



Consistency in Ethics Review: Utilizing a Standard Ethics Assessment Form in Reviewing Social Science Research

Parallel Session 2A – November 25, 2024



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BACKGROUND: SINGLE JOINT RESEARCH ETHICS BOARD (SJREB), DEPARTMENT OF HEALTH, PHILIPPINES

DOH Administrative Order No. 2019-0049, “Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi- Site Researches in the Department of Health”

Pertinent provision:

- Covers all DOH units including regional offices, hospitals, and attached agencies with research ethics committees
- Public and private hospital RECs who choose to participate in the review process.



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

NOV 05 2019

ADMINISTRATIVE ORDER
NO. 2019 - 0049

SUBJECT: Guidelines for the Operationalization of the Single Joint Ethics
Review Process for Multi-Site Researches in the Department of Health

BACKGROUND: PH-DOH

During the **COVID-19 outbreak**,

- SJREB has been designated as the central research ethics committee to review COVID vaccine protocols.
- SJREB also reviews social science research, especially studies implementing and recruiting at community levels.



PHILIPPINE HEALTH RESEARCH ETHICS BOARD
Philippine National Health Research System
c/o Philippine Council for Health Research and Development
Department of Science and Technology

PHREB Resolution No.20-003
Series of 2020
October 15, 2020

PCHRD	
Records Section	
Rec'd by:	<i>Noraine</i>
Time:	<i>8:00 am</i>
Date:	<i>10/20/2020</i>
Ref. No:	<i>002554</i>

RESOLUTION

**"PHREB Resolution on the Timelines of Approval for COVID-19
Clinical Trial Proposal"**
submitted ad referendum on 15 October 2020

Mindful of the urgent nature of scientific studies like clinical trials, and the urgent need to conduct COVID-19 Clinical Trials in the Philippines; and

Considering the need to streamline and facilitate the Ethics review of COVID 19 vaccine proposals;

The Philippine Health Research Ethics Board (PHREB), in consultation with the Committee on Standards and Accreditation (CSA), is hereby authorizing the PHREB Level 3 accredited Research Ethics Committees (RECs) to amend their Standard Operating Procedures (SOPs) to:

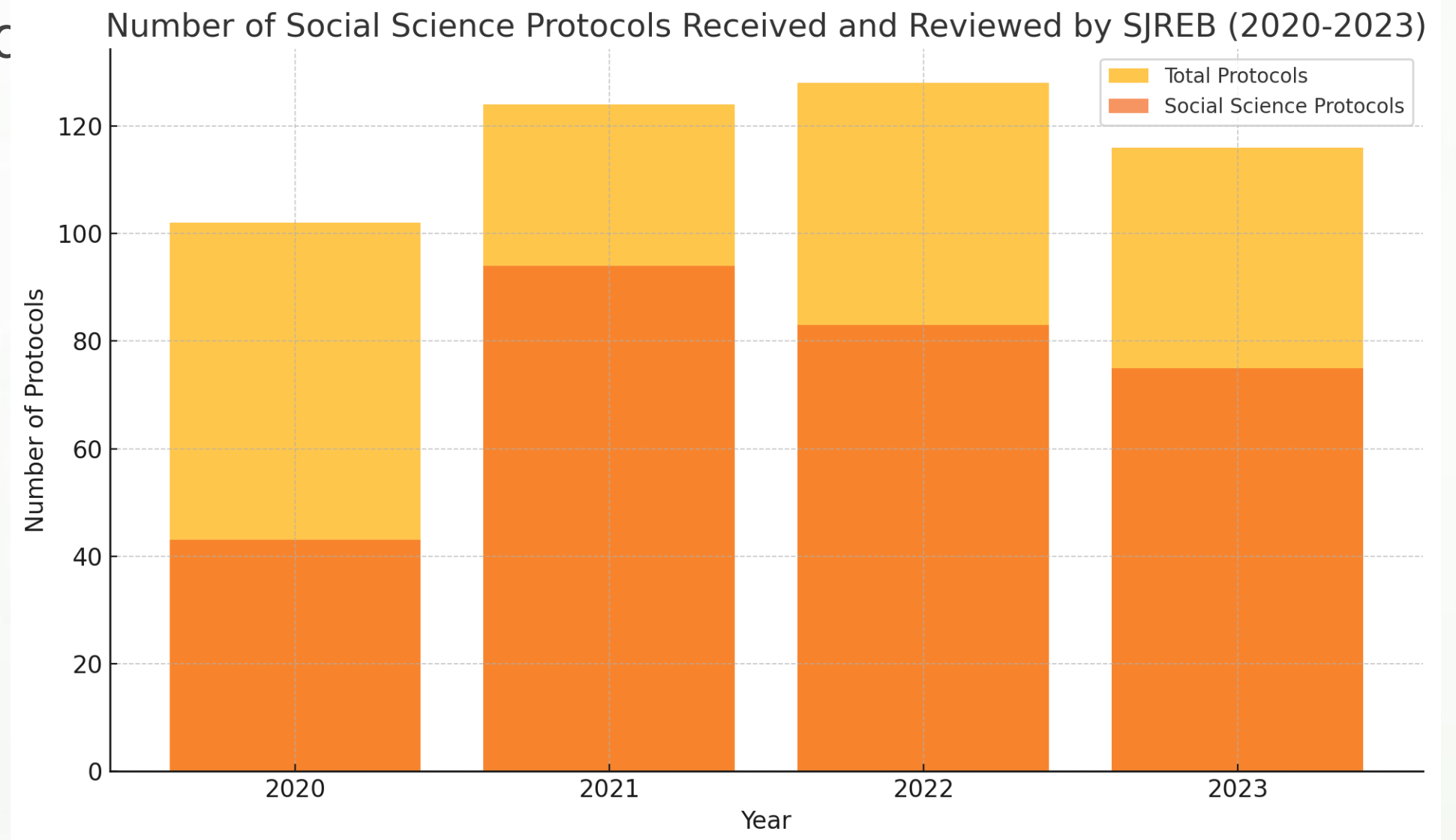
1. Incorporate provisions to enable their participation in Single Joint Review Ethics Board (SJREB) deliberations to act on pertinent COVID-19 Trial proposals; and
2. Incorporate the option to accept the SJREB's decision as their own institutional REC's decision or to opt out of participation in the ethics review deliberations and in the corresponding trial.

SOCIAL SCIENCE RESEARCH IN SJREB

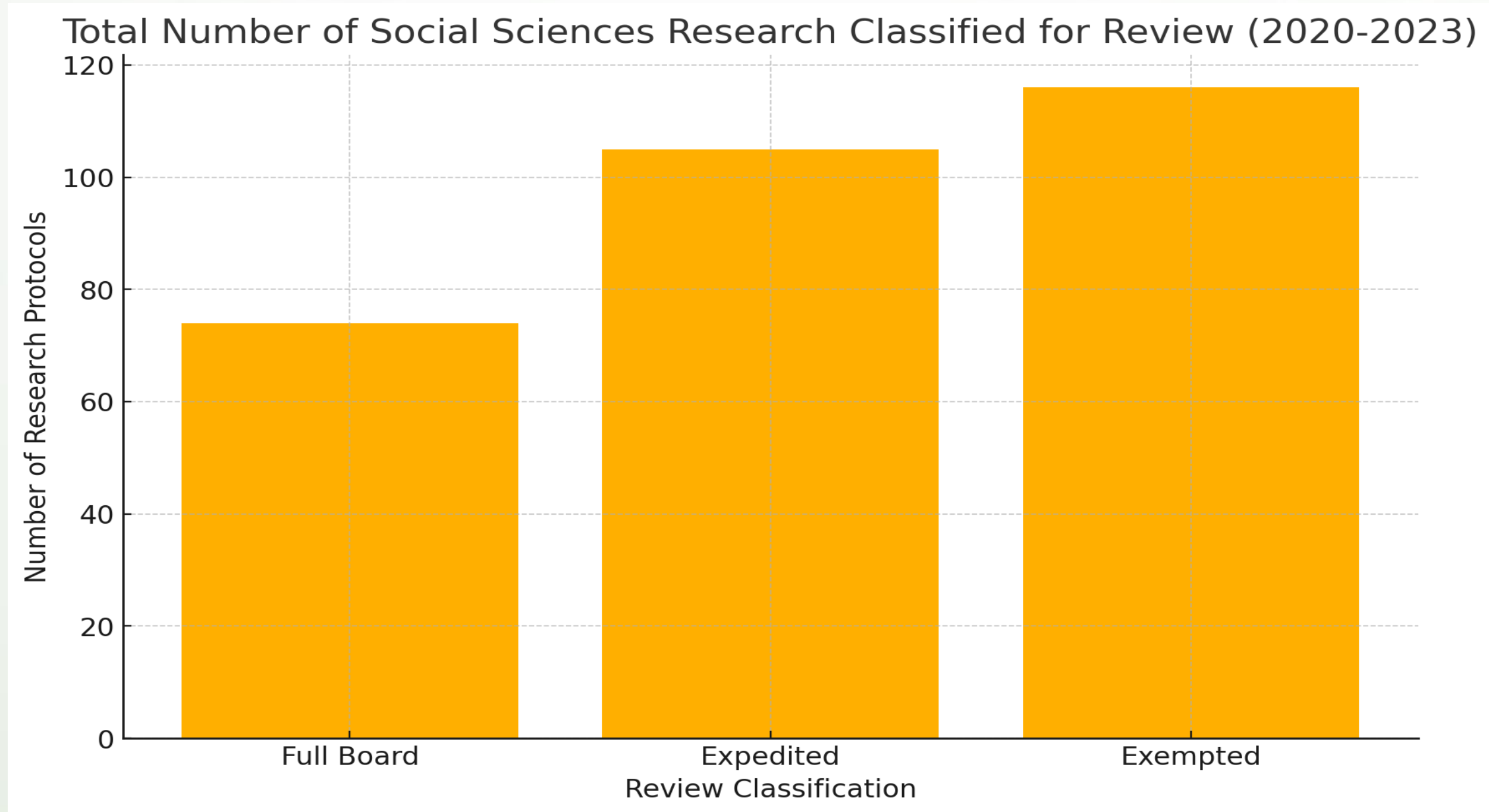
Number of Social Science protocols received and reviewed by SJREB from 2020 to 2023:

- a. 2020 - **43** social science research of 102 protocols
- b. 2021 - **94** social science research out of 124 protocols.
- c. 2022- **83** social science research out of 128 protocols
- d. 2023 - **75** social science research out of 116 protocols

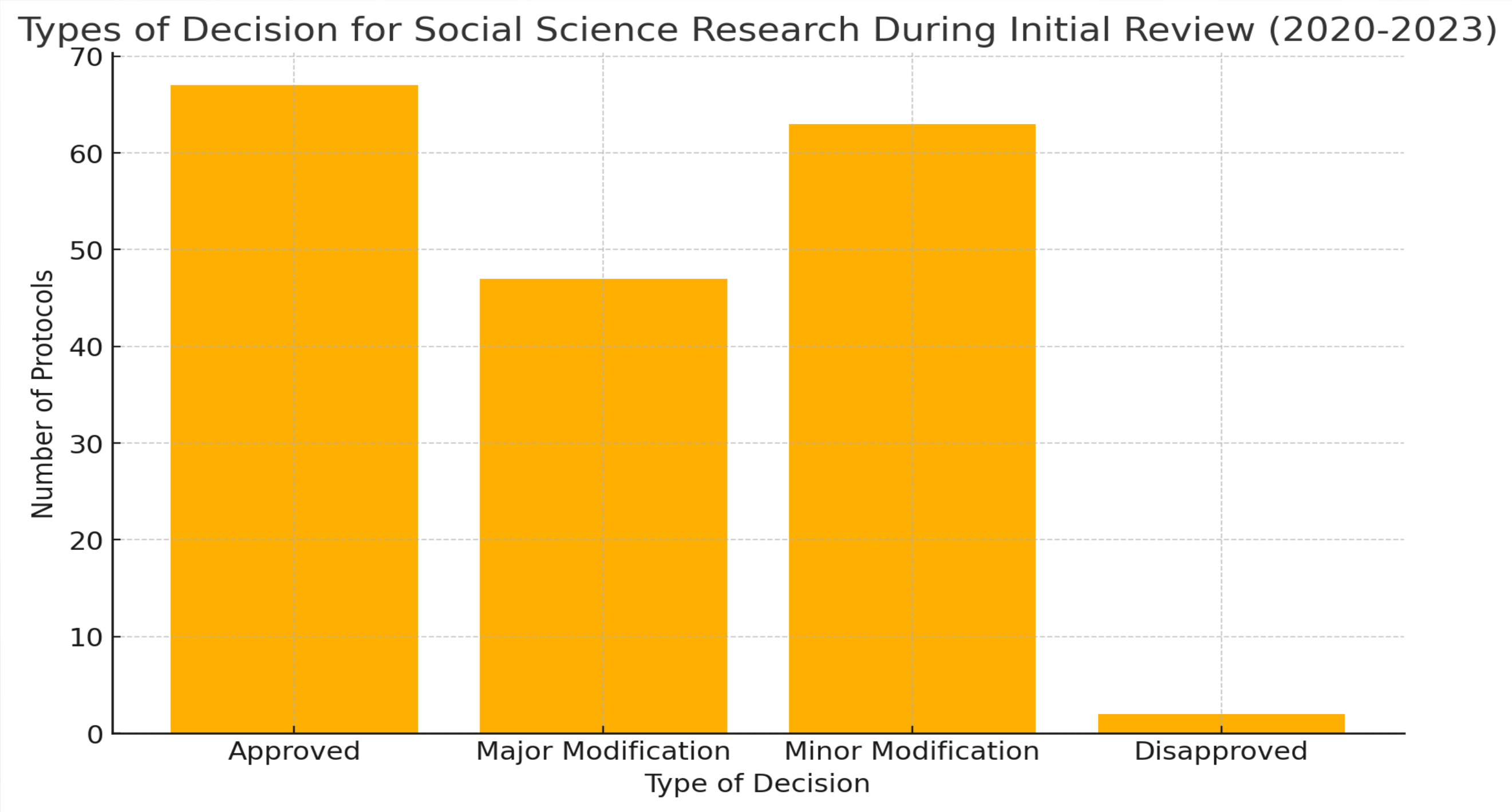
TOTAL = **295/470 SOCIAL SCIENCE RESEARCH PROTOCOLS**



CLASSIFICATION OF REVIEW FOR SOCIAL SCIENCE RESEARCH (2020-2023)



TYPES OF DECISION FOR SOCIAL SCIENCE RESEARCH DURING INITIAL REVIEW (2020-2023)



SJREB STANDARD FORMS

SJREB uses two separate forms in reviewing both protocols (**SJREB FORM 5**) and informed consent forms (**SJREB FORM 6**)

Both review forms were given to assigned SJREB Primary Reviewers and Site Primary Reviewers.

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 6 Version Number: 2.0
INFORMED CONSENT ASSESSMENT FORM Effectivity Date: October 2024

SJREB protocol code	
Study title	
Coordinating principal investigator	
Sponsor	
CRO (if applicable)	

To be filled up by primary reviewer
Instructions: Please do literature search to update your knowledge about this protocol

A. INFORMED CONSENT DOCUMENT REVIEW
(please put an X before your choice and N/A on the comments if there are no further comments)

Study sections	Yes	No	Comments (put N/A if no comments)
1. Does the Informed Consent document state that the procedures are primarily intended for research?			
2. Are procedures for obtaining Informed Consent appropriate?			
3. Is the recruitment procedure appropriate?			
4. Does the Informed Consent document contain comprehensive and relevant information?			
5. Is the information provided in the protocol consistent with those in the consent form?			

SJREB FORM 6

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5 Version Number: 2.0
PROTOCOL ASSESSMENT FORM Effectivity Date: October 2024

SJREB protocol code	
Study title	
Coordinating principal investigator	
Sponsor	
CRO (if applicable)	

Type of review
(full board, expedited)

To be filled up by primary reviewer
Instructions: Please do literature search to update your knowledge about this protocol

Total number of participants	
Expected number of participants in the Philippines	
Number of study sites in the Philippines	
Duration of the study	

Type of study:

<input type="checkbox"/> Intervention	<input type="checkbox"/> Epidemiology	<input type="checkbox"/> Observational
<input type="checkbox"/> Documents review	<input type="checkbox"/> Case study	<input type="checkbox"/> Genetic
<input type="checkbox"/> Social Survey	<input type="checkbox"/> Others (specify):	

Description of the Study in brief (mark whatever applies to the study)

<input type="checkbox"/> Randomized	<input type="checkbox"/> Drug	<input type="checkbox"/> Use of Genetic Materials
<input type="checkbox"/> Double-blind	<input type="checkbox"/> Medical Device	<input type="checkbox"/> Multicenter Study

SJREB FORM 5

SJREB PROTOCOL ASSESSMENT FORM

1. Objective and Outcomes
2. Literature review
3. Research design and methodology
4. Inclusion criteria
5. Exclusion criteria
6. Vulnerability
7. Risks and Risk Mitigation
8. Withdrawal criteria

4%

Study sections	Yes	No	Comments (put N/A if no comments)
1. Are the study objectives clear?			
2. Is there a clear need for human participants?			
3. Is the background information sufficient?			
4. Is the methodology clear?			
5. Is the recruitment process acceptable?			
6. Is there <u>sufficient</u> number of participants?			
7. Is there a control arm (e.g., placebo) provided? <input type="checkbox"/>			
8. Is the data analysis plan appropriate?			
9. Are the study outcomes defined?			
10. What is the level of risk; low, medium, high ? Explain.			
11. Is the risk mitigation appropriate?			
12. Is the benefit to participants appropriate?			
13. Are the inclusion criteria appropriate?			
14. Are the exclusion criteria appropriate?			
15. Are the withdrawal criteria appropriate?			
16. Is there involvement of vulnerable participants?			
17. Is the protection of vulnerable participants appropriate?			
18. Is the study voluntary; is there non-coercive recruitment?			

SJREB PROTOCOL ASSESSMENT FORM

1. Researcher's qualification
2. Conflict of Interest
3. Data Sharing and Local Capacity Building

4%

Other study aspects	Yes	No	N/A	Comments (put N/A if no comments)
19. Are the qualifications and experience of the coordinating investigators/participating investigators, <u>research team</u> appropriate?				
20. Are there disclosure of potential conflicts of interest				
21. Are the facilities and infrastructure of participating sites appropriate?				
22. Is there community consultation/s?				
23. <u>Are</u> there involvement of local researchers and communities in the protocol preparation and implementation?				
24. Does the study contribute to local capacity building?				
25. Is there <u>benefit</u> to <u>local</u> community?				
26. <u>Are</u> there <u>sharing</u> of study results?				
27. Are blood or tissue samples sent abroad?				

Study sections	Yes	No	Comments (put N/A if no comments)
1. Does the Informed Consent document state that the procedures are primarily intended for research?			
2. Are procedures for obtaining Informed Consent appropriate?			
3. Is the recruitment procedure appropriate?			
4. Does the Informed Consent document contain comprehensive and relevant information?			
5. Is the information provided in the protocol consistent with those in the consent form?			
6. Are <u>study related</u> risks mentioned in the consent form?			

SJREB ICF ASSESSMENT FORMS

1. Basic Information
2. Procedures for Obtaining Consent
3. Recruitment Procedures
4. Study Risks

4%

7. Is the language in the Informed Consent document understandable?			
8. Is the Informed Consent translated into the local language/dialect?			
9. Are there vulnerable participants?			
10. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?			
11. Are names and contact numbers from the research team and the REC in the informed consent?			
12. Does the ICF provide privacy & confidentiality protection?			
13. Is there any undue inducement for participation?			
14. Is there <u>provision</u> for medical/psychosocial support?			
15. Is there <u>provision</u> for <u>treatment</u> of study-related injuries			
16. Is the amount paid to participants stated?			

SJREB ICF ASSESSMENT FORMS

1. Language
2. Types of Consent
3. Contact Details
4. Privacy and Confidentiality
5. Support
6. Study-related Injuries
7. Reimbursement

4%

IMPORTANCE OF STANDARD FORMS IN REVIEWING SOCIAL SCIENCE RESEARCH

Using our standard form, SJREB ensures that all critical aspects of social science protocols are systematically and consistently evaluated.

- Scientific Soundness**
- Risk and Benefits (individual and community)**
- Privacy and Confidentiality**
- Protection of Vulnerable Participants**
- Conflict of Interest**

CONCLUSION

In conclusion, SJREB standard review forms are vital for ensuring that social science research is conducted ethically and rigorously. It provides a structured approach to evaluate scientific soundness, assess risks and benefits, safeguard privacy, protect vulnerable participants, and manage conflicts of interest, **fostering consistency and accountability** in both the implementation of the research at the community level and the ethics review process of the SJREB.



Maraming Salamat po!



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