

## Supplementary Material

### **Sex and Gender Consideration by Research Ethics Committees: A scoping review**

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This scoping review was based on the methodology described by Arksey and O'Malley<sup>1</sup> and reported based on the guidance available at the EQUATOR network<sup>2</sup>. A review protocol was developed and agreed upon by the four co-authors and followed for purposes of data collection and review. The search string described in the manuscript was agreed upon in a research team meeting followed by a discussion with a specialist in scoping and systematic reviews. Based on an initial reading of the abstracts of all the included articles, an initial data extraction framework was developed that charted the basic information about each study (See Table 1). Subsequently 4 separate data extraction tables - one for each focus area covering the issues bulleted in Table 2 were developed keeping in mind that the articles studied REC functions and composition in disparate ways, and adding Notes, recommendations, and/or observations made by the authors in the last column.

Two EXCEL table were used to chart the findings. Findings were summarised and reported using narrative descriptions based on the four identified themes: Consideration (or lack thereof) of gender by RECs, strengthening RECs to recognise sex and gender related ethical concerns, vulnerabilities including in pregnant women and gender (im)balance in RECs.

Table 1: Extraction Framework for basic information about studies included in the scoping review

category	Sub-category	Description	Additional observation/recommendation by authors
Authors			
Country of origin of first author's institution		LMIC or HIC	
Title of study			
Journal			
Year of publication		Before or after 2010	

<sup>1</sup> Hilary Arksey & Lisa O'Malley (2005) Scoping studies: towards a methodological framework, International Journal of Social Research Methodology, 8:1, 19-32, DOI: [10.1080/1364557032000119616](https://doi.org/10.1080/1364557032000119616)

<sup>2</sup> Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850).

Origin of publication		First author from HIC or LMIC	
Type of study		Primary data/secondary data/case study/commentary	
Study design		Survey of researchers/survey of RECs or REC Chairs/observation of REC meetings/analysis of meeting minutes/analysis of REC recommendations/	
Focus of research		Papers addressing issues considered by RECs/ Studies in which special women's groups were studied/ Papers addressing how to strengthen RECs to integrate sex and gender issues/ Papers addressing composition of RECs/Any other focus	

Table 2: Extraction framework for each focus area identified in the scoping review.

Category	Sub-category	Description	Additional observation/recommendation by authors
<b>A. Papers addressing issues considered by RECs</b>			
Type of data		Primary data/secondary data/case study/commentary	
Study design		Survey of researchers/survey of RECs or REC Chairs/observation of REC meetings/analysis of meeting minutes/analysis of REC recommendations/	
Does study directly address sex and gender consideration by RECs?		Yes/No	
Sex and gender based issues specific for surveys		Do surveys include gender related questions	
		Do the open ended questions receive responses that are gender related	
		Do surveys include questions related to criteria that could be used as markers for gender considerations such as representativeness, fair	

		participation, standards of care, vulnerability etc.	
Sex and gender based issues for studies based on observation of RECs or analysis of meeting minutes of REC recommendations		Did the RECs employ a sex/gender lens?	
		Did the studies report on any of the following: Equitable recruitment Fair participation Equitable/appropriate distribution of risks and benefits Representative sampling Fair inclusion criteria	
<b>B. Papers in which special women's groups were studied (gender based violence, pregnancy)</b>			
Type of data		Primary data/secondary data/case study/commentary	
Sex and gender based issues discussed		Concerns and challenges faced with respect to ethics review/ Any other issue	
<b>C. Papers addressing how to strengthen RECs</b>			
Type of data		Primary data/secondary data/case study/commentary	
What tools have been suggested		Types of tools suggested	
Do (proposed) evaluation frameworks or outcome measures include sex and gender considerations?		Yes/No	
<b>D. Papers addressing composition of RECs</b>			
Type of data		Primary data/secondary data/case study/commentary	
Study design		Survey of RECs or REC Chairs/analysis of guidelines, laws, regulations etc.	
Sex and gender based issues		Do studies mention the following: representative balance of REC members Gender expertise Gender training	

Table 3 is the completed PRISMA ScR checklist.

**Table 3: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist**

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
<b>TITLE</b>			
Title	1	Identify the report as a scoping review.	Title Page
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Page 1
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	Page 3, under Introduction
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	Page 3 under Introduction
<b>METHODS</b>			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	A protocol was developed and is available with the lead author if required. It was not registered.
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	Page 3
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	Page 3
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Page 3 and 4
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	Page 3 and 4
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	Data was charted independently on an EXCEL sheet
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Page 4

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	The results are presented in a descriptive format
<b>RESULTS</b>			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Page 4 and Figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Page 4
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Pages 4-10
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	Page 10
<b>DISCUSSION</b>			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	Pages 8-10
Limitations	20	Discuss the limitations of the scoping review process.	Page 11
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	11
<b>FUNDING</b>			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	12

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

\* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA ScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. [doi: 10.7326/M18-0850](https://doi.org/10.7326/M18-0850).