

Factors shaping the responsible conduct of research on humans at the intersection of biomedical and non-biomedical sciences in Brazil

Doctoral Forum



UFRJ
UNIVERSIDADE FEDERAL
DO RIO DE JANEIRO

LECCS
Laboratório de Ética em Pesquisa,
Comunicação Científica e Sociedade

IBqM
Instituto de Bioquímica Médica Leopoldo de Meis

CAPES

Karina de Albuquerque Rocha

**Science Education Program - Institute of Medical
Biochemistry Leopoldo de Meis (IBqM)/Federal
University of Rio de Janeiro (UFRJ)/Brazil**

**Supervisor: Professor Sonia Vasconcelos
IBqM/UFRJ/Brazil**

“Brazil is a scientific superpower”

- “After 200 years of Independence, Brazil became a scientific superpower responsible for 51.08% of scientific production in Latin America (SJR SCImago Journal & Country Rank) and a reference in several areas of knowledge, such as agriculture and tropical medicine. A measure of our innovation is the number of patents granted, which jumped from 3,623 in 2010 to 21,298 in 2020 (INPI). We also increased the amount of scientific articles published by SCOPUS from 48.5k in 2010 to 89.2k in 2020.”

<https://www.gov.br/en/government-of-brazil/latest-news/brazil-is-a-scientific-superpower>

Version 1. [F1000Res.](https://doi.org/10.12688/f1000research.134574.1) 2023; 12: 1239.

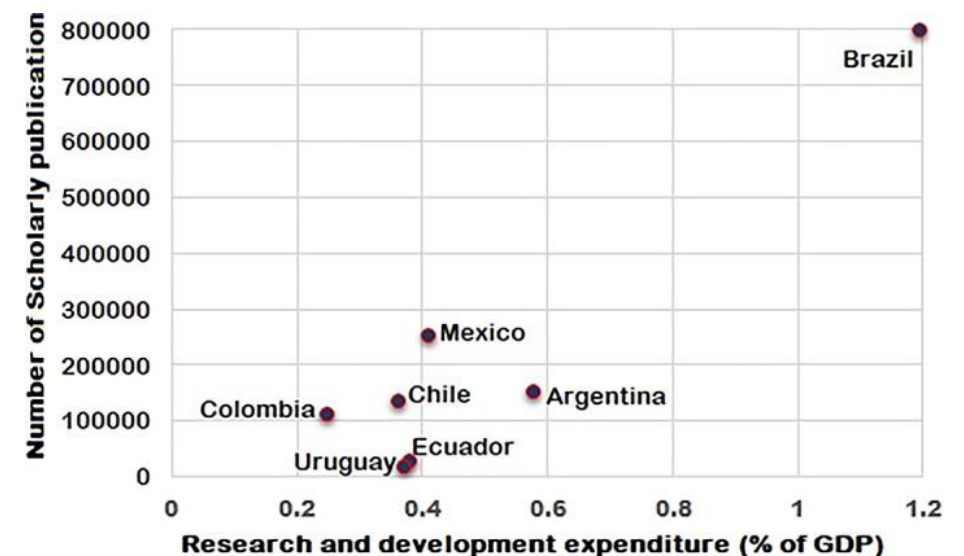
PMCID: PMC10696296

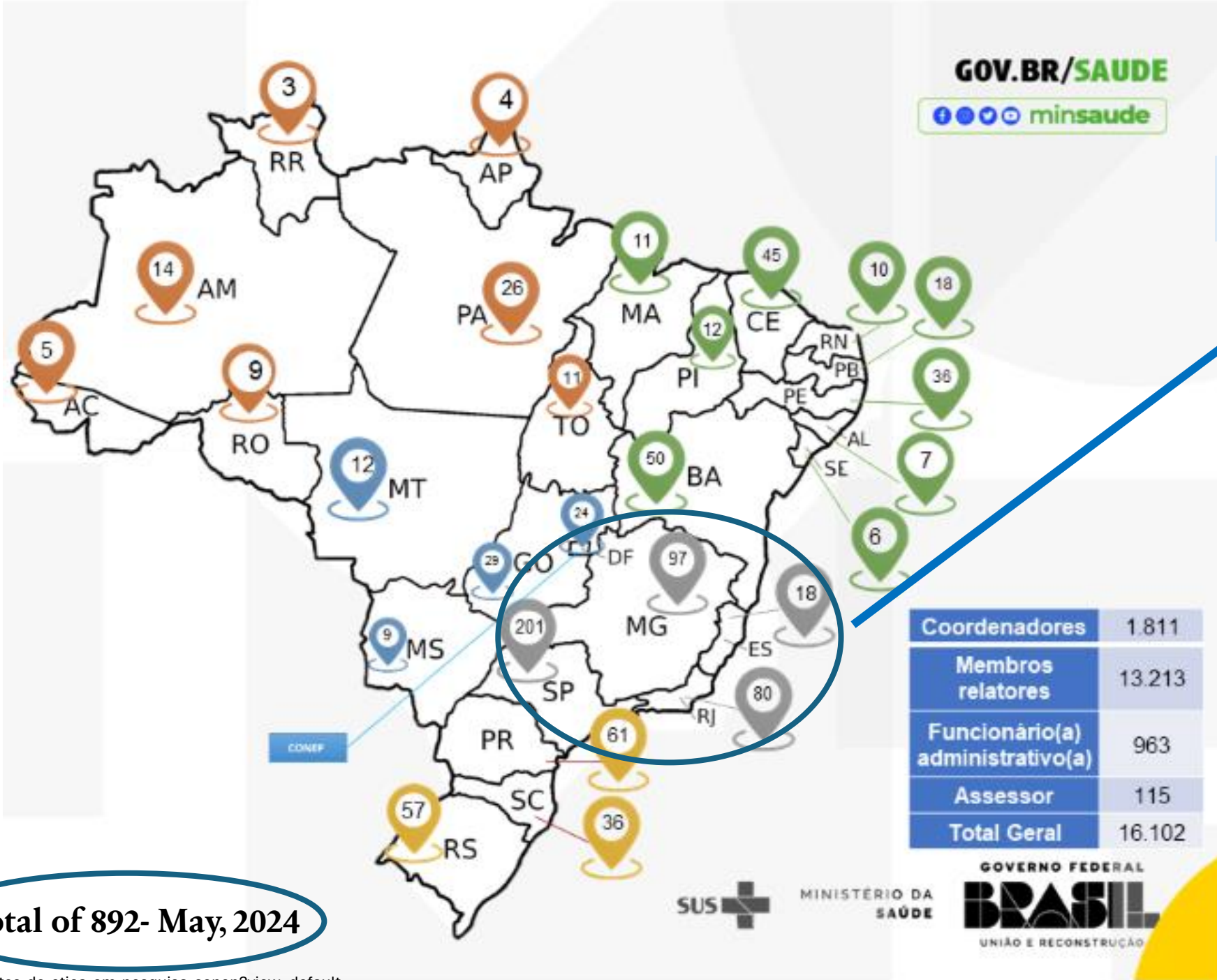
Published online 2023 Sep 28. doi: [10.12688/f1000research.134574.1](https://doi.org/10.12688/f1000research.134574.1)

PMID: [38059135](https://pubmed.ncbi.nlm.nih.gov/38059135/)

A bibliometric analysis of publication output in selected South American countries

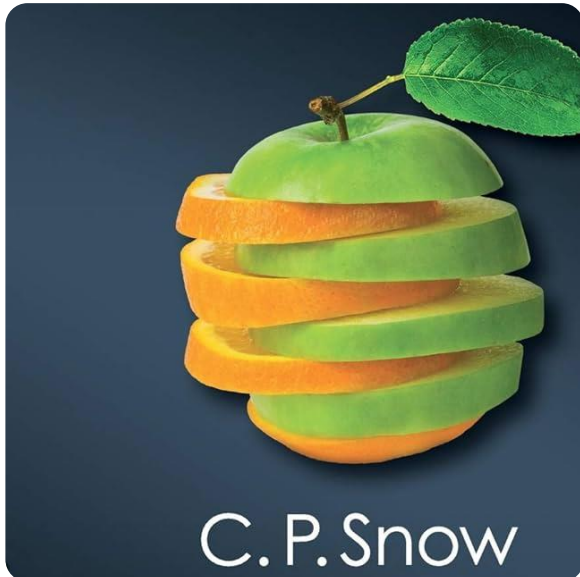
[Aparna Narayan](#), Conceptualization, Data Curation, Formal Analysis, Methodology, Visualization, Writing – Original Draft Preparation,¹ [Bharti Chogtu](#), Data Curation, Formal Analysis, Methodology, Validation, Writing – Original Draft Preparation,² [Manthan Janodia](#), Formal Analysis, Methodology, Resources, Validation, Writing – Review & Editing,³ [Raghu Radhakrishnan](#), Methodology, Resources, Validation, Writing – Review & Editing,¹ and [Santhosh K. Venkata](#), Conceptualization, Data Curation, Formal Analysis, Writing – Original Draft Preparation^{1a,4}





Main research hub in Brazil

Total of 892- May, 2024



<https://www.amazon.com.br/Two-Cultures-C-P-Snow/dp/1107606144>




Notwithstanding the conflicts underlying the ethics review of human-subject research in biomedical and non-biomedical sciences (Mainardes, 2014; Duarte, 2017; Alves & Teixeira, 2020), these two cultures somewhat mingle in the CEP/CONEP System.



Despite the lack of mutual understanding over the ethics of human-subject research in biomedical and non-biomedical fields, discussions on criteria for ethics review of HSS research protocols have put research ethics in the spotlight in Brazil.



 **BMC** Part of Springer Nature

PT.22

Are notions of the responsible conduct of research associated with compliance with requirements for research on humans in different disciplinary traditions in Brazil?

Karina de Albuquerque Rocha, Sonia Maria Ramos de Vasconcelos
Universidade Federal do Rio de Janeiro (UFRJ), Rio de Janeiro, Brazil

Correspondence: Karina de Albuquerque Rocha
(karinagmm@gmail.com) - Universidade Federal do Rio de Janeiro
(UFRJ), Rio de Janeiro, Brazil

Research Integrity and Peer Review 2016, **1(Suppl 1):PT.22**

<https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0012-9>



As part of a scientific initiation project, I participated as an undergraduate student at UFRJ; we asked whether "notions of the responsible conduct of research [RCR] would be associated with compliance with requirements for research on humans in different disciplinary traditions in Brazil."



At that time, we reasoned that biomedical and non-biomedical sciences would conceive RCR on humans differently, when Brazilian academia experienced higher exposure to this topic. The study evolved into a broader investigation of how the changing landscape would reflect in the ethics regulatory framework for-non biomedical research.

Compliance with National Ethics Requirements for Human-Subject Research in Non-biomedical Sciences in Brazil: A Changing Culture?

Original Paper | Published: 06 February 2018
Volume 25, pages 693–705, (2019) [Cite this article](#)



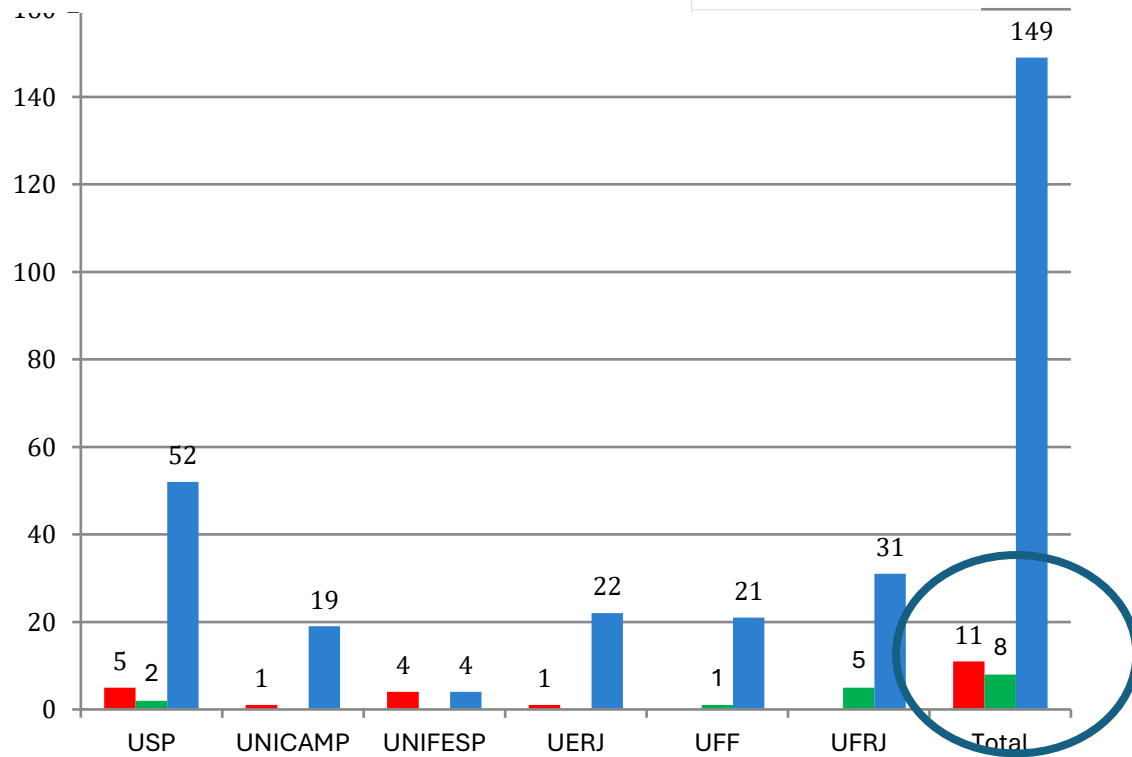
Science and Engineering Ethics

[Aims and scope](#) →

[Submit manuscript](#) →

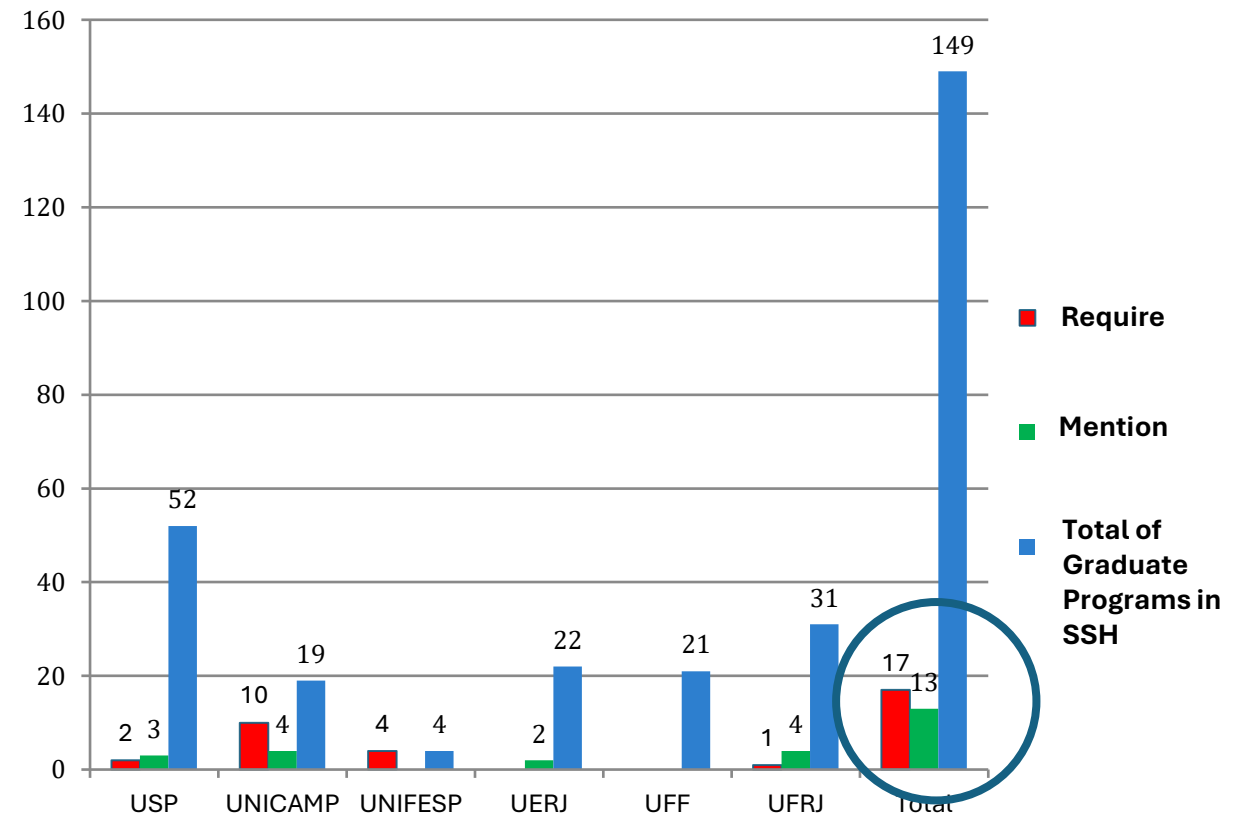
Karina de Albuquerque Rocha & Sonia M. R. Vasconcelos

[Access this article](#)



2014-2015 (adapted from ROCHA & VASCONCELOS, 2019)

Documentary (manual) analysis of more than 3,000 documents from graduate programs in highly-ranked Brazilian public universities




2018-2020 (Masters)

Perceptions of Social Sciences and Humanities Graduate Program Coordinators

PE Práxis
Educativa

ISSN 1809-4031
eISSN 1809-4309

 <https://doi.org/10.5212/PraxEduc.v.18.21955.073>

Thematic Section:

Research Ethics and Academic Integrity in Humanities and Social Sciences: Updating the debate

Seção temática:


Ética em Pesquisa e Integridade Acadêmica em Ciências Humanas e Sociais: Atualizando o debate

Ethics review of research on humans in the biomedical and non-biomedical sciences: bridging "two cultures" in Brazil?*


Revisión ética de la investigación con seres humanos en ciencias biomédicas y no biomédicas: ¿reduciendo la distancia entre "dos culturas" en Brasil?

Revisão ética da pesquisa com seres humanos nas ciências biomédicas e não biomédicas: reduzindo o distanciamento entre "duas culturas" no Brasil?

Karina de Albuquerque Rocha**

 <https://orcid.org/0000-0001-8165-7888>

Sonia M. R. Vasconcelos***

 <https://orcid.org/0000-0001-6315-6510>

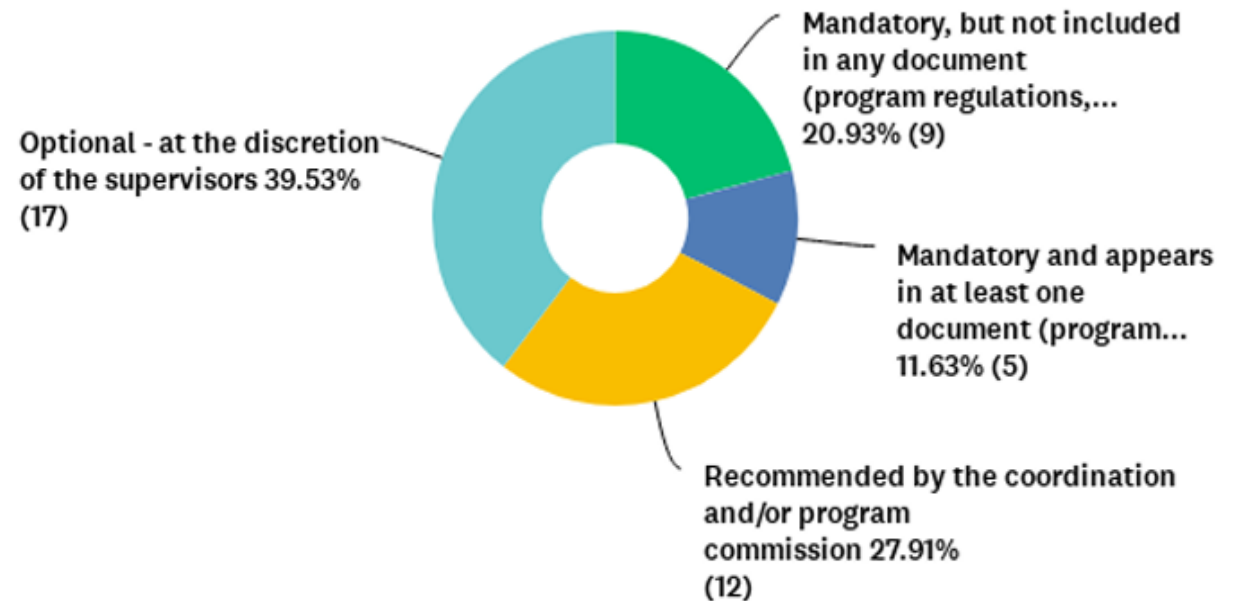


Figure 3 – Distribution of 43 graduate programs in humanities and social sciences represented by participants who responded to question P8 (n= 43), on the kind of normative guidance (if any) or recommendation they had for submission of research projects involving humans to the CEP/CONEP System.

Práxis Educativa, Ponta Grossa, v. 18, e21955, p. 1-15, 2023
Disponível em: <<https://revistas2.uepg.br/index.php/praxiseducativa>>

Doctoral Project

- The ongoing doctoral project builds upon the knowledge gained during my master's, revealing an exciting setting to investigate whether reluctance and even hostility towards the ethics review of research among the non-biomedical community would be counterbalanced by a willingness to address the issue. **We look at various dimensions of this phenomenon, especially institutional policies at the intersection of biomedical and non-biomedical fields – the latter including anthropologists, linguists, political scientists, engineers, and architects.**
- The project has **a mixed-methods design, with descriptive and explanatory approaches to the problem investigated.**

Research Cultures

Ongoing disputes and dialogues at the intersection of biomedical and non-biomedical sciences

The bedrock of
Brazilian science

The bedrock of
the ethics regulation of research
on humans in Brazil



**Responsible conduct
of research on humans**

Graduate Programs

**Research ethics
committees**

Survey Instrument

A survey instrument was designed as a follow-up of a previous study that looked at a changing landscape in Brazil that was shaping and being shaped by different attitudes toward the responsible conduct of research on humans. **It took about one year to design and validate it with an expert panel, and it was being conceived while hot debates and actions in non biomedical forums were evolving (with refinements along the way) in the country.**

The survey was launched and is now ongoing, after final approval by the REC - National Commission of Research Ethics System – 100 respondents (as of May 30, 2024)

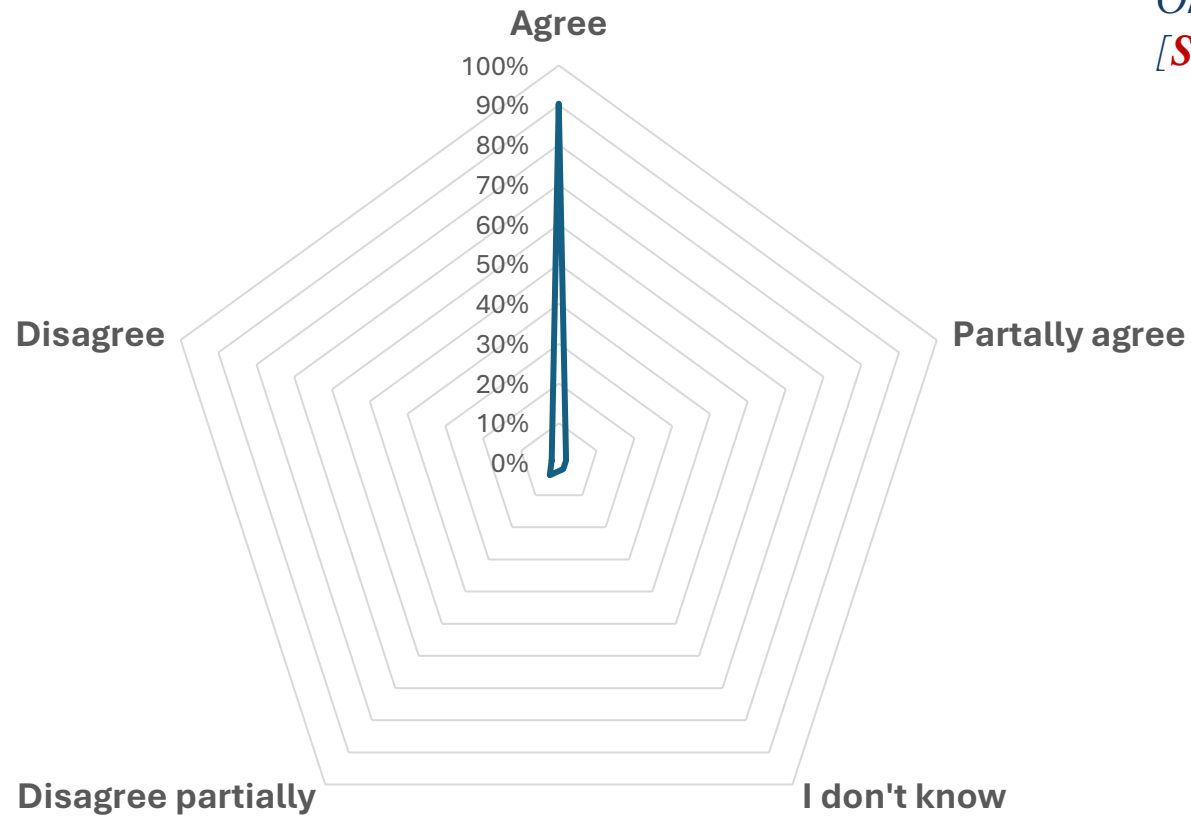


Figure 1 - Distribution of responses across different levels of agreement for the assertion that **RECs should have a multidisciplinary composition of members that allows both biomedical and non-biomedical protocols** (including those with SSH* methodologies/approaches embedded in the health sciences) to be evaluated by the ethics review committee (n=52).

*Social sciences and humanities

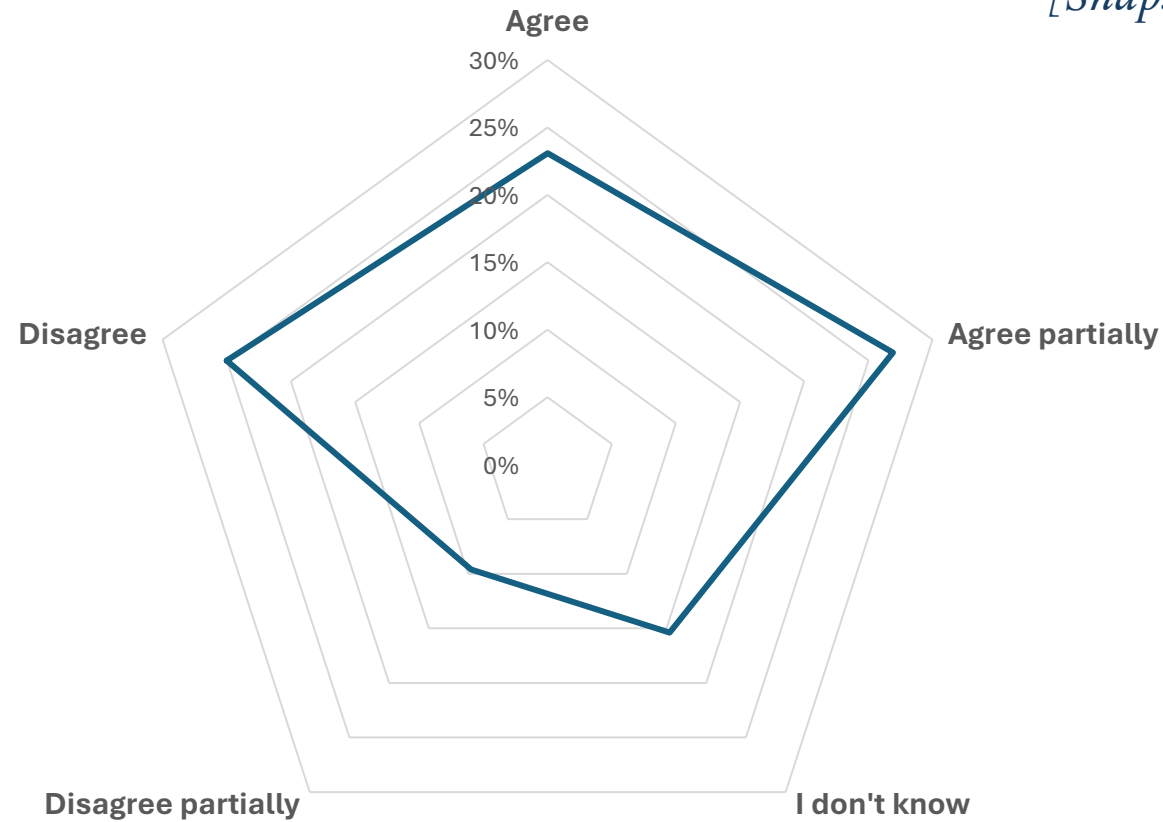


Figure 2 - Distribution of responses across different levels of agreement for the assertion that the creation of RECs **exclusively dedicated to SSH research is an advance** for the system of ethical regulation of research involving humans in Brazil (n=51).

*Social sciences and humanities

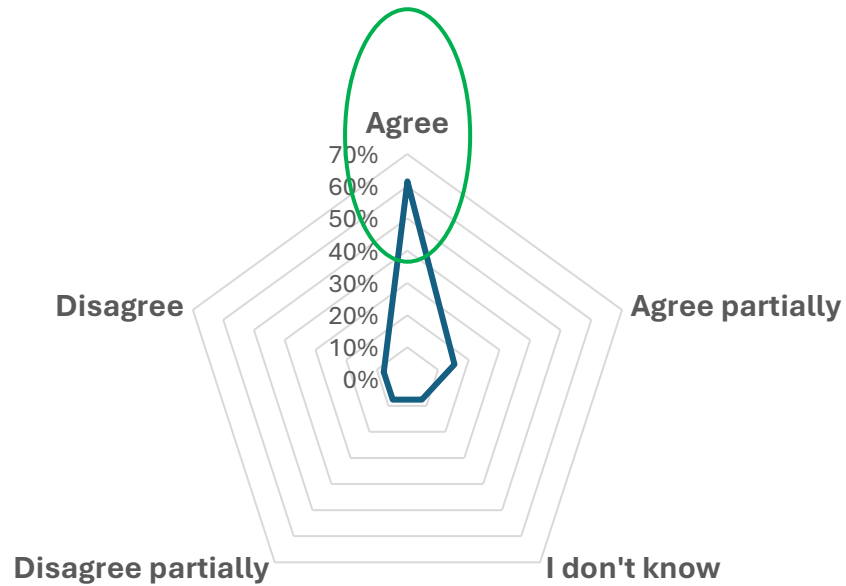
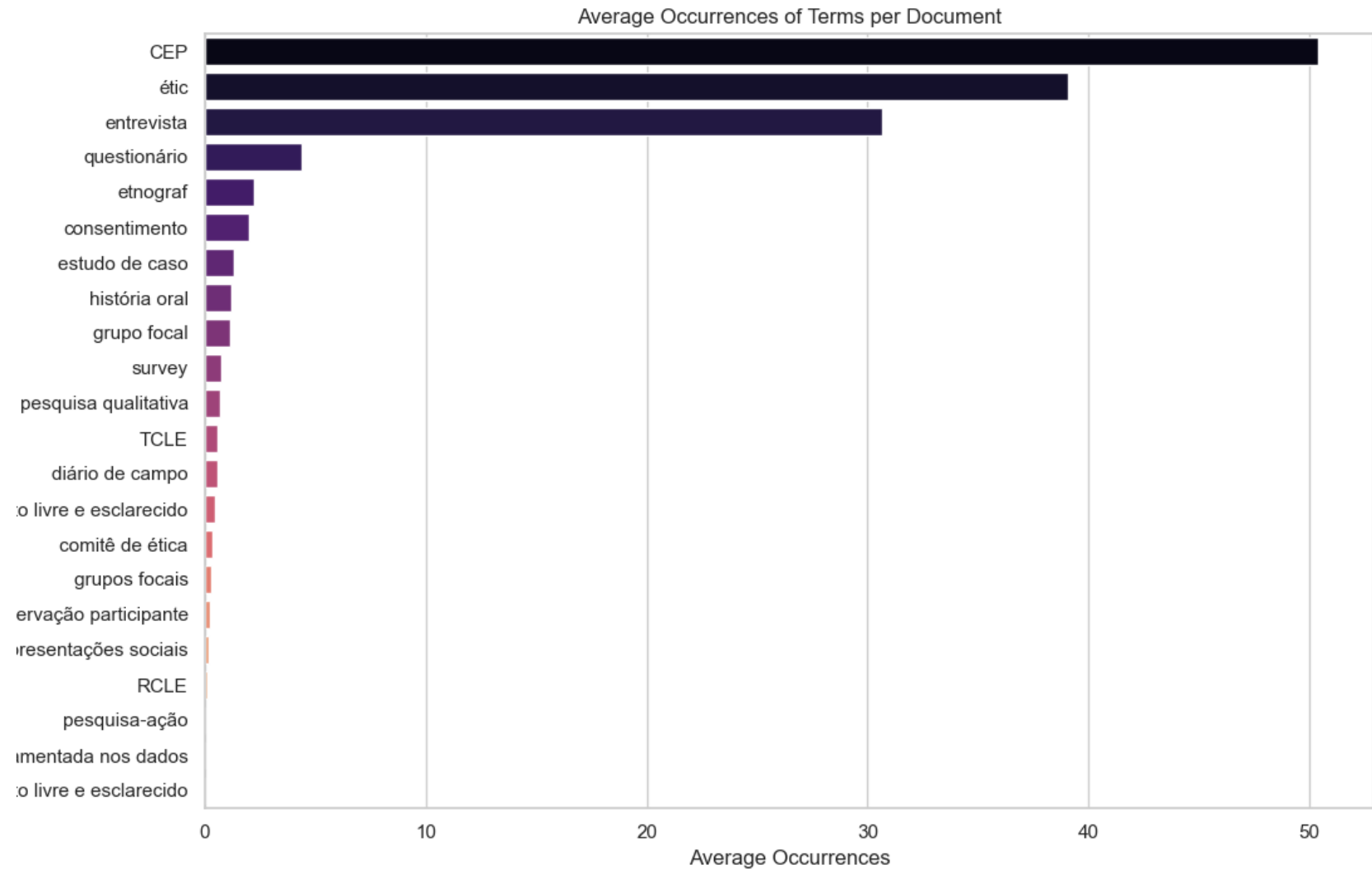
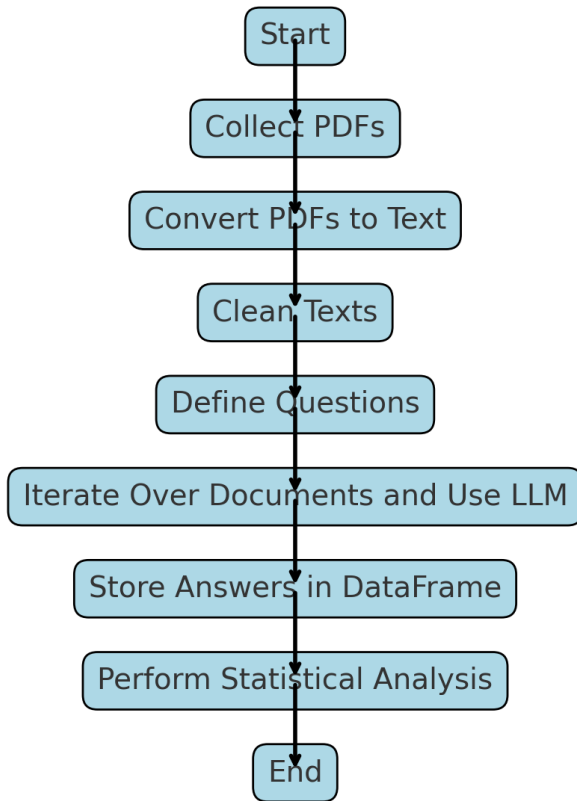


Figure 3 - Distribution of responses across different levels of agreement for the assertion that **RECs not exclusively dedicated to SSH* research, i.e., with multidisciplinary membership** (both from biomedical and non-biomedical areas) are the ideal model of ethical appreciation for any research involving humans. (n=52).

*Social sciences and humanities

“Yes, multidisciplinary RECs, whose members include both biomedical and non-biomedical areas, have the potential to significantly increase the quality of ethical assessment of human research protocols, through diversity of perspectives, more comprehensive understanding of risks and holistic assessment”

This is a perception that resonates with most of the 51 comments on this question up to May 28, 2024.



Pilot Study as the basis (departing from 400 documents) for a statistically valid sample of theses and dissertations available from about 1,500 graduate programs in non - biomedical sciences (an estimate of about 500,000 documents – defenses from 2022-2023 at all programs, including public and private universities). Collaboration with professor Jesus Mena-Chalco from the Center of Mathematics, Computation and Cognition (CMCC), Federal University of ABC (UFABC)

Conversations between these two research cultures to discuss the responsible conduct of research on humans tend to gain momentum as of now that a LAW has been laid out by the federal government - on May 28, 2024.



**Presidência da República
Casa Civil
Secretaria Especial para Assuntos Jurídicos**

LEI Nº 14.874, DE 28 DE MAIO DE 2024

Dispõe sobre a pesquisa com seres humanos e institui o Sistema Nacional de Ética em Pesquisa com Seres Humanos.

"Art. 63. This Law and its terms apply to research with human beings in all areas of knowledge, as applicable, and in accordance with regulations." [**“COMPLIANCE” FOR NON-BIOMEDICAL RESEARCH WILL ADD ANOTHER LAYER OF COMPLEXITY TO THE PROBLEM**]

“The regulation will provide for possible specificities of research in human and social sciences, with a view to the progress of science and the implementation of this Law.”

https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2024/lei/L14874.htm#:~:text=LEI%20N%C2%BA%2014.874%2C%20DE%2028%20DE%20MAIO%20DE%202024&text=Disp%C3%B5e%20sobre%20a%20pesquisa%20com,em%20Pesquisa%20com%20Seres%20Humanos.

Questions for feedback

- One question is whether drawing upon theses and dissertations would capture the attitude of the authors and their supervisors towards the ethics review of their studies – should we address compliance with the system [as per any mention of submission and approval by a Research Ethics Committee] as a proxy for the responsible conduct of research on humans among masters and doctoral students in non-biomedical graduate programs? Note that the perspective of graduate students is part of another student in our group's doctoral project.
- Should we discuss the phenomenon that is unfolding in Brazil as an isolated issue related to the responsible conduct of research on humans as a case in point in the Global South or should we approach this problem in light of a broader panorama of a research community that cultures the biosciences in framing notions of responsible conduct of research? Note that Udo Krautwurst is one of our theoretical frameworks. As he is an anthropologist, some bias would permeate the analysis in my PhD.
- Our aim is to obtain a probabilistic sample of dissertations and theses in non-biomedical graduate programs (approximately 1,500 in Brazil) to investigate how the ethics review is addressed for research involving humans. Should we turn into a non-probabilistic sample instead so that the authors of the works can be reached for us to explore how they conceive the responsible conduct of research on humans in their fields and training?