THE PREPARED CODE

A GLOBAL CODE OF CONDUCT FOR RESEARCH DURING PANDEMICS

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A Global Code of Conduct for Research during Pandemics

Research ethics and integrity challenges during pandemics are not unique, but they are vastly magnified during crises.

The PREPARED Code for researchers, **research ethics committees and research integrity offices** applies throughout a pandemic. The code was developed by an international consortium and is based on research undertaken in English, Chinese, French, German, Hindi, Japanese, Korean, Russian, and Spanish. It was refined through a human rights analysis and extensive consultation with relevant stakeholders. Input from marginalized populations was obtained throughout.

THE PREPARED CODE:

- Provides guidance across all research disciplines.
- Presents concise statements in clear language to promote accessibility.
- Complements the **TRUST Code** and the **European Code of Conduct for Research Integrity** as risks associated with inequitable research and breaches of research integrity can increase during times of crisis.
- Links each guidance article to the values of fairness, respect, care and honesty.

VISION:

Pandemic research should be trustworthy and the results accessible to all.

FAIRNESS

ARTICLE 1

Data and scientific insights from pandemic research should be **shared** as swiftly as possible with the scientific community and other relevant stakeholders, and without detrimental impact on the sharer.

ARTICLE 2

Research coordination and cooperation is essential to avoid unnecessary duplication of studies which can result in wasted resources and place unfair burdens on participants.

ARTICLE 3

A fair plan for **access to the benefits** of pandemic research should be agreed, early on in any project, in collaboration with relevant stakeholders.

ARTICLE 4

Where possible, **community engagement** should be continued or even enhanced during a pandemic, to address the most pressing needs of communities and to help maintain trust in science.

ARTICLE 5

People's vulnerabilities increase during pandemics. Where possible, research approaches should be adapted to ensure the **ethical inclusion of vulnerable persons** - with adequate protections - rather than adopting patronizing or convenience exclusions.

ARTICLE 6

Research teams should ensure that **additional responsibilities** associated with a pandemic should be shared fairly across the team and not exacerbate existing inequalities.

RESPECT

ARTICLE 7
Vital research must not be delayed unduly, but **research ethics committee** guidance and approval is essential also during pandemics and must be obtained and respected. RECs should strive to facilitate timely evaluation of research proposals that address urgent societal needs without compromise of rigorous ethical standards.

ARTICLE 8
Community researchers are part of the research team and must be treated and respected as researchers, including during pandemics.

ARTICLE 9
The urgent need to conduct research can never be an excuse for putting pressure on potential research participants or their proxies to make a hasty decision about involvement in a study. **Sufficient time** is needed to achieve **genuine informed consent.**

ARTICLE 10
Changes to the process of seeking informed consent must not compromise understanding for potential participants.

ARTICLE 11
Where healthcare staff rather than researchers obtain consent during crises, special attention must be given to ensuring that research participants do not mistake research for treatment **('therapeutic misconception').**

ARTICLE 12
The informed consent process should explain the study **risks** and benefits fully and clearly in terms of what is known, what is **uncertain** and what is unknown.

ARTICLE 13
During pandemics, actors across the research cycle should strive for **respectful engagement** with each other in the spirit of equitable and collaborative problem-solving.

ARTICLE 14
Researchers must use **respectful language** in the press or the media at all times, including when under pressure.

CARE

ARTICLE 15
Public health responses must not be compromised by research. In particular, any involvement of clinical staff in research should not have a detrimental impact upon patient care.

ARTICLE 16
Especially during pandemics, researchers who handle **biological materials** must be adequately **trained** and equipped to safeguard public health.

ARTICLE 17
Researchers must consider how pandemic conditions may impact upon all stakeholders in a study (including participants, healthcare staff, support staff etc.) and take appropriate measures to **mitigate additional burdens.**

ARTICLE 18
When **prioritizing pandemic research**, it must be ensured that research participants in other ongoing studies are not left worse off than before they entered their study.

ARTICLE 19
If research participants depend on research studies for access to medication and services, **study modifications** during pandemics need to be managed responsibly to ensure that lives and health are not endangered.

ARTICLE 20
Where no rescue therapy is available, studies involving healthy volunteers can only be started during pandemics if space in Intensive Care Units is assured for the needs of healthy volunteers and all patients in routine care.

ARTICLE 21
During pandemics, researchers may experience a **heightened risk of hostility** and related safety and security concerns. Research ethics committees should check that risk management plans are in place.

HONESTY

ARTICLE 22
Even under significant pressure, it is vital that researchers uphold the **highest standards of research integrity** to ensure the reliability of pandemic research results and to maintain public trust in science.

ARTICLE 23
In the context of uncertainty, researchers must **review their study protocols regularly** to ensure that new findings are taken into account as they emerge.

ARTICLE 24
Participants and research ethics committees should be **promptly** and fully informed about changes in the risks or burdens of participation in a clinical trial if **new, relevant information** becomes available during the trial.

ARTICLE 25
Regulatory requirements for the **secondary use** of personal data and biological materials apply equally for pandemic and non-pandemic research unless an explicit exception has been enacted.

ARTICLE 26
Researchers should offer their time to **support** rigorous, **fast-track scientific review** to help combat the erosion of good science during pandemics. They should also support quality control mechanisms for open communication modalities such as pre-print servers or social media.

ARTICLE 27
To promote public trust, **publishers' research ethics questions** should be answered in full by researchers, also in rapid review submissions.

ARTICLE 28
Researchers **who communicate with the public** during a pandemic must ensure the veracity and reliability of the information they share. Deception and sensationalist exaggerations of results must be avoided at all times.

PREPARED CONSORTIUM MEMBERS

The code was drafted by the PREPARED project under the leadership of Prof. Doris Schroeder. Existing guidelines have played an important role in formulating the code.

The code was developed for pandemics but may also be useful for epidemics and public health emergencies of international concern.

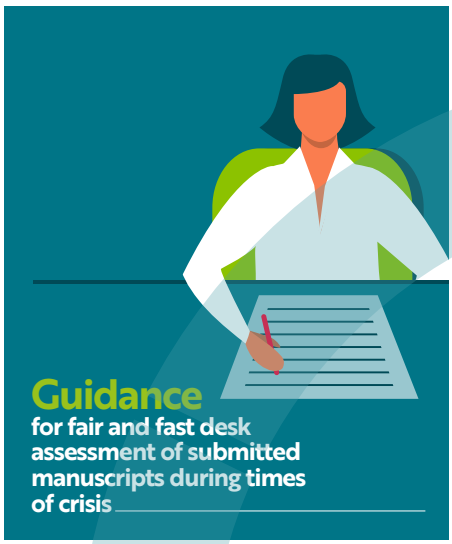
On the website (website address), additional material is available, in particular:

- List of authors
- List of ethics guidance, which inspired this code
- Training and video materials

PREPAREDNESS CONSIDERATIONS

Resilience develops during periods of stability rather than during crises.

The PREPARED team also offer the following guidance, to be acted upon **before** the next pandemic..



TBC

REC Guideline on the Prioritization of Research Studies

Coming...

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REC Financial Resources Statement

Coming...

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Guideline on how to deal with the politization of science

Coming...

Policy Brief

Coming...

USEFUL LINKS:

PREPARED project - https://prepared-project.eu/
TRUST Code: https://www.globalcodeofconduct.org/