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 stakeholders. Input from marginalized populations was obtained at every stage.

THE PREPARED CODE:

- Respects the **Declaration of Helsinki** as the primary source of research ethics guidance during pandemics.
- Provides support across all research disciplines.
- Presents concise statements in clear language to encourage access.
- Combines guidance on research ethics and integrity.
- Complements the **TRUST Code** and the **European Code of Conduct for Research Integrity**, because the risks of inequitable research and breaches of research integrity can increase during a 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 about new infectious agents should be quality controlled and **shared** as swiftly as possible with the scientific community and other stakeholders, without prejudice to the sharer.

ARTICLE 2

Research coordination and cooperation are essential to avoid the unnecessary duplication of studies, which could place unfair burdens on participants and waste time and resources.

ARTICLE 3

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

ARTICLE 4

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

ARTICLE 5

Vulnerabilities increase during pandemics. Where possible, research approaches should be adapted to ensure the **ethical inclusion of persons in vulnerable situations** – with adequate protections – rather than adopting patronizing or convenience exclusions.

ARTICLE 6

Research teams should share the **additional responsibilities** associated with a pandemic fairly among their members to avoid exacerbating existing inequalities.

RESPECT

ARTICLE 7

Research ethics committee (REC) guidance and approval should be sought and respected at all times, including during pandemics. RECs should **expedite the evaluation** of research proposals that address urgent societal needs without compromising rigorous ethical standards.

ARTICLE 8

Community researchers are part of the research team and should 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 hasty decisions about their involvement in a study. **Genuine informed consent** needs **time.**

ARTICLE 10

Changes to the process of seeking **informed consent** must not be allowed to compromise potential participants' understanding of a research project. This includes ensuring that research participants do not mistake research for treatment ('therapeutic misconception'), especially when healthcare staff rather than researchers seek consent.

ARTICLE 11

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 12

During pandemics, all those involved in the research cycle should strive for **respectful engagement** with each other in the spirit of equitable and collaborative problem-solving.

ARTICLE 13

Researchers must always use **respectful language** when communicating through the press or the media, even when under pressure.

CARE

ARTICLE 14

Research must not compromise **public health responses.** In particular, the involvement of clinical staff in research should not affect patient care negatively.

ARTICLE 15

Especially during pandemics, researchers who handle potentially infectious **biological materials** should be adequately **trained** and equipped to safeguard public health.

ARTICLE 16

Researchers should keep in mind how pandemic conditions may affect all stakeholders in a study (participants, healthcare staff, support staff etc.) and take appropriate measures to **ease any additional burdens.**

ARTICLE 17

When **research is prioritized during a pandemic**, research participants in ongoing studies must not be left worse off than before they joined their original study.

ARTICLE 18

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

ARTICLE 19

During pandemics, studies involving **healthy volunteers** in which novel compounds are administered to humans or no rescue therapy is available should only be started if space in intensive care units is assured for the needs of healthy volunteers, as well as for all patients in routine care.

ARTICLE 20

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

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

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

ARTICLE 23

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

ARTICLE 24

Existing regulatory requirements for the **secondary use** of personal data and biological materials must prevail during pandemics, unless an explicit exception has been enacted.

ARTICLE 25

Researchers should actively **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 channels such as pre-print servers or social media.

ARTICLE 26

Researchers should answer **publishers' research ethics questions** in full, even in rapid review submissions.

ARTICLE 27

In **public communications**, researchers should ensure that the scientific information presented is reliable. They should be clear about study limitations and avoid exaggeration, sensationalism and deception.

PREPARED CONSORTIUM MEMBERS

The code was drafted as part of the PREPARED project under the lead author Prof. Doris Schroeder.

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

The website (https://preparedcode.uclancyprus.ac.cy/) offers additional material, in particular:

- A list of authors
- Training and video materials
- A book on how the code was developed