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Approval of the Resolution governing the ethics of research in social sciences, the humanities, and other disciplines that use methodologies characteristic of these areas: challenges and achievements

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Introduction

On April 6 2016, the National Board of Health (CNS) approved the Resolution governing the ethical specificities of research in social sciences and the humanities, as well as in other disciplines that use methodologies characteristic of these areas (SSH Resolution). This is the first Brazilian standard focused specifically on these areas. The text is waiting for approval from the Ministry of Health and publication in the Federal Daily Gazette (DOU).

Herein we present the Working Group in Social Sciences and the Humanities of the National Research Ethics Committee (SSH/CONEP WG), its working processes and the main progress and challenges of the SSH Resolution.

In July 2013, the National Research Ethics Committee (CONEP) organized a working group to draft the minutes of a resolution on the ethical specificities of research in social sciences and the humanities across its full range of diversity, yet keeping a focus on protecting the human rights of study participants. Creating the SSH/CONEP WG was the result of old claims on the part of CONEP members in Social and Human Sciences (SSH), and of researchers and scientific associations. This claim was also recently reiterated by the Forum on Human, Social and Applied Human Sciences. The initial result of this strong demand was recognition, in CNS Resolution 466/12, of the need to draft such a resolution.

The GHS WG was the first CONEP working group whose composition was not limited to members of CONEP. It also includes representatives of researcher associations. CONEP invited representatives of national associations for SSH research and graduate studies to participate, resulting in the following WG composition: 18 representatives of SSH associations, representatives of the National Board of Health (CSN) and of the Ministry of Health Department of Science and Technology (DECIT/SCTIE/MS). Over 30 meetings were held in Brasília, funded by the DECIT/SCTIE/MS. This WG worked between August 2013 and March 2016, using the process described below:

The first *draft,* which the SSH WG delivered to CONEP in October 2014, was discussed at the Extraordinary Meeting of the National Research Ethics Committees (ENCEP) held in November of that same year, organized specifically to receive suggestions made regarding the various drafts, among them one regarding ethics in Social Sciences and the Humanities. This was discussed in three rooms for an entire day, each one holding 100 people. All of the suggestions were registered and combined in a single document. Following an analysis of the ENCEP suggestions, and extensive re-discussion of the draft by the SSH/CONEP, coordinated by CONEP and involving members of the CNS board, the CNS submitted the draft to a public hearing,

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and was available for suggestions between July 21 and September 4 2015.

The SSH/CONEP WG received 394 contributions, 59 of them collective. O these, six were from Research Ethics Committees (RECs). People and institutions in several different disciplines and areas of knowledge were involved in the query. The WG analyzed all of the suggestions made, and accepted many of them. Thus a new version was delivered to CONEP on September 18 2015, and submitted to the 2015 ENCEP. New suggestions and comments were then made and duly incorporated.

On January 28 2016, CONEP forwarded the SSH/CONEP WG draft to the CNS, together with a document presenting its contributions to the draft, asking that the board of directors intervene with the Board of Health to accept the draft. A meeting of the CNS board, representatives of CONEP and the SSH/CONEP WG arrived at a consensus regarding the wording of seven of the nine points suggested by CONEP. Two of them were later discussed and decided by the board of directors. This process for preparing the draft was approved by the National Board of Health.

Advances in the SSH Draft

Important progress was made in National Board of Health acceptance of the claims made by SSH professionals and institutions. The most important of these were:

1. Equitable composition of CONEP and involvement of SSH members in reviewing the protocols for these areas.

Article 33 states that "states that "CONEP membership shall respect the distribution of members and alternates appointed by the RECs in the area of Social Sciences and the Humanities and the other areas included, ensuring balanced representation of the different areas in drafting standards and managing the REC/CONEP System. Equitable composition of CONEP is essential, as this Committee is responsible for drafting the resolutions addressing the ethical aspects of research involving human beings in all areas of knowledge, and for registering and overseeing the RECs. It would be ethically questionable if a committee made up exclusively of members of a single area of knowledge were to draft the rules valid for the entire scientific community. Furthermore, we would highlight Article 26, which states that the ethical review of SSH protocols "can only be done by Research Ethics Committees that have an equitable representation of members from the Social Sciences and the Humanities, with the reporters being selected from among those members qualified in this area of knowledge."

2. Recognition that scientific merit must be assessed by competent areas.

Article 25 states that scientific merit should be assessed by the competent areas in the country, and that the REC/CONEP system is responsible for keeping the focus on protecting study participants, checking if what the researcher proposes to do implies in any risk for study participants. Numerous Brazilian publications discuss inadequate requests made by RECs, especially in regards to qualitative surveys.

3. Discrimination between the process of obtaining and registering consent.

Chapter 3 of the SSH draft talks about the consent process, describing the process of consent as being different from the process of registering consent given. Thus it advances as it expands the means of recording consent, as stated in Article 15. "Registration of Consent and Assent is the means through which participants provide their free and informed consent in written, oral, image or other format that meets the needs of the study and the participants. Informed consent documents must be written in language that is clear and easy to understand, and provide enough data to explain the study."

4. Explanation of studies that do not require analysis by the REC/CONEP system, where the preliminary steps are not assessed.

The first article lists the study projects that do not require analysis by the REC/CONEP system. Among these are systematic reviews that are not included in the definition of research involving human beings, where some institutions mistakenly required approval by the REC/CONEP system. Article 24 states that: "Not all of the preliminary steps required for a researcher to design a project are the target of assessment by the REC/CONEP system." This article is extremely important, as there were concrete situations in which RECs demanded prior approval before a researcher could even walk into a healthcare unit and initiate preliminary contacts to explore certain realities, with a view to developing suitable research strategies and actually go out into the field. This article clearly provides for this possibility, providing researchers with conditions to collect sufficient data to prepare their research project and submit it to the REC/CONEP System for analysis. Article 2.XII defines these preliminary steps.

Ciência & Saúde Coletiva, 21(8):2619-2629, 2016

Implementation challenges

Article 32 is essential to list the various ethical aspects involved in different research traditions, as it states that the ethical review of SSH studies should be governed by a specific resolution. In the course of the work done by the SSH/CONEP WG, members of the legal community stressed that should the SSH resolution be lacking in any point, then Resolution 466/12 would apply. However, resolution 466/12 adopts a positivist conception of science, which has important implications for the quality of the relationship between researcher and participants. Thus, it does not suitably identify the ethical aspects of research that is based on other paradigms. Considering both of these positions, the SSH/CONEP WG checked Resolution 466/12 as part of its undertakings, so as to properly include all of the aspects this resolution deals with and that apply to SSH. The intention is that SSH studies be reviewed by the REC/CONEP system in light of the SSH Resolution, rather than Resolution 466/12. For this reason, Article 32 is worded as follows: The provisions of items VII, VIII, IX and X of CNS Resolution # 466 of December 12 2012 shall apply as applicable and whenever there is no conflict with this Resolution".

However, inclusion of the sole paragraph of Article 32 expands the possibility of applying Resolution 466 to SSH studies where, according to the header, this would be limited to items VII, VIII, IX and X, and even then only if applicable and thin the absence of any conflict with the SSH Resolution. Care must be taken in enforcing this paragraph. If taken in an acritical manner, it would allow an REC to require that the SSH researcher fulfill the requirements of Article III.2.s of Resolution 466/12, which reads: "s) consider that studies involving pregnant women be preceded by studies of women outside the gestational period, except where pregnancy is the essential object of the study". This is clearly nonsensical. This item is important for biomedical studies, which are the focus (albeit not explicitly so) of Resolution 466/12. However, it makes absolutely no sense for an SSH study. For instance, in a study to observe the waiting rooms of healthcare services, why would it need to first address women outside the gestational period before including pregnant women? Unfortunately, the text as approved enables such questions, as the SSH resolution could be considered "lacking" as regards the inclusion of pregnant women in studies. However, it is important to explain that this item was intentionally removed as it does not apply to SSH. Thus, although this is a rather striking example, there are several other situations whose peculiarities may demonstrate the inadequacy of Resolution 466/12 for SSH studies.

It is worth pointing out that the SSH Resolution includes important guidelines for suitable ethics review to be handled by the REC/CONEP System, but it does not change the processing of SSH study protocols. A resolution is right now being drafted that will describe and scale the risks, creating a system in the country for the REC/CONEP system to process protocols in a manner proportional to the risks involved. The commitment made by the working groups and CONEP coordinators is that this resolution will have two chapters, one that will describe and scale research in SSH, and another for research in biomedical sciences.

This is a time of celebration and much hard work. We are now starting to disclose the SSH Resolution and initiating a broad discussion within the REC/CONEP system on how to review SSH protocols. The Resolution must become part of the day-to-day activities of all those involved, helping establish ethical relationships between researchers, study participants and the REC/CONEP system.

Draft resolution on the "Ethical specificities of research in the social sciences and the humanities, and others using the methodology characteristic of these areas"

The Plenary Meeting of the National Board of Health, at its XXXrd Ordinary Meeting held on april 6th and 7th 2016, pursuant to its responsibilities under Law # 8,142 of December 28 1990, and considering:

That ethics is a human, and therefore historical, social and cultural construct;

That research ethics implies in respect for human dignity and suitable protection of participants in scientific studies involving human beings;

That ethical behavior of the researcher requires informed and free action on the part of participants;

That research in Social Sciences and the Humanities demands respect and ensuring the full exercise of participant rights, hence studies should be designed, assessed and conducted in a manner that prevents and avoids potential damage to participants;

That Social Sciences and the Humanities have specificities in the design and undertaking of stu-

dies, to the extent that a pluralistic view of science prevails in such studies, with multiple theoretical-methodological perspectives, and that these studies deal with attributes of meaning, practices and representations of a specific risk and degree of risk, and do not involve direct intervention in the human body;

That the relationship between researcher and participant builds up constantly throughout the study, and can be redefined at any moment in a dialog of subjectivities, implying in reflexivity and the development of non-hierarchical relationships;

The documents that constitute the pillars of recognition, affirmation of dignity, freedom and autonomy, such as the 1948 Universal Declaration of Human Rights, and the 1948 Inter-American Declaration of Human Rights and Duties;

The existence of a Research Ethics Committee system and the National Research Ethics Committee;

That Resolution 466/12, article XIII.3 recognizes the ethical specificities of research in Social Sciences and the Humanities and other areas using methodology characteristic of these areas;

That scientific output should imply in current or potential benefits for human beings, the society to which they belong and society in general, enabling the promotion of dignified quality of life based on respect for civil, social and cultural rights, and an ecologically balanced environment;

The importance of creating a clear and accurate regulatory framework that can be easily understood by all those involved in research in Social Sciences and the Humanities,

Decides:

Article 1 - This Resolution describes the standards that apply to research in Social Sciences and the Humanities, whose methodological procedures involve the use of data obtained directly from participants or personally identifiable data or other data that may involve a greater risk than exists in day-to-day life as defined in this Resolution.

Sole paragraph. The following shall not be registered or assessed by the REC/CONEP system:

I - Public opinion surveys with non-identified respondents;

II - Studies using publicly available information under the terms of Law # 12,527 of November 18 2011;

III - Studies that use information in the public domain;

IV - Census surveys;

V - Studies using databases comprised of aggregate data where it is not possible to identify the individual;

VI - studies comprised exclusively of literature surveys;

VII - studies for further theoretical knowledge in spontaneous and contingency situations of professional practice, so long as they do not reveal any data that might identify the subjects;

VII - activities undertaken exclusively for education, teaching or training in undergraduate, technical or professional specialization courses, and are not intended as scientific research.

Paragraph 1 The previous item does not include End of Course Papers, monographies and the like, in which case a research protocol must be submitted to the REC/CONEP system;

Paragraph 2 If, during the planning or execution of education, teaching or training activities, it becomes the intent to incorporate the outcome of these activities in a research project, a research protocol to that effect must be submitted to the REC/CONEP system.

Chapter I
Terms and definitions

Article 2 For the purposes of this Resolution the following terms and definitions shall be adopted:

I - Free and informed consent: consent by the study participant: child, adolescent or individuals who are temporarily or permanently unable to consent, to the extent of their ability to understand and respecting their uniqueness, after explanations of the nature of the study, its justifications, objectives, methods, and potential risks and benefits. Consent does not eliminate the need for consent by a parent or guardian;

II - Care for the study participant: the care provided to remedy non-material damages that are the direct or indirect result of the study;

III – Benefits: current or potential contributions of the study for human beings, the society to which they belong and society in general, enabling the promotion of dignified quality of life based on respect for civil, social and cultural rights, and an ecologically balanced environment.

IV - Confidentiality: the guarantee that information provided in trust will be safeguarded and protected from unauthorized disclosure.

V - Free and Informed Consent: consent given by the study participant or his/her legal representative free of any simulation, fraud, error

or intimidation, following an explanation of the nature of the study, its justification, objectives, methods, and potential risks and benefits;

VI - Publicly available information: data that can be used for research and knowledge sharing and is freely available to researchers and citizens in general, and not subject to limitations regarding privacy, security or access control. This information may or may not be processed and supported on any media, support for format, produced or managed by government or private entities.

VII - Material damage - any injury affecting the study participant's patrimony as a result of the characteristics of results of the study processes, imposing pecuniary expenses or reducing revenue received or that might have been received;

VIII - Non-material damage: any injury to a right or assent, such as physical and mental integrity, health, honor, image and privacy, illegally caused to the study participant due to characteristics or results of the study process;

IX - Discrimination**:** social characterization or treatment of an individual or group that violates human dignity or human and social rights and the fundamental freedoms of the individual or group;

X - Explanation: a process of clear and understandable explanation of the nature of the study, its justification, objectives, methods, and potential risks and benefits, designed so as to enable understanding of the participants, bearing in mind their individual, social, economic and cultural characteristics, and based on the methodological approach used. All of these elements will determine if consent shall be given in writing, in image format or orally, and whether it will be registered or not;

XI - Stigma: association of negative content with one more characteristics (stigma) of an individual or group, consequently violating human dignity, human rights and the fundamental freedoms of this individual or group;

XII - Preliminary research steps: these are the activities the researcher must undertake to check the feasibility of conducting the study, including document searches, direct contact with potential participants without identifying them and with no public and formal recording of the data thus obtained. These should not be confused with exploratory studies or pilot surveys, which must be considered research projects. Visits to communities and services and conversations with community leaders, among other activities, are considered preliminary steps;

XIII - Survey participant: an individual or group that is not part of the study team, but voluntarily and knowingly participates in the study by issuing consent and, as applicable, assent, as described in this resolution;

XIV - Public opinion surveys: *ad-hoc* written or oral queries using specific methodology, where the participant is invited to share preferences, opinions or feelings associated with themes, the behavior or people or organizations, products or services, where it is impossible to identify the respondent (participant);

XV – Veiled study: a study conducted without informing participants of the goals and procedures, and with no informed consent provided before or during the study. A veiled study is only justified where information about the objectives and procedures would change the study's target behavior, or when this method is the only way to conduct the study, in which the REC must be informed of the procedure used by the researcher when interacting with the participant in terms of risk, communication with the participant and use of the data collected, as well as whether or not confidentiality is ensured. Whenever feasible, participant consent should be secured after the fact;

XVI - Studies in Social Sciences and the Humanities: those that focus on knowledge and understanding the conditions, existence, experience and knowledge of people and groups, their social and institutional relationships, their cultural values, history and politics, their forms of subjectivity and how they communicate, both directly and indirectly, including interventionary studies;

XVII - Researcher in charge: a person with at least a Bachelor's, Licenciate or Technologist degree, who is responsible for coordinating and performing the study and for the integrity and well -being of the participants throughout the process. In the case of undergraduate students doing research for the End of Course Papers (TCC), the study must be registered with the REC, under the responsibility of the TCC advisor;

XVIII - Prejudice: a negative value assigned to an individual or group, with the subsequent violation of their civil, political, economic, social or cultural rights;

XIX - Privacy: study participant right to control his/her choices and personal data and safe-

guard his/her intimacy, image and personal data, ensuring that these life choices will not be unduly invaded by government, state or non-state controlled entities, and that participants shall not be the subject of social rejection based on the study characteristics or outcome;

XX - Informed consent and assent process: a process based on developing a trust-based relationship between researcher and researcher participant that fits their culture and is constantly open to dialog and questioning. Informed consent need not be obtained in writing;

XXI - Research protocol a set of documents, including a cover sheet and the study project, describing its fundamental aspects and providing data on study participants, the qualifications of the researchers and all of the responsible levels. The provisions of the applicable CNS standard or any other that replaces it apply insofar as they do not contradict this Resolution;

XXII - Registration of consent or assent: a document of any format and on any media such as paper, audio, film, electronic or digital media recording the granting of free and informed consent or assent, with the manner of record being selected based on the individual, social, linguistic, economic or cultural characteristics of the study participant, and as a function of the methodology applied;

XXIII - Final report: the end of study report covering all of the results;

XXIV - Reimbursement: material compensation of the expenses resulting from participating in the study. In other words, participant and companion expenses such as transportation and meals;

XXV - Study risk: the possibility of physical, mental, moral, intellectual, social or cultural damage to the human being at any point during the study or resulting therefrom;

XXVI - Vulnerability: a situation in which an individual or group has its ability to make decisions and offer resistance to the study situation is diminished due to individual, psychological, economic, cultural, social or political factors.

Chapter II

On the ethical principals of research in the social sciences and humanities

Article 3 - The ethical principles of research in the Social Sciences and the Humanities are:

I - Recognition of the freedom and autonomy of all those involved in the study process, including scientific and academic freedom;

II - The defense of human rights and the rejection of arbitrariness and authoritarianism in the relationships associated with research processes;

III - Respect for cultural, social, moral and religious values, as well as for the habits and customs of study participants;

IV – Make every effort to expand and consolidate democracy through the socialization of the knowledge resulting from research, including in a format to which the study group or population has access and is able to understand;

V - Reject all forms of discrimination, encouraging respect for diversity, and the participation of individuals and groups who are vulnerable and discriminated against, and the differences in research processes;

VI - Ensure informed consent or assent by the study participants, including an explanation of the meaning and implications of the study;

II – Ensure the confidentiality of participant data and privacy, and protection of their identity, including the use of their image or voice;

VIII - Researcher assurance that the information obtained as a result of the study will not be used to harm participants;

IX - Commitment by all those involved in the study not to create, maintain or expand individual or collective risk or vulnerability situations, and not to increase stigma, prejudice or discrimination;

X - Commitment to provide care and support in the event of material and immaterial damages resulting from participation in the study, as the case may be and as necessary.

Chapter III

The process of free and informed consent or assent

Article 4 The process of free and informed consent or assent involves the development of a trust-based relationship between researcher and participant, one that is continuously open to dialog and questioning. Consent may be obtained or recorded at any stage of the research, and withdrawn at any stage with no prejudice to the participant.

Article 5 Communication of free and informed consent or assent may be oral, written, in sign language or in any other suitable way considering the individual, social, economic and cultural characteristics or the individual or group participating in the study and the methodological approaches used.

Paragraph 1 Communication of free and informed consent or assent must be spontaneous, clear and objective, given in an environment of

Ciência & Saúde Coletiva, 21(8):2619-2629, 2016

mutual trust, avoiding excessively formal approaches to ensure full and interactive communication.

Paragraph 2 In the process of communicating free and informed consent or assent, the participant must be given the opportunity to ask and have all of his/her questions answered, and have enough time to make an independent decision.

Article 6 The researcher will look for the right moment, condition or location to provide explanations on the study, taking into consideration the specificities of the individual invited to participate, to whom the right of refusal shall always be granted.

Article 7 The researcher must provide the time and means for participants to ask questions or voice their concerns during the actual study, avoiding any form of imposition or embarrassment, always respecting the participant's culture.

Article 9 Information about the study must be transparent and communicated in a manner that is easily understandable by the person invited to participate or his/her legal representative, enabling the independent, conscious, free and informed manifestation of their will.

Article 9 The following are participant rights:

I - be informed about the study

II - withdraw consent to participate in the study at any time, with no loss;

III - have their privacy respected;

IV - ensure the confidentiality of personal data;

V - decide if their identity may be disclosed and what information provided may be considered public information;

VI - be compensated for damage or injury resulting from the study, under the terms of the Law;

VII - be reimbursed for direct expenses resulting from his/her participation in the study.

Section I

On obtaining Consent and Assent

Article 10 The researcher must explain to potential participants - to the extent that they are able to understand and respecting their uniqueness -, about the nature of the study, its objectives, methods, rights, risks and potential benefits.

Article 11 Consent by study participants must be specifically ensured by those who, although fully capable, are exposed to specific conditions or subject to a relationship of authority or dependence, which are situations where autonomy may be limited.

Article 12 The protocol to be submitted for approval to the REC/CONEP system must include a justification for the use of children, adolescents and people of diminished capacity.

Sole paragraph. In the cases described in the header, participant assent and free and informed consent must be obtained via the legal representatives of the study participants, preserving participant rights to information and autonomy, according to their capacity.

Article 13. In communities whose culture recognizes the authority of the leader or collective over the individual, such as is the case in some traditional, native Indian or religious communities for example, obtaining authorization for the study should respect these specificities, without prejudice to individual consent, as possible and desirable.

Article 14. When it is impossible to carry out the Free and Informed Consent Process, the waiver of this process must be justified and submitted by the researcher in charge to the REC/CONEP system for analysis and approval.

Section II.

On Registering Assent and Consent

Article 15. Registration of Consent and Assent is the means through which participants provide their free and informed consent in written, oral, image or other format that meets the needs of the study and the participants. Informed consent documents must be written in language that is clear and easy to understand, and include sufficient data to explain the study.

Paragraph 1 When there is no record of consent or assent, the researcher must deliver a document to the participant with all of the information about the study required for providing free and informed consent.

Paragraph 2 Consent may also be proven by a witness that is not part of the study team and who witnessed the manifestation of consent.

Article 16. The researcher must justify the most suitable means of registration, considering in this decision the degree of risk involved, and the characteristics of the study process and the participant.

Paragraph 1 In cases where it is not feasible to record Free and Informed Consent or Assent, or where registration would imply in significant risk to the privacy and confidentiality of participant data or the relationship of trust between researcher and research subject, waiver must be submitted to the REC/CONEP system by the researcher in charge.

Paragraph 2 Waiver of the requirement to register consent or assent does not release the re-

searcher from the process of consent or assent, except in those cases *described in this Resolution.*

Paragraph 3 The waiver of the requirement to Register Consent shall be analyzed and approved by the REC/CONEP system.

Article 17. Registration of the Free and Informed Consent in its different formats must include enough explanations on the research, including:

I - Study justification, objectives and procedures, including information on the methods to be used, all of this in language that is clear and easy for participants to understand, respecting the nature of the research;

II - An explanation of the possible damages resulting from participation in the study, in addition to a list of the measures and precautions to be used to avoid situations that may cause damage to study participants, considering their individual characteristics;

III - Ensure participants are entirely free to decide whether or not to participate, and allowed to withdraw consent at any stage of the research, with no loss;

IV - Ensure that study participant confidentiality and privacy are maintained throughout the study, except where there as otherwise stated explicitly, even after the end of the study, whether the participant is an individual or a group;

V - Information about follow-up and care to which study participants will have a right, including any benefits;

VI - Ensure participants have access to the study results;

VII - Details of participant assurance of reimbursement and a description of how participant expenses resulting from the study will be covered, as applicable; VIII - Contact information - address, e-mail and telephone of those in charge of the study;

IX - A brief explanation of what the REC is, including the local REC address, e-mail and telephone and, if applicable, those for CONEP;

X - Information that the participant will have acess to the records of consent whenever desired

Paragraph 1 In situations where any of the items are not included in the type of registration selected, this information shall be handed over to the participant as a separate document, ensuring that participants are informed of all of the items mentioned above.

Paragraph 2 In cases where free and informed consent or assent is not recorded in writing, participants shall have access to the record of consent or assent whenever he/she asks for it.

Paragraph 3 In cases where free and informed consent or assent is recorded in writing, the participant shall be given a copy signed by the participant and researcher in charge.

Paragraph 4 The record of consent must include assent by the study participant.

Chapter IV
Risks

Article 17. In research projects in the area of Social Sciences and the Humanities, the definition of degree of risk is the result of an analysis of the methodological procedures and potential to cause greater damage to the participant than what the participant would face in his/her daily life, according to the process and nature of the dialog in these studies.

Article 19. The researcher must be aware of the risks the study may pose for participants as a result of the procedures employed at all time, and precautionary and protective measures must be adopted to avoid or mitigate damages caused.

Paragraph 1 Whenever the researcher realizes the possibility that participants may be harmed as a result of participating in the study, he or she shall discuss with participants applicable measures, which could include closing the study and informing the REC/CONEP system.

Paragraph 2 If a study participant suffers any harm or injury resulting from his/her participation in the study, whether or not this is recorded in the Free and Informed Consent, the participant has the right to care and support and to seek reparation.

Article 20. The researcher shall adopt all applicable measures to protect participants who are children, adolescents, have diminished autonomy or are subject to a relationship of authority or dependence that limits their autonomy, recognizing that they are particularly vulnerable, regardless of the study level of risk.

Article 21. The degree of risk established in the protocol shall be rated minimal, low, moderate or high, based on the magnitude of the risk and the characteristics and circumstances of the project, as defined in specific Resolution about risk type and gradation and the processing of research protocols

Paragraph 1 Protocol processing shall differ based on the degree of risk.

Paragraph 2 Degree of risk shall differentiate different levels of precaution and protection of study participants.

Ciência & Saúde Coletiva, 21(8):2619-2629, 2016

Chapter V
Procedures for ethical analysis within the RC/CONEP system

Article 22. The protocol to be submitted for ethics assessment may only be processed if it includes all of the documentation required by the REC/CONEP system, as described in the applicable CNS operating standard, in so far as there is no conflict with this Resolution, bearing in mind the nature and specificities of each study.

Article 23. Research projects shall be recorded in *Plataforma Brasil* for ethical analysis, as established in this Resolution and in specific Resolution on risk type and degree and on the processing of protocols.

Article 24. Not all of the preliminary steps required for a researcher to design a project are the target of assessment by the REC/CONEP system.

Article 25. The analysis to be undertaken by the REC/CONEP system shall apply to the ethical aspects of the studies, considering all risks and suitable protection of study participant rights.

Paragraph 1 The scientific analysis of the theoretical aspects of projects subject to this Resolution is the responsibility of the specific academic instances, such as academic research committees, graduate study examiner boards, and institutions to foster research, among others. The REC/CONEP system is not responsible for analyzing the methodological design of the study.

Paragraph 2 The analysis performed by the REC/CONEP system will apply only to methodological procedures that may imply in participant risk.

Article 26. The ethical analysis of the study projects to which this Resolution refers can only be done by Research Ethics Committees that have an equitable representation of members from the Social Sciences and Humanities area, with the reporters being selected from among those members qualified in this area of knowledge.

Article 27. Studies undertaken by undergraduate and graduate studies that are part of a project undertaken by their advisor and already approved by the REC/CONEP system may be submitted as an amendment to the approved project, so long as there is no essential change in the original project objectives and methodology.

Chapter VI
The researcher in charge

Article 28. Researcher responsibility may not be refused or transferred, and includes both ethical and legal aspects, including:

I - Submit the duly complete protocol to the Resolution system and wait for ethics approval prior to starting the study, as defined in specific resolution for the type and degree of risk;

II - Lead THE PROCESS OF FREE AND INFORMED CONSENT OR ASSENT

III - Present all information required by the REC or CONEP at any time;

IV - Keep all of the study data in a paper or digital file under his/her responsibility for at least 5 years after the end of the study;

V - Submit the final report on the study performed, as defined, justifying any change or interruption, if applicable.

Chapter VII
Transitional provisions

Article 29. A CONEP panel will be created to implement, monitor, and propose updates to this Resolution and the form for registering protocols concerning Social Sciences and the Humanities projects on *Plataforma Brasil*, and to propose training and education projects in this area.

Sole paragraph. The panel to which the header refers will be made up of CONEP members in the Social Sciences and Humanities, representatives of national scientific and Social Sciences and Humanities associations, REC Social Sciences and Humanities members and user representatives.

Article 30. The addition of Social Sciences and Humanities researchers and other professionals to the existing REC collegiates should be encouraged, as well as the creation of new RECs of multi-disciplinary composition.

Article 31. Aspects related to the changes required in *Plataforma Brasil* shall be in effect when the system is updated.

Chapter VIII
Final provisions

Article 32. The provisions of Items VII, VIII, IX and X of Resolution 466 of December 12, 2012 shall apply as long as there is no conflict with this Resolution.

Sole paragraph. In situations not covered by this Resolution, the ethical provisions of Resolution CNS 466 of 2012 shall apply.

Article 33. CONEP membership shall respect the distribution of members and alternates appointed by the RECs in the area of Social Sciences and the Humanities and the other areas included, ensuring balanced representation of the different areas in drafting standards and managing the REC/CONEP System.

Article 34. This Resolution becomes effective on the date it is published.

Ronald Ferreira dos Santos
President of the National Board of Health

Ratify the Resolution CNS 510, of April 7th 2016, under the terms of Decree Competency Delegation of November 12th 1991.

Marcelo Castro
Minister of Health

Ciência & Saúde Coletiva, 21(8):2619-2629, 2016

National Research Ethics - SSH/CONEP WG
Working Group in Social Sciences and Humanities - Composition through March 2016

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Jorge Venâncio- Coordenador da CONEP e Conselheiro do CNS
Gabriela Marodin – Coordenadora adjunta da CONEP

Representatives of the Ministry of Health Department of Science and Technology
(DECIT/SCTIE/MS): Márcia da Luz Mott; Cristiane Alarcão Fulgêncio; Mary Lee dos Santos

Representatives of Scientific and Professional Associations
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Associação Brasileira de Psicologia do Desenvolvimento (ABPD): Jane Farias Chagas Ferreira e Júlia Sursis Nobre Ferro Bucher-Maluschke
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Associação Brasileira de Psicologia Social (ABRAPSO): Simone Maria Hüning
Associação Brasileira de Psicologia Escolar e Educacional (ABRAPEE): Lygia de Sousa Viégas e Flávia Cristina Silveira Lemos
Associação Nacional de História (ANPUH): Neuma Brilhante Rodrigues, Wenceslau Coelho Neto e Benito Schmidt
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Sociedade Brasileira de História da Ciência (SBHC): Márcia Regina Barros da Silva
Associação Brasileira de Estudos Sociais das Ciências e das Tecnologias (ESOCITE.BR): Ivan da Costa Marques
Associação Brasileira de Pós-Graduação em Saúde Coletiva (ABRASCO), GT Bioética: Sérgio Rego e Comissão de Ciências Sociais e Humanas: Maria Lúcia Bosi
Associação Brasileira de Antropologia (ABA), Associação Nacional de Pós-Graduação em Ciências Sociais (ANPOCS) e Fórum de Ciências Humanas e Sociais: Luiz Fernando Dias Duarte
ANPOCS e ABA: Cynthia Sarti
Sociedade Brasileira de Sociologia (SBS): Fernanda Sobral, Carlos Benedito Martins e Emil Albert Sobottka
Conselho Nacional de Pesquisa e Pós-Graduação em Direito (CONPEDI) e Academia Brasileira de Direito Constitucional (ABDConst): Ilton Norberto Robl Filho
Sociedade Brasileira de Bioética (SBB): Aline Albuquerque Sant'Anna de Oliveira
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Consultants
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Sueli Gandolfi Dallari – Universidade de São Paulo - Centro de Estudos e Pesquisas de Direito Sanitário (CEPEDISA) e Núcleo de Pesquisas em Direito Sanitário

ERRATUM

p. 2629

where it reads:
Associação Brasileira de Ensino e Pesquisa em Serviço Social (ABEPSS): Helder Boska M Sarmento e Luciana Maria Cavalcante Melo

reads up:
Associação Brasileira de Ensino e Pesquisa em Serviço Social (ABEPSS): Helder Boska M Sarmento, Luciana Maria Cavalcante Melo e Silvana Mara de Morais dos Santos

where it reads:
Associação Nacional de Pesquisa e Pós-Graduação em Psicologia (ANPEPP): Irme Salete Bonamigo

reads up:
Associação Nacional de Pesquisa e Pós-Graduação em Psicologia (ANPEPP): Selma Leitão Santos

where it reads:
Associação Brasileira de Psicologia Social (ABRAPSO): Simone Maria Hüning

reads up:
Associação Brasileira de Psicologia Social (ABRAPSO): Irme Salete Bonamigo e Simone Maria Hüning