

RDA COVID-19 WG

Cross-cutting

Ethical and Legal Guidance

Introduction

The intention of these guidelines is to help researchers, practitioners and policy-makers deal ethically and legally with all aspects of pandemic response and in particular with regard to key ethical principles of *equity, utility, efficiency, liberty, reciprocity and solidarity*^{[1],[2]}. In times of public health emergency, it is right to consider how best to respond in terms of increased data and research outcome sharing. However, it is important that legal and ethical principles are incorporated into research design from the outset. The law supports research and enables data sharing^[3]. Knowing compliance with the law protects individual researchers, research more generally and the common good. The rule of law cannot be overlooked, therefore, and needs to be taken into consideration along with respect for overarching concerns related to human rights and dignity^[4]. Especially where marginalisation or other forms of stigmatisation are at stake, these rights and values should inform appropriate research practices directed towards the common good.

These guidelines have been produced by the RDA-COVID working group between March and May 2020 during the ongoing coronavirus disease (COVID-19) pandemic. The aim is to identify and collate existing recommendations and guidelines in order to increase the speed of scientific discovery by enabling researchers and practitioners to:

1. Readily identify the guidance and resources they need to support their research work
2. Understand generic and cross-cutting ethical and legal considerations
3. Appreciate country- or region-specific differences in policy or legal instruments
4. Identify the institutional stakeholders best placed to provide relevant ethical and legal guidance

Scope

The COVID-19 pandemic has created significant confusion for researchers in terms of whether, and in which way, existing ethical and legal principles remain relevant. The COVID pandemic does not serve to remove the basic validity of the rights and interests on which these documents and principles are based. The emergency does, however, mandate a reconsideration of the balance between these rights and interests - in particular between research subject's right to privacy and the public interest in the

outcome of research. In some cases, this reconsideration has led to legitimate time limited adaptations of, or derogation from, normally applicable principles.

This document will therefore provide a high-level overview of:

- Cross cutting principles
- Hierarchy of norms
- Where to seek guidance
- Initial Recommendations
- Existing relevant policy statements

The assumption here is that there will be an official statement of *when* the international community deems the pandemic to have finished. This may then vary by country.

A separate, more detailed report expands on the information here.

Cross-cutting principles

All activities, especially in times of pandemic or other public emergencies, should be guided by:

- The FAIR (Findable, Accessible, Interoperable and Re-usable) principles of data to ensure ongoing, beneficial research^[5];
- The CARE principles to ensure ethical treatment of individuals and communities^[6];
- The Global Code of Conduct, specifically Fairness, Respect, Care and Honesty in research activities, to maximise equanimity in research outcome benefit^[7];
- The Five Safes of research data governance^[8];
- Research Integrity guidelines^[9].

Hierarchy of obligations

Ethics and the law exist in a symbiotic, mutually supportive relationship. Ethical and legal considerations related to research are elaborated in four key types of document: ethical guidelines; policy guidance; codes of conduct; and legal instruments. The distinction between these types of instrument is not always obvious. The following principles, therefore, may prove useful for COVID-19 researchers considering the interaction between instruments:

- Ethical guidelines are often defined and publicised by non-law-making bodies, while legal instruments will be adopted by governments or other legislative bodies.
- Many ethical instruments are mandatory for researchers or clinicians, such as those imposed by professional associations or bodies, healthcare institutions, or governmental and funding agencies.

- Instruments exist in a hierarchy, with legal instruments being generally assumed to take precedence over ethical guidance and policy guidance.
- Jurisprudence and other official guidelines providing authoritative interpretations of legal instruments will often be complementary to related ethical instruments.
- Both legal and ethical instruments should be consulted together to understand all the pertinent issues which need to be taken into consideration.
- Ethical instruments are generally interpreted harmoniously with the law, and can guide the interpretation of the law if the law does not address a particular issue.
- Many ethical instruments are mandatory for researchers or clinicians, such as those imposed by professional associations or bodies, healthcare institutions, or governmental and funding agencies.

Common obligations in using health data that are found in many laws and ethical guidelines include the following:

- The obligation to respect privacy and confidentiality
- The obligation to ensure data accuracy
- The obligation to use anonymised data instead of personal data, or minimise personal data use
- The obligation to limit the identifiability of personal data as far as possible - including via pseudonymisation techniques
- The need to process for a specific, authorized, purpose and only to process for secondary purposes provided certain conditions are fulfilled and not processing for purposes beyond scientific research / healthcare e.g. not sharing with employers or other agencies
- To hold oneself accountable to, and remain transparent towards, the individuals concerned by the data used
- To provide individuals access to their data, and to rectify errors or biases in the data on request
- To provide individuals the opportunity to request the deletion or return of their data in certain circumstances if this is possible or required by law^[10]
- The obligation to ensure that data are collected from representative sub-populations and not confined to one group^[11]
- The obligation to ensure equanimity across cohorts to:
 - Prevent marginalisation of vulnerable groups
 - Encourage trust and engagement from vulnerable groups^[12]
- The obligation to share data and the benefits of research outcomes fairly and without regard to discipline, region or country^[13]
- The obligation to apply legal and ethical practice to all stages of data collection, processing, analysis, reporting and sharing
- The obligation for data providers as well as data users to validate and verify the provenance of data, and ensure appropriate consent or other legal basis for the data's use
- The obligation to ensure that de-identified or aggregated data made public does not contain data elements or rich metadata that could easily lead to identify specific persons
- To include sunset clauses in the retention and exploitation of data collected during a public emergency with a view to future review of the continued use and usefulness of the data.

Such obligations are formalised through ethical guidance^{[14],[15],[16],[17]}. Especially in times of pandemic specific attention to vulnerable groups and guidance on related global justice issues are to be commanded.

Seeking guidance

In times of pandemic or other public emergencies, it is important to be aware of existing and *ad hoc* resources and guidance. For example:

- For researchers attached to an academic institution,
 - the Institutional Review Board (IRB) or Research Ethics Committee (REC) will provide guidance as well as review
 - the Information Governance Board will provide support on data management
 - the Data Protection Officer will provide support and guidance on data protection issues
 - Data and Biospecimen Access Committees will advise on sharing or providing access to data, as well as Intellectual Property issues
 - Technology transfer offices provide guidance regarding intellectual property and related issues
- For those in Low and Middle-Income Countries, if no local support is available, may contact the UN Ethics Office^[18]
- For professionals affiliated to a professional body, the latter will provide guidance on ethical research activities
- For medical or other clinical staff, the institution (such as a hospital) will provide research integrity support, including ethical approvals required and an *ad hoc* mechanisms to support emergency research efforts; or the appropriate governing body (e.g., the NHS in the UK) will provide training and support both ongoing and in exceptional circumstances.
- Hospitals, much like academic institutions, are often staffed by a Data Protection Officer, personnel specialized in research ethics including IRBs or REBs, and administrators responsible for authorizing the sharing of health data

Researchers and other professionals should always consult their institutional support personnel as well as professional bodies. Often in cases of health emergencies such as the COVID-19 pandemic fast track procedures are put in place, allowing the approval processes to be accelerated without diminishing the protection of the rights of persons.

Initial Recommendations

A set of recommendations are currently being collected and collated. They include:

- Access to research and research outcomes should be shared with all
 - in particular, thinking of vulnerable groups
 - in particular, encouraging the engagement and trust of vulnerable groups

- Ethical guidelines on data collection, analysis, sharing and publication should not be confined to clinical and biological (omic) data. Such guidelines should also extend to all areas of Open Science
- In the spirit of the Open COVID Pledge^[19], organisations with potentially useful datasets outside the research communities should be encouraged to make those data available to those research communities during emergency, pandemic situations
- Ethical and legal policies should be drawn up to monitor and regulate the impact of algorithmic profiling and data analytics, not least in terms of design and implementation
- During a pandemic or similar public emergency, ethical review and approval should be expedited, optionally but beneficially involving the public in approval decisions^[20]
- Policy making should be underpinned by empirical research (evidence based) such that decision makers are held to account
- Provide guidance and support for non-research organisations to make the data they hold available to the research community
- All stakeholders (researchers, policy-makers, editors, funders and so forth) should encourage communication across all disciplines and all areas in the spirit of Open Science

In the following version of this document, we also intend to identify areas where more research is needed.

Relevant policy and non-policy statements

The RDA Covid-19 Ethical-Legal group endorses and recommends guidance published as follows:

the OECD Privacy Principles
[\(http://oecdprivacy.org/\)](http://oecdprivacy.org/)

the UNESCO International Bioethics Committee (IBC) and World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) in their STATEMENT ON COVID-19: ETHICAL CONSIDERATIONS FROM A GLOBAL PERSPECTIVE
<https://unesdoc.unesco.org/ark:/48223/pf0000373115>

the Council of Europe pointers to national resources from national ethics committees or other related to COVID-19: <https://www.coe.int/en/web/bioethics/covid-19>

the Council of Europe statement on bioethics during COVID-19: <https://rm.coe.int/inf-2020-2-statement-covid19-e/16809e2785>

the European Group on Ethics in Science and New Technologies statement on solidarity
https://ec.europa.eu/info/sites/info/files/research_and_innovation/ege/ec_rtd_ege-statement-covid-19.pdf

the Global Alliance for Genomics and Health (GA4GH) Framework for Responsible Sharing of Genomic and Health-Related Data

(<https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/>)

The Statement of the African Academy of Sciences' Biospecimens and Data Governance Committee on COVID-19: Ethics, Governance and Community engagement in times of crisis

(<https://www.aasciences.africa/sites/default/files/2020-04/COVID-19%20Ethics%20Governance%20and%20Community%20engagement%20in%20times%20of%20crises%20April2020.pdf>)

Committee on Economic, Social and Cultural Rights, Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights

(<https://www.ohchr.org/en/hrbodies/cescr/pages/cescrindex.aspx>)

[1] https://apps.who.int/iris/bitstream/handle/10665/70006/WHO_CDS_EPR_GIP_2007.2_eng.pdf;

[2] <https://unesdoc.unesco.org/ark:/48223/pf0000373115>

[3] https://edpb.europa.eu/our-work-tools/our-documents/other/statement-processing-personal-data-context-covid-19-outbreak_en

[4] <https://www.coe.int/en/web/human-rights-rule-of-law/covid19>

[5] <https://www.force11.org/fairprinciples>

[6] http://www.newcarestandards.scot/?page_id=15

[7] <https://www.globalcodeofconduct.org/>

[8] <https://www.ukdataservice.ac.uk/manage-data/legal-ethical/access-control/five-safes>

[9] https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

[10] Some EU Member States, for example, allow for data to be held indefinitely when used for scientific and research purpose

[11] E.g., the traditional white, Caucasian upper-middle-class male.

[12] See, for example, <http://trust-project.eu/wp-content/uploads/2017/03/San-Code-of-RESEARCH-Ethics-Booklet-final.pdf>

- [13] <https://unesdoc.unesco.org/ark:/48223/pf0000233230>
- [14] For example, the Caldicott principles (<https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx>),
- [15] https://www.echr.coe.int/Documents/Convention_ENG.pdf
- [16] <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164>
- [17] <https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights>
- [18] <https://www.un.org/en/ethics/index.shtml>
- [19] <https://opencovidpledge.org>
- [20] Cf. the Green / Amber / Red system of risk assessment applied in the UK