Survey Instrument from "Factors shaping the ethics review of research on humans at the intersection of biomedical and non-biomedical sciences – looking ahead to next challenges".

This is the English version of the original online survey described in the Methods section of the article. The survey instrument was developed and distributed in Portuguese via the Survey Monkey platform to all chairs of Research Ethics Committees (RECs) in Brazil (n=864), 2024.

Plataforma Brasil is the official digital platform of the Brazilian National Health Council for the submission and ethics review of research protocols involving human participants, including both biomedical and non-biomedical studies.

Welcome!

Dear Research Ethics Committee (REC) Chair,

Thank you for taking the time to participate in this study.

Your contribution is extremely valuable and will help expand knowledge on the subject through this research. The estimated time to complete this online survey is approximately 12 minutes.

This research has been approved by the Research Ethics Committee (CAAE 78749724.6.0000.0268).

Please access the free informed consent form at the following link: [*Link to participants to access the free informed consent form in Portuguese, according to the Brazilian national regulatory ethics guidelines for human research*]

After reading the free informed consent, please indicate whether or not you agree to participate by selecting the appropriate option.

Thank you!

***After reading the free informed consent, do you agree to participate?**

( ) Yes
( ) No

Section 1 – In this section, we seek to obtain specific information about the Research Ethics Committee (REC) you coordinate, including the length of your term as Chair and the operational profile of the REC under your coordination.

*2. Are you the chair of a REC that is part of the REC/CONEP [Brazilian National Commission on Research Ethics] system?

( ) Yes
( ) No

*3. How long have you served as REC chair?

( ) Less than one year
( ) Between 1 and 3 years
( ) Between 3 and 5 years
( ) More than 5 years

*4. Have you served as REC chair prior to your current term?

( ) Yes
( ) No

5. If yes, for how long?

( ) Less than one year
( ) Between 1 and 3 years
( ) Between 3 and 5 years
( ) More than 5 years

6. **According to CNS Resolution No. 510/2016, research in the Social Sciences and Humanities (SSH) is defined as research "directed toward understanding the conditions, experiences, and knowledge of individuals and groups in their social and institutional contexts, cultural values, historical and political frameworks, and modes of subjectivity and communication. This includes both direct and indirect methods, as well as research involving intervention and other methodologies typical of SSH." (https://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf)**

Considering this definition, answer the following question:

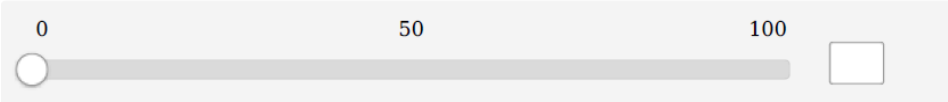
Which area(s) best represent(s) the focus of the REC you chair?

( ) Biomedical
( ) Non-biomedical (including SSH and other areas using SSH methodologies)
( ) Exclusively SSH
( ) Predominantly SSH in Health
( ) Hybrid (both biomedical and non-biomedical, including SSH and SSH in Health)
( ) I don't know

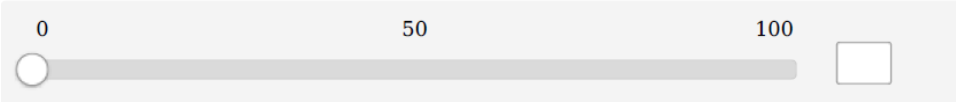
[Optional comment box]

Considering the composition of the REC you chair, please estimate:
If you do not know, please skip the question(s).

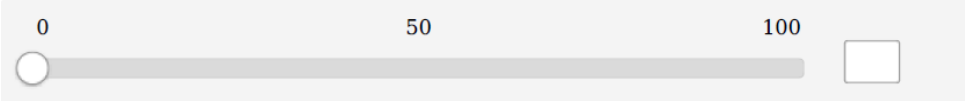
7. Estimated percentage of REC members **with degrees (bachelor's and/or licentiate) in SSH fields** (based on CAPES classification, https://www.gov.br/capes/ptbr/acesso-a-informacao/acoes-e-programas/avaliacao/sobre-a-avaliacao/areas-avaliacao/sobreas-areas-de-avaliacao/colegio-de-ciencias-da-vida).



8. Estimated percentage of REC members **with degrees (bachelor's and/or licentiate) in the biosciences** (based on CAPES classification, https://www.gov.br/capes/ptbr/acesso-a-informacao/acoes-e-programas/avaliacao/sobre-a-avaliacao/areas-avaliacao/sobreas-areas-de-avaliacao/colegio-de-ciencias-da-vida).

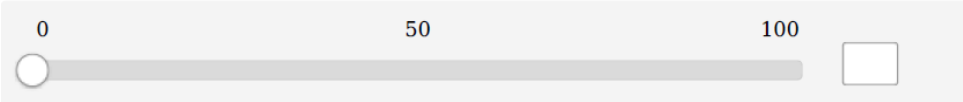


9. Estimated percentage of members **without degrees in SSH but with research experience using SSH methodologies** (e.g., authorship, co-authorship, and/or supervision in undergraduate, graduate projects and/or publications).



Section 2 – In this section, we are interested in identifying the estimated percentage of protocols approved by the RECs surveyed, considering different conditions. Please estimate:

10. The percentage of protocols reviewed in the last 12 months under CNS Resolution 510/2016:



11. Could you estimate the proportion of **non-biomedical (nonbiomed, including SSH and SSH in Health)** protocols relative to **biomedical (biomed)** protocols reviewed by your REC in the last 12 months?

( ) 1 nonbiomed for every 10 biomed
( ) 2 nonbiomed for every 10 biomed
( ) 3 nonbiomed for every 10 biomed
( ) 4 nonbiomed for every 10 biomed
( ) 5 nonbiomed for every 10 biomed
( ) More than 5 nonbiomed for every 10 biomed
( ) Only nonbiomed protocols are reviewed
( ) Only biomed protocols are reviewed
( ) I don't know

[Optional comment box]

Section 3 – In this section, we aim to understand the practices related to the ethics review of research protocols from non-biomedical fields by RECs.

Based on your experience at the REC you chair, indicate the frequency and/or degree of agreement, depending on the type of question, with the following statements. Please use the comments section for your observations if you wish:

12. For the ethics review of non-biomedical protocols (including SSH and SSH in Health), CNS Resolution 510/2016 is applied.

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

13. CNS Resolution 466/2012 is sufficient for reviewing both biomedical and non-biomedical protocols (including SSH and SSH in Health).

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

14. CNS Resolution 510/2016 meets the needs of ethics review for non-biomedical protocols (including SSH and SSH in Health).

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

15. CNS Resolution 466/2012 should only be used for **ethics review** of non-biomedical protocols when Resolution 510/2016 does not apply.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

16. CNS Resolution 466/2012 **should complement** the ethics review of non-biomedical protocols (including SSH and SSH in Health):

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

17. CNS Resolution 466/2012 **should not be applied** in the ethics review of non-biomedical protocols (including SSH and SSH in Health).

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

18. **In the REC under my coordination**, the ethics review of non-biomedical protocols (including SSH and SSH in Health) is **primarily** based on CNS Resolution 510/2016.

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

Section 4 –In this section, we would like to hear your perspective on more specific issues related to RECs.

19. RECs should have a multidisciplinary composition enabling the review of both biomedical and non-biomedical protocols (including SSH and SSH in Health).

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

20. When answering the previous question, your concept of multidisciplinary in the case of REC members refers to:

( ) Undergraduate education
( ) Graduate education
( ) Either undergraduate or graduate education
( ) Both undergraduate and graduate education
( ) Research experience (e.g., as authors, coauthors, or supervisors)

[Optional comment box]

21. Creating RECs exclusively dedicated to SSH research is a **step forward** for Brazil's research ethics oversight system.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

22. The creation of RECs exclusively dedicated to SSH research **should be encouraged** in Brazil.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

23. RECs not exclusively dedicated to SSH, that is, with multidisciplinary membership (from both biomedical and non-biomedical areas), are the ideal model for ethics review of **any type** of human research.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

24. The risks to research participants **associated with studies in non-biomedical fields, specifically, with methodologies typical of the Social Sciences and Humanities**, are, in general, lower compared to the risks involved in studies in biomedical fields.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree

( ) Disagree

[Optional comment box]

Considering the diversity of areas of training of members in many RECs in Brazil, give your opinion on the following two assertions:

25. Multidisciplinary RECs - with members from both biomedical and non-biomedical areas (including SSH and SSH in Health) - enhance the quality of ethics review of human research protocols.

[Open question]:

26. "§1. The scientific evaluation of the theoretical aspects of protocols submitted under this Resolution falls under the responsibility of specific academic bodies, such as academic research committees, graduate thesis committees, and research funding institutions. It is not the role of the REC/CONEP System to analyze the methodological design itself." (https://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf)

[Open question]:

Section 5 – In this section, we would like to understand how the REC you coordinate and you, the Chair, perceive and/or grade risk and exemption from ethics review.

27. According to CIRCULAR NOTICE No. 12/2023/CONEP/SECNS/DGIP/SE/MS, dated July 27, 2023, "[c]onsidering the provisions of CNS Resolution No. 510 of April 7, 2016, Circular Letter No. 17 of 2022, and Article 26 of CNS Resolution No. 674/2022, surveys that fall exclusively into the following situations are exempt from ethics review by the REC/CONEP System: I - Public opinion surveys with non-identifiable participants; According to Circular Letter No. 17/2022/CONEP/SECNS/MS, dated July 2022."
[The following questions refer only to item I of the list in the cited document. https://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/SEI_MS_0035011614_Oficio_Circular.pdf].

Therefore, conducting printed or online surveys with non-identifiable participants are exempt from ethics review by the REC/CONEP System.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

28. This exemption "I – non-identifiable public opinion research", as referred to in the document, is a source of doubt for REC members.

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

29. This exemption "I – non-identifiable public opinion research" as referred to in the document, is a source of doubt for researchers who use the REC under my coordination.

( ) Always
( ) Almost always
( ) Sometimes
( ) Rarely
( ) Never

[Optional comment box]

30. Protocols qualifying as "I – non-identifiable public opinion research" should still be submitted via Plataforma Brasil to receive formal exemption.

( ) Agree
( ) Partially agree
( ) I don't know
( ) Partially disagree
( ) Disagree

[Optional comment box]

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31. **In this section, you can add final comments on any aspects already answered or not addressed in this instrument, but that you feel are relevant to mention.**

[Open question]: