

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 within legal constraints with all aspects of pandemic response and in particular with regard to key ethical principles of *equity, utility, efficiency, liberty, reciprocity and solidarity*¹. 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, this does not mean that the principle of law² may be overlooked, nor that overarching concerns related to human rights and dignity³, especially where this may lead to marginalisation or other forms of stigmatisation, should not inform appropriate research principles directed towards the common good.

These guidelines have been produced by the RDA-COVID working group in March-April 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, Legal and Social Implication (ELSI) principles remain relevant. In principle, the COVID pandemic does not constitute an emergency in

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

² https://edpb.europa.eu/our-work-tools/our-documents/other/statement-processing-personal-data-context-covid-19-outbreak_en

³ <https://www.coe.int/en/web/human-rights-rule-of-law/covid19>

relation to which all existing ELSI documents and principles lose validity. 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 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
- Existing relevant policy statements

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 research⁴;
- The CARE principles to ensure ethical treatment of individuals and communities⁵;
- The Global Code of Conduct, specifically Fairness, Respect, Care and Honesty in research activities, to maximise equanimity in research outcome benefit⁶.

Hierarchy of obligations

ELSI considerations related to research are elaborated in three key types of document: ethical guidelines; policy guidance; and legal instruments. The distinction between these types of instrument is not always obvious. The following principles are 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 orders, healthcare institutions, or governmental funding agencies.
- Instruments exist in a hierarchy, with legal instruments assumed to take precedence. It should be remembered, however, that it is usually possible to continue to work ethically whilst adhering to the law.
- Jurisprudence and other official guidelines providing authoritative interpretations of legal instruments will also take precedence over ethical guidelines.

⁴ <https://www.force11.org/fairprinciples>

⁵ http://www.newcarestandards.scot/?page_id=15

⁶ <https://www.globalcodeofconduct.org/>

- When legal instruments do not address a point, or leave room for interpretation on a point, ethical instruments can be used to guide practice.

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

- The obligation to preserve 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 to only process for secondary purposes provided certain conditions are fulfilled
- 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

Researcher ethical obligations may be summarised as:

- To ensure non-malevolence
- To aim to maximise benevolence
- To ensure fair, balanced and timely access to research outcomes
- Wherever possible, to respect individual autonomy
- To share data and research findings
- To support cross-disciplinary collaboration

Such obligations are formalised through ethical guidance⁷. 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

⁷ For example, the Caldicott principles (<https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx>), Medical Ethics (Beauchamp & Childress (2001) Principles of Biomedical Ethics; ISBN 9780195143324)

- the Data Protection Officer will provide support and guidance on data protection issues
- Technology transfer offices provide guidance regarding intellectual property and related issues
- 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.

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/>)

the UNESCO 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/>)

Work in progress

The ELSI group are currently expanding upon initial discussion and investigations to develop the following:

RECOMMENDATIONS

Specific

- What do we already know to be part of *best practice*?
- What are the common pitfalls that we are aware of?

Aspirational

- What would we like to see?
- What *should* be looked at in the future?

DATA COLLECTION PRINCIPLES and PRACTICE

- Consent
- Provenance
- Trustworthiness
- Community *vs* Individual

DATA SHARING

- Cross-border sharing
- Equitable sharing
- Cross-disciplinary sharing

EMERGENCY PROVISIONS

- What is available during emergencies
- What must still be done / avoided
- How to future-proof data and findings

RESOURCES

- What is available
- How to find it
- Who to ask?

The WG welcomes requests from other groups and disciplines about specific issues and concerns they may encounter in their own domains.