

Methodology Supplement



# Recommendations

for expediting ethics review  
during times of crisis \_\_\_\_\_



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# Methodology Supplement

## Recommendations for expediting ethics review during times of crisis

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### DOCUMENT INFORMATION

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## Introduction

For those with an interest in the methodology used to formulate the “**Recommendations for expediting ethics review during times of crisis**”, this supplement summarizes the main steps taken. The recommendations integrated data generated at various stages of the PREPARED project and benefit from the wide range of methodologies employed by all partners.

## Scoping and literature reviews in eight languages

Using reports available in 8 languages and covering **research ethics and integrity challenges during crisis**, the main challenges for research ethics committees (RECs) were extracted.

The English, Russian, Mandarin, French, Korean, and Hindi **PREPARED** reports are reviews of the available literature.<sup>1</sup> The German report is a scoping review of the available literature covering all German-speaking countries in Europe.<sup>2</sup> The Japanese report focuses on a particularly important case of research ethics and integrity challenges following the 2011 tsunami.<sup>3</sup> Whilst other crises were covered in some reports, COVID-19 was the main focus. The reports became available from November 2022 (Russian) to May 2023 (Japanese).

An initial extraction of the most relevant information to RECs from the language reports was conducted by the project co-ordinator, Doris Schroeder, as guidance for further refinement and further identification of relevant sources.

The main extraction of challenges faced by RECs under pressure to fast-track study protocol submissions in times of crisis was undertaken by KK, AM, NK, and CS.

## Survey on REC challenges for stakeholder needs report

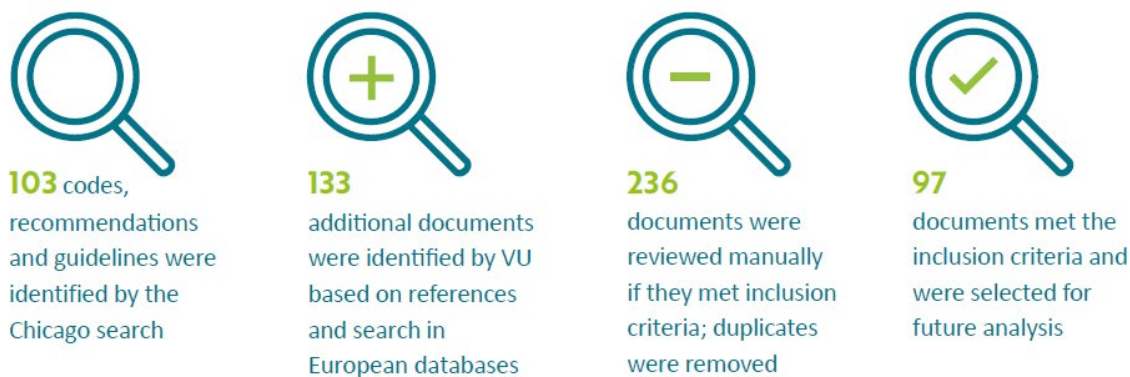
A November 2022 survey undertaken by PREPARED partner EUREC identified challenges faced by REC members during the COVID-19 pandemic. The survey fed into a **Stakeholder Needs Report** disseminated internally to all team members in March 2023.<sup>4</sup> For the purposes of the “Recommendations for expediting ethics review during times of crisis”, NK, CS, KK, and AM extracted qualitative survey data concerning ethical challenges, as well as suggested good practices, in order to build a more comprehensive understanding of

the most pressing challenges faced by REC members for expediting reviews in times of crisis.

## COVID-19 guidance

In December 2022, **PREPARED** received the results of a literature review commissioned to the Illinois Institute of Technology in Chicago, the hosts of the largest ethics code data base in the world. The search focused on ethics and integrity guidance combined with the following terms: “Pandemic”, “Pandemics”, “Global crises”, “Global crisis”, “COVID-19”, and “Coronavirus”. Details of the “**Chicago Search**”, which returned 103 documents of direct relevance to PREPARED, are available in the “Values-based framework for global crises”.<sup>5</sup> Further identification of relevant documents and their inclusion for or exclusion from further analysis was undertaken by PREPARED partner Vilnius University as illustrated in Figure 2.


Figure 2 – Document search and inclusion process



The **resulting code system based on 97 documents** was subsequently analysed by NK, KK, and AM to identify challenges and good practices concerning fast-track REC reviews as well as concrete reports from international, regional, and national organisations and institutions addressing these challenges.

## Validation workshop findings

Project findings, including from the eight language reports and the stakeholder needs report, were validated and refined by a PREPARED workshop with REC members hosted by PREPARED partner VUMC and EUREC in October 2023. The workshop aimed to explore



the experiences and perspectives of experts regarding the challenges faced during global crises, against the findings in the literature, to identify additional research ethics and integrity challenges from the experts' own experiential knowledge, and to explore their opinions on appropriate policy responses.<sup>6</sup> CS extracted insights relevant to expedited ethics reviews that were generated from this workshop from the validation report, which became available in December 2023.

## Literature review and integration of findings

To help integrate the above, AM, KK, and CS conducted a **second focused literature review** to identify additional recommendations and good practices related to expedited research ethics review. Google Scholar was searched, using “fast-track ethics review research ethics committees” and “expedited ethics review research ethics committees” as keywords. The snowball method (e.g. following additional material from the reference section of academic papers) was subsequently used to identify further relevant literature, as needed.

## Decisions about the format of the recommendations

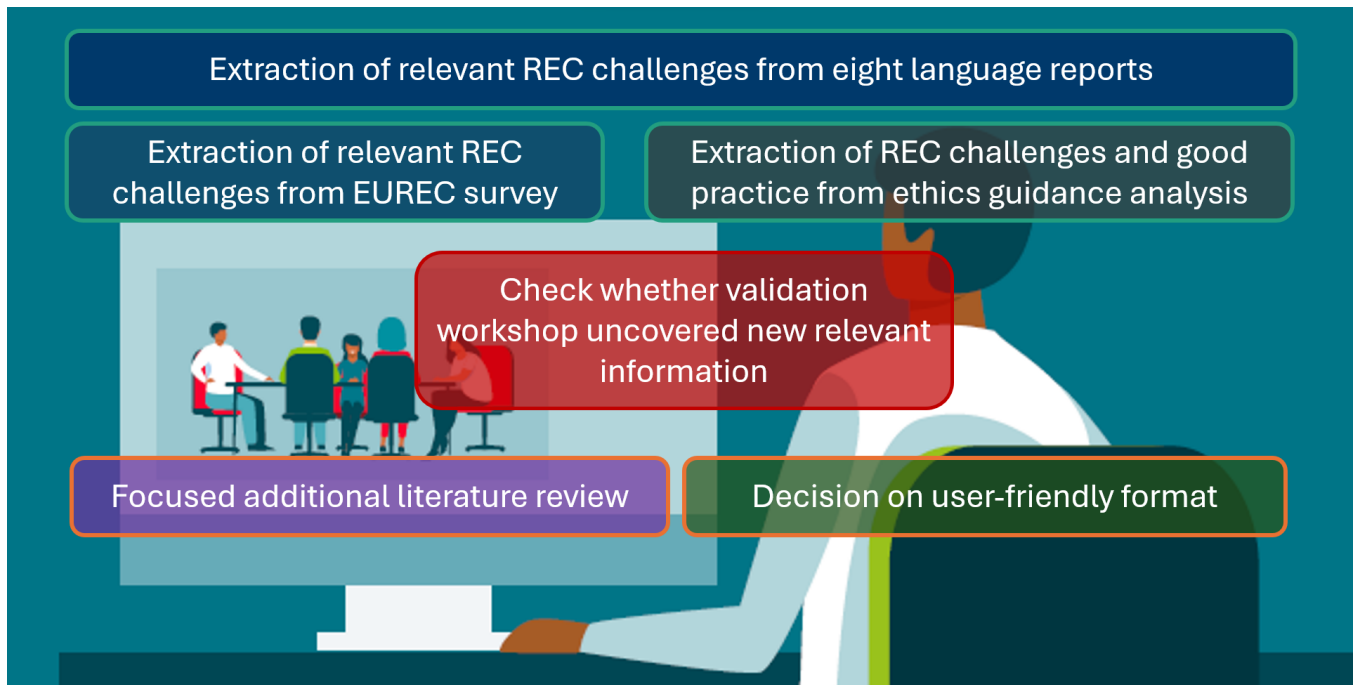
In collaboration with the project Co-ordinator DS, it was decided to make the deliverable as user-friendly as possible, especially given that most of the addressees were expected to be extremely busy. The following decisions were taken:

- Each challenge should be accompanied by a recommendation and good practice. It was assumed that this would be more user-friendly than a challenges section, followed by a good practices section, followed by a recommendations section. This way, people could go to their preferred topic and only read what they need to know on one topic.
- The methodology section should be moved to a supplement to ensure that the guidance itself is as short as possible.
- The guidance was going to be professionally designed, whilst to save resources, this methodology supplement was not.

## Conclusion

A diagram summarizing the individual steps taken to produce the “Recommendations for expediting ethics review during times of crisis” is shown in Figure 2.

Figure 2 – Overview of how the recommendations were developed



## Endnotes

<sup>1</sup> As many of the reports have been submitted for publication (see footnote 2, the German report has already been published), the reports are internal documents, available on request.

<sup>2</sup> Seedall, C., & Tambornino, L. (2024). Research ethics and integrity in the DACH region during the COVID-19 pandemic: balancing risks and benefits under pressure. *Research Ethics*, 0(0). <https://doi.org/10.1177/17470161241229207>.

<sup>3</sup> The Japanese report is available on request and is currently being prepared as a case study for the PREPARED app.

<sup>4</sup> Seedall C and Tambornino L (2023) Research ethics and integrity in times of global crisis – Stakeholder Needs, a report for the PREPARED project, available at: <https://prepared-project.eu/>

<sup>5</sup> Chatfield K, Schroeder D, Lukaševičienė V, Partington H, Gefenas E (2023) Values-based framework for global crises, a report for PREPARED, available at: <https://prepared-project.eu/wp-content/uploads/2023/12/PREPARED-Values-Framework-Final.pdf>.

<sup>6</sup> N. Evans, L. Mlotshwa, M. Singh, C. Seedall and K. Videnoja, Preliminary Report on the Expert Validation Workshop Series, a report for the PREPARED project (Internal report)