genetic manipulation of gametes or use of cells embryonic stem, pre-embryos, embryos or fetuses;

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

d) research involving the sending of human biological material abroad;

e) the research aims to: evaluate a drug, medicine, biological product, equipment or therapeutic device already registered in the Anvisa; perform a bioequivalence study;

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

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

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

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

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

Chapter VII
THE PROCESSING OF PROTOCOLS

Art. 13 There are four ways of processing protocols in the System CEP/Conep: express, simplified, collegiate and special collegiate.

§1 The procedures provided for the types of research protocols they are:

a) express procedure: types A1 and A2;

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

c) collegiate procedure: types B2 and C1;

d) special collegiate procedure: type C2.

§2° The modulation factors may change this procedure, according to Annex II of this Resolution.

§3 At the initiative of the rapporteur or the coordinator of the CEP, upon justification, the protocol may have its modality of processing modified, consistent with the type of research and with the applicable modulation factors.

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

§1 The opinions are issued to the researcher by the coordinator of the POCKET.

§2 The summary and substantiated opinions follow forms established in the Brazil Platform.

Art. 15 In the express procedure, the ethical analysis is based, above all, on checking, by the rapporteur, the type of research, the modulation factors filled in by the researcher on the Brazil Platform and the documents presented.

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

a) be research type A1 or A2;

b) there is no modulation factor that alters the procedure (Annex II).

c) there are no ethical obstacles.

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

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

Art. 16 In the simplified procedure, the ethical analysis is based, above all, on checking, by the rapporteur, the type of research, the modulation factors filled in by the researcher on the Brazil Platform and the documents presented.

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

a) be research type A3, A4 and B1;

b) there is no modulation factor that alters the procedure (Annex II);

c) there are no ethical obstacles.

§2° In case of approval of the protocol by the rapporteur, the opinion is forwarded to the coordinator for issuing the Consolidated Opinion. Analysis by the collegiate is waived, and the resolution must be recorded and communicated at the next collegiate meeting.

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

I - Initial opinion is of non-approval;

II - Pending response opinion is of non-approval;

III - Resource analysis.

§4° In other situations of pending analysis, the procedure *ad referendum* is possible. In this case, the resolution must be communicated at the next collegiate meeting.

Art. 17 In the collegiate procedure, the ethical analysis is based, above all, on checking the type of research, the modulation factors filled in by the researcher on the Brazil Platform, the documents presented and the appreciation of the CEP collegiate.

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

a) be research type B2 and C1;

b) there is no modulation factor that alters the procedure (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 before the issuance of the Opinion consubstantiated by the coordinator, in the cases of:

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

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

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

IV - Resource analysis.

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

Art. 18 In the special collegiate procedure, the ethical analysis is based, above all, on checking the type of research, the modulation factors filled in by the researcher on the Brazil Platform, the documents presented and the assessment by the accredited CEP or Conep collegiate.

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

a) be research type C2;

b) there is no modulation factor that alters the procedure (Annex II);

c) there are no ethical obstacles.

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

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

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

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

IV - Resource analysis.

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

§4 The special collegiate procedure follows the rite provided for in Chapter VII of CNS Resolution No. 506, of February 3, 2016.

Art. 19 In case of doubts about the typification of the research or the associated modulation factors, the CEP coordinator must forward the rapporteur's opinion for the collegiate's appreciation.

Art. 20 In the case of a multicenter study, the initial procedure takes place in the CEP of the coordinating center or accredited CEP, when applicable, and is subsequently forwarded for analysis by the CEP of the other co-participating centers and/or institutions, after approval.

Chapter VIII
DEADLINES FOR PROCESSING THE PROTOCOLS

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

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

Single paragraph. If there is a change in the procedure, by evaluation of the CEP, the deadline will start with the new procedure.

Art. 23 The researcher has a period of up to 30 (thirty) days, which may be extended upon justification, to respond to a CEP pending opinion, on the Plataforma Brasil.

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

Single paragraph. The deadline for requesting the appeal is up to 30 (thirty) days for each instance.

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

Chapter IX
SURVEYS EXEMPTED FROM REGISTRATION ON THE PLATFORM BRAZIL

Art. 26 The CEP/Conep System does not need to assess the surveys that fall exclusively into the following situations:

I - Public opinion survey with unidentifiable participants;

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

III - Research that uses public domain information;

IV - Census research 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, as long as they do not reveal data that can identify the individual;

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

a) Undergraduate Course Completion Works, Master's Dissertations, Doctoral Theses,
Monographs and the like, in which case the research protocol must be submitted to the CEP/Conep System;

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

IX - Market research;

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

XI - Activity whose purpose is to describe or analyze the productive or administrative process exclusively for organizational development purposes.

Chapter X
FINAL PROVISIONS

Art. 27 Research considered to be of strategic interest to the SUS will be forwarded to Conep for consideration and will undergo a special procedure within 10 (ten) days.

Art. 28 In surveys in which the Ministry of Health is the proposing institution, Conep will be the CEP responsible for the analysis, following the typification of the survey and the procedure under the terms of this Resolution.

Art. 29 The registration of biobank development protocols is the exclusive attribution of Conep, and the concept of research typification and modulation factors is not applicable.

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

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

Art. 32 Research protocols for the thematic areas provided for in item IX.4, subitems 1 to 8 of CNS Resolution No. 466, of December 12, 2012, must follow the typification of the research and the method of processing, under the terms of this Resolution.

Single paragraph. The CEP may forward the research protocol to Conep for consideration, at its discretion, with due justification.

Art. 33 This Resolution will come into effect upon the implementation of adjustments to the Brazil Platform for its operation.

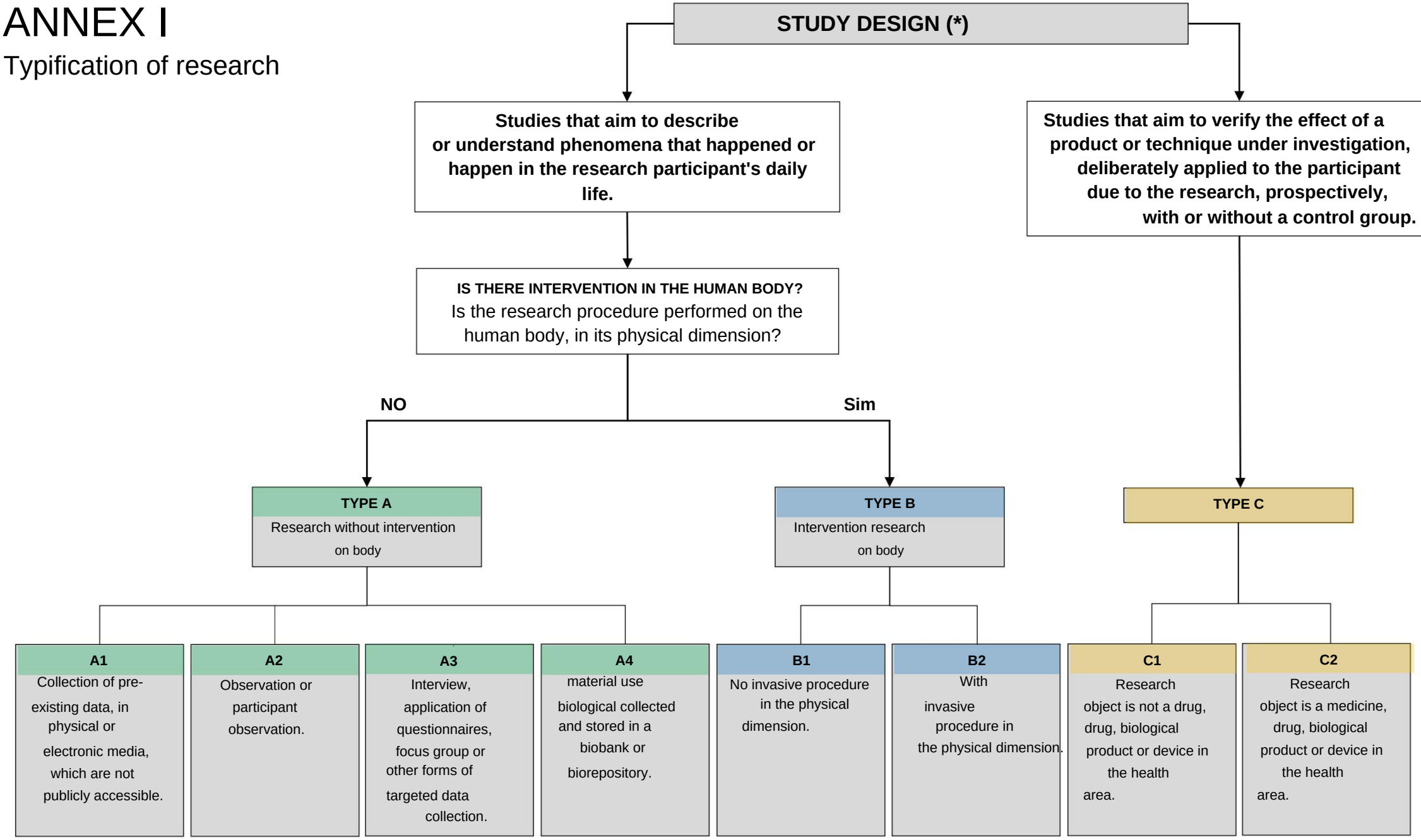
FERNANDO ZASSO PIGATTO
President of the National Health Council

I ratify CNS Resolution No. 674, of May 6, 2022, pursuant to Law No. 8.142, of December 28, 1990.

MARCELO ANTÔNIO CARTAXO QUEIROGA LOPES
Minister of State for Health

ANNEX I

Typification of research



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

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

MODULATION FACTORS	TYPE OF RESEARCH							
	A1	A2	A3	A4	B1	B2	C1	C2
	Procedure expresses	**Procedure expresses**	**simplified procedure**	**simplified procedure**	**simplified procedure**	**collegiate procedure**	**collegiate procedure**	**Special collegiate procedure**
I. CHARACTERISTICS OF THE CONSENT AND CONFIDENTIALITY PROCESS								
The. The research foresees the request for waiver of the participant's consent for the use of their biological material previously stored in a biobank or biorepository, for research purposes. B. The				**Colegiadaÿ**				
research provides for the request for waiver of consent to access a collection that has personal data identifying the participant. w. The confidentiality of participant or third party data is not guaranteed by the circumstances of the research.	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ			
d. There is impracticability of obtaining the Registration/Term of Free Informed Consent or Term of Nod. It is	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ			
It is. Covert research or where consent will be obtained a posteriori.		**Collegiate** ÿ	**Collegiate** ÿ		**Collegiate** ÿ			

f. The research involves situations that can limit the participant's autonomy, generated by hierarchical, authoritarian or dependent relationships.		**Simplified** ÿ **Collegiate** ÿ			**Collegiate** ÿ			
g. Research realized in communities whose culture recognizes the authority of the leader or the collective over the individual.	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ	**Collegiate** ÿ			
II. CHARACTERISTICS OF RESEARCH METHODS								
H. Research provides for the irreversible anonymization of data.				**Collegiate** ÿ	**Collegiate** ÿ			
i. Research with genetic manipulation of gametes; or use of embryonic stem cells, pre-embryos, embryos or fetuses.				**Collegiate Special** ÿ	**Collegiate Special** ÿ	**Collegiate Special** ÿ	**Collegiate Special** ÿ	
j. Research involves the interaction of research participants with genetically modified organisms or collective high-risk organisms.				**Collegiate Special** ÿ	**Collegiate Special** ÿ	**Collegiate Special** ÿ	**Collegiate Special** ÿ	
k. Research involves forwarding human biological material abroad.				**Colegiadaÿ**	**Collegiate** ÿ			
l. The research aims to: drug, evaluate one medicine, biological product, equipment or therapeutic device already registered with Anvisa; perform a bioequivalence study.								**Colegiadaÿ**

m. The research evaluates or analyzes: food, enteral nutrition and parenteral nutrition; personal hygiene products, cosmetics and perfumes; sensory analysis of food and materials.								**Collegiate** ÿ
n. Studies that exclusively aim to evaluate the teaching-learning process.			**Express** ÿ				**Simplified** ÿ	**Collegiate** ÿ
O. Action-research or research that involves: participant protagonism; invitation to participants for data analysis.			**Express ÿ**					