



COMFOCUS

Community on Food Consumer Science



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Literature Review on Ethical, Legal and Social Issues (ELSI) Relevant to COMFOCUS: A conceptual framework for Responsible Research and Innovation (RRI)



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Literature Review on Ethical, Legal and Social Issues (ELSI) relevant to COMFOCUS:

A conceptual framework for Responsible Research and Innovation (RRI)

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Glossary

Abbreviation	Full form
AnaEE	Analysis and Experimentation on Ecosystems
BBMRI	Biobanking and BioMolecular resources Research Infrastructure
BIDS	Brain Imaging Data Structure
CDRC	Consumer Data Research Centre
COMFOCUS	Community on Food Consumer Science
CSO	Civil Society Organization
DPUK	Dementias Platform United Kingdom
EATRIS	European Infrastructure for Translational Medicine
EC	European Commission
ECG	Electrocardiogram
ECRIN	European Clinical Research Infrastructure Network
EEG	Electroencephalogram
ELSI	Ethical, Legal and Social Issues
EOSC	European Open Science Cloud
ERIC	European Research Infrastructure Consortium

ERS	Economic Research Service
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
FAIR	Findable, Accessible, Interoperable and Re-usable
FOSTER	Facilitate Open Science Training for European Research
GDPR	General Data Protection Regulation
GODAN	Global Open Data for Agriculture and Nutrition
H2020	Horizon 2020
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICMJE	International Committee of Medical Journal Editors
ICT	Information Communication Technology
IP	Intellectual Property
IPR	Intellectual Property Rights
JRI	Joint Research Initiatives
ML	Machine Learning
MRI	Magnetic Resonance Imaging
NGO	Non-governmental organization
NHS	National Health Service
ODC	Open Data Charter
OSC	Open Science Cloud
R & I	Research & Innovation
RDA	Research Data Alliance
RICHFIELDS	Research Infrastructure on Consumer Health and Food Intake using E-science with Linked Data Sharing
RRI	Responsible Research and Innovation
SDG	Sustainable Development Goals
SRIA	Strategic Research and Innovation Agenda
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UKRN	United Kingdom Reproducibility Network
UN	United Nations

UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States
USDA	United States Department of Agriculture
WHO	World Health Organization
WP	Work package
XR	Extended Reality (virtual reality, augmented reality and mixed reality)

Executive Summary

COMFOCUS aims to embed reflexivity and responsibility into its activities and to develop procedures and outcomes (frameworks, COMFOCUS Knowledge Platform and best practice guidelines) in line with the principles of RRI. Broadly defined, RRI calls for research and innovation (R&I) actors to align processes and outcomes of research with the needs and values of society. It broadens the conceptualisation of ethics, addressing the purposes, intentions, motivations, and interests early on in the process of research and innovation, with the guiding principles of **transparency, reflexivity, and anticipation**. It requires greater societal engagement of actors that are able to engage throughout the process, under the principles of **openness, inclusion and responsiveness**. It focuses on **collective responsibility and care** about the processes and outcomes of research and innovation.

The current document reviews the relevant literature related to RRI and highlights the ethical, legal and societal frameworks that should inform this. This is done by paying particular attention to the specific characteristics of R&I within the context of food consumer science and highlighting the unique features of research based on traditional, hypothesis-testing approach, and the data-driven approach based on big data. The report identifies a range of values that inform ethical frameworks, and summarises these in terms of respect for autonomy, beneficence, non-maleficence, justice, and explicability. Many of these are reflected in the legal frameworks that are developed to ensure transparent and enforceable procedures of research, primarily implemented through actions of ethics committees and office for data governance within research institutions. Here, the concept of privacy, anonymity, informed consent, data ownership, the right to be forgotten, conditions for data sharing and transparent data management processes are core elements.

The extant ethical values and legal principles are reinforced by the rise of open science agenda that calls for Quality and Integrity, Collective benefit, Equity and Fairness and Diversity and Inclusiveness in the process of doing science. It highlights the FAIR principles (data must be findable, accessible, interoperable and re-usable) that should help scientists comply with the principles of Open Science and drive the collective benefit and responsibility. Nevertheless, the review identifies challenges of applying open science in practice as it pre-supposes activities that can often directly contradict some of the established legal principles such as informed consent, data ownership and the rights to be forgotten. Informed consent, in particular, will need to be addressed by COMFOCUS because in the era of big data and the exponential drive towards

greater openness, the main principles behind informed consent may be over-ridden by the value of collective benefit guiding the agenda of open science.

The report finishes with the framework for reflecting on ethical and legal issues, that was generated through this literature review, and elaborated upon by the members of the COMFOCUS consortium through an interactive, deliberative workshop. Through a process of collaborative reflection, the framework identifies specific tasks and activities within each WP of COMFOCUS that may pose ethical, legal and social challenges, and, through the process of co-creation, it provides solutions to resolve these.

Going forward, it is recommended that each task within each work package must have an item on the agenda dedicated to ethics and governance, so that ethics and governance are included by design. As the Open Calls application process will soon be developed, it is especially important that ethics and governance as well as societal engagement are built into to the Open Calls application process. There also is a need for systematic and broad engagement of a range of stakeholders within COMFOCUS, with Non-Governmental Organisations and citizen representatives (identified in a systematic and transparent way) having an equal say to industry participants. Prior to data collection, specific issues such as the right to be forgotten (withdrawal of data) need to be defined and mechanisms put in place whereby they may be enacted.

It is also of great importance that consideration be given now to the future institutional structure of COMFOCUS. Governance processes need to be embedded into the operations of the future knowledge platform as it is being built. It is not too early to start thinking about the development of university-level agreements, initiatives and standards for working responsibly that will set clear expectations of those coming to COMFOCUS in terms of the conditions and processes they need to comply with.

Ethical and data governance processes, although related, need to be defined in their own right. Steps to ensure the appropriate governance of the COMFOCUS knowledge platform need to include:

- > 1. a standards-setting body to ensure ethical compliance;
- > 2. a minimum set of ethical standards for interacting with COMFOCUS;
- > 3. a gate keeper who ensures compliance and audits the processes;
- > 4. an implementation/enforcement process and structure.

Additional clarity is also needed in relation to the allocation of responsibilities within the research & innovation eco-system, which include not only legal but also ethical and societal responsibilities, in order to ensure greater transparency and instigate collective responsibility.



1. Food consumer science: challenges and opportunities

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COMFOCUS has been set up with an aim of fostering harmonized, user-relevant data-rich science relevant to the study of food choice. This is done through integration of diverse European data sets and research infrastructures contending with the inter-disciplinary nature of the field. COMFOCUS will create an e-infrastructure that will provide methodological guidelines for the optimal measures, best practice for the utilisation of relevant tools and will integrate diverse datasets to enrich and enlarge the pool of data to enable new research insights. A fundamental part of this international initiative is the development of a knowledge platform that enables innovative science in the domain of food choice, using ICT technology and machine learning (ML). The ambition of COMFOCUS is to follow the concepts and principles of open science (Burgelman et al., 2019); it will be developed through adherence to the recommendations for FAIR data. Throughout the lifetime of the project and beyond, COMFOCUS will explore and commit to the principles of Responsible Research and Innovation (RRI).

The current deliverable is a first step towards developing the culture of RRI and informing the development of responsible and ethical governance of the future e-infrastructure/knowledge platform focusing on the determinants of food consumption. Within it we provide an overview of the key principles of RRI, and challenges associated with the core objectives of COMFOCUS from both the ethical and legal point of view, including: the definition and principles of RRI; the ethical and legal frameworks underpinning COMFOCUS; the principles and challenges of open science; the challenges of ethical and responsible research using big data; and the practice of RRI within COMFOCUS. We also recommend an RRI framework based on this literature with a specific focus on the activities and objectives of COMFOCUS. This latter element of the work we report in this deliverable pre-empt the planned activities in T8.3. Here, the RRI framework will be further elaborated through a process of co-production with the whole COMFOCUS Consortium, focusing on the specific ELS issues and challenges facing COMFOCUS, and aiming to create a set of concrete steps to be undertaken in order to address these.

2. Responsible Research and Innovation

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3. Ethical codes of conduct, social and environmental principles, and legal frameworks

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3.1 Ethical Frameworks and Codes of Conduct

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Table 1. Exemplar ethical codes of conduct to inform the working of COMFOCUS

Source	Values	Checking issues
<p>The Belmont Report (1979) – the American Code of Conduct for Bioethics Research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979)</p>	<ul style="list-style-type: none"> - Respect for Persons - Beneficence - Justice 	<p>Values:</p> <ul style="list-style-type: none"> - Respect for Persons <ol style="list-style-type: none"> (1) the requirement to acknowledge autonomy (2) the requirement to protect those with diminished autonomy. - Beneficence <ol style="list-style-type: none"> (1) do not harm and (2) maximize possible benefits and minimize possible harms. - Justice <ol style="list-style-type: none"> (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, (5) to each person according to merit. <p>Applications:</p> <ul style="list-style-type: none"> - Informed consent <ol style="list-style-type: none"> (1) Adequate information (2) Comprehension of information (3) Voluntariness - Assessment of risk and benefits <ol style="list-style-type: none"> (1) Nature and scope of risks and benefits (2) Systematic assessment of risks and benefits

		- Selection of Subjects: fair procedures and outcomes in the selection of research subjects.
ALLEA The European Code of Conduct for Research Integrity, Revised Edition (ALLEA, 2017)	<ul style="list-style-type: none"> - Reliability - Honesty - Respect - Accountability 	<ul style="list-style-type: none"> - Reliability - Honesty - Respect - Accountability
World Health Organization. Code of Ethics and Professional Conduct (WHO, 2017a) and Code of Conduct for responsible Research (WHO, 2017b)	<ul style="list-style-type: none"> - Integrity - Accountability - Independence and Impartiality - Respect for the dignity, equality, diversity and privacy of all persons - Respect for persons and communities, and professionalism in their research engagements. 	<ul style="list-style-type: none"> - Integrity - Accountability - Independence - Impartiality - Dignity of all persons and communities - Personal equality - Personal diversity - Privacy
The British Psychological Society Ethics Code of Conduct (Ethics Committee of the British Psychological Society, 2018)	<ul style="list-style-type: none"> - Respect for the dignity of persons and peoples - Competence - Responsibility - Integrity 	<ul style="list-style-type: none"> - Respect for the dignity of persons and peoples: (1) Privacy and confidentiality; (2) Respect; (3) Communities and shared values within them; (4) Impacts on the broader environment – living or otherwise; (5) Issues of power; (6) Consent; (7) Self-determination; (8) The importance of compassionate care, including empathy, sympathy, generosity, openness, distress tolerance, commitment and courage.

		<p>- Competence</p> <ul style="list-style-type: none"> (1) Possession or otherwise of appropriate skills and care needed to serve persons and peoples; (2) The limits of their competence and the potential need to refer on to another professional; (3) Advances in the evidence base; (iv) The need to maintain technical and practical skills; (4) Matters of professional ethics and decision-making; (5) Any limitations to their competence to practise taking mitigating actions as necessary; (6) Caution in making knowledge claims. <p>- Responsibility</p> <ul style="list-style-type: none"> (1) Professional accountability; (2) Responsible use of their knowledge and skills; (3) Respect for the welfare of human, non-humans and the living world; (4) Potentially competing duties. <p>- Integrity</p> <ul style="list-style-type: none"> (1) Honesty, openness and candour; (2) Accurate unbiased representation; (3) Fairness; (4) Avoidance of exploitation and conflicts of interest (including self-interest); (5) Maintaining personal and professional boundaries; (6) Addressing misconduct.
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3.2 Social and Environmental Principles: Sustainable Development Goals

Table 2. UN Sustainability Goals – the social and environmental principles to inform the working of COMFOCUS

Source	Values	Checking issues
UN Sustainability Development Goals (United Nations)	Sustainable Development Goals	<ol style="list-style-type: none"> 1. End poverty 2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture 3. Ensure healthy lives and promote well-being 4. Inclusive and equitable quality education and promote lifelong learning opportunities 5. Gender equality 6. Water and Sanitation 7. Access to affordable, reliable, sustainable and modern energy 8. Sustained, inclusive and sustainable economic growth, full and productive employment and decent work 9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation 10. Reduce inequality within and among countries 11. Make cities and human settlements inclusive, safe, resilient and sustainable 12. Sustainable consumption and production patterns 13. Climate change 14. Conserve and sustainably use the oceans, seas and marine resources for sustainable development 15. Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss 16. Peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions 17 Strengthen the means of implementation and revitalize the global partnership for sustainable development

3.3 Legal frameworks

Table 3. Legal frameworks to inform the working of COMFOCUS

Source	Values	Checking issues
Universal Declaration of Human Rights (UN General Assembly, 1948)	<ul style="list-style-type: none"> - Human rights values. Specific to science: <ul style="list-style-type: none"> - Free participation in the cultural life of the community, and to share in scientific advancement and its benefits. - Right to the protection of the moral and material interests resulting from any scientific production of which he is the author. 	<ul style="list-style-type: none"> - Human rights values - Participation - Intellectual Property Rights (IPR)
International Covenant on Economic, Social and Cultural Rights (UN General Assembly, 1966)	<ul style="list-style-type: none"> - To take part in cultural life. - To enjoy the benefits of scientific progress and its applications. - To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. - Conservation, development and the diffusion of science and culture. - Respect the freedom indispensable for scientific research and creative activity. 	<ul style="list-style-type: none"> - Participation - Access to results - Application of the results - Archive of the results - Access to academic carrier - Freedom for research
European Convention on Human Rights (Council of Europe, 1950)	(Analogous to the UCHR and ICESCR)	
EU Charter of Fundamental Rights (European Commission, 2012)	(Analogous to the UCHR and ICESCR) <ul style="list-style-type: none"> - Privacy 	- Values from GDPR (See GDPR)
GDPR ("General Data Protection Regulation GDPR, Regulation (EU) 2016/679 ", 2018)	<ul style="list-style-type: none"> - Lawfulness, Fairness, and Transparency - Limitations on Purposes of Collection 	<ul style="list-style-type: none"> - Lawfulness, Fairness, and Transparency - Limitations on Purposes of Collection

Source	Values	Checking issues
	<ul style="list-style-type: none"> - Processing, and Storage Data Minimization - Accuracy of Data - Data Storage Limits - Integrity and Confidentiality 	<ul style="list-style-type: none"> - Processing and Storage Data Minimization - Accuracy of Data - Data Storage Limits - Integrity and Confidentiality
UNESCO's open science values (UNESCO, 2021)	<ul style="list-style-type: none"> - Collective Benefit - Equity and Fairness - Quality and Integrity - Diversity - Inclusiveness 	<ul style="list-style-type: none"> - Collective Benefit - Equity and Fairness - Quality and Integrity - Diversity - Inclusiveness

4. Informed Consent

Informed consent is a principal instrument to enable compliance with legal and ethical requirements of doing scientific research with human subjects. Our modern day ethical and legal compliance requirements related to *'Informed Consent'* for research involving human subjects have essentially resulted from the need to protect two fundamental human rights, those of *'Autonomy'* and *'Privacy'*.

4.1 Autonomy

Section redacted

4.2 Protection of privacy through data protection

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5. Open science and open innovation: principles, values and the relevance to COMFOCUS

The context within which GDPR and ethical frameworks are being applied is rapidly changing. One of the biggest recent advances is in promoting the principles of Open Science and innovation, in line with the concepts of RRI. As an early initiative, the impact of shifting scientific processes towards greater openness is still being assessed and debated. What is clear is that it will challenge scientists on how they are to simultaneously uphold the principle of openness whilst at the same time protecting privacy through implementing the established approaches to informed consent. Below we discuss in greater detail the principles, values, goals and challenges of the Open Science and innovation initiative.

5.1 Definition, principles, and values

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5.2 Limits and challenges related to open science

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5.3 Other open science initiatives

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6. COMFOCUS and big data: Ethical issues in data-driven research

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7. Doing RRI in COMFOCUS

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Table 4. Values to inform COMFOCUS work:

Values	Issues/challenges	Main data activities involved
Respect for autonomy	informed consent ownership of data and access conditions privacy regarding data content right to withdraw	Collect Process Curate Custody Analyse Link Normalize Delete Disseminate
Beneficence	incidental findings	Process Curate Custody Analyse Link Normalize
Non-maleficence	incidental findings privacy	Same as in the above cell but related to data which content is private.
Justice	accessibility bias equality non-discrimination no bias	Collect Process Curate Custody Analyse Link Normalize Delete Disseminate
Explicability	equality non-discrimination open access openness accessibility interoperability	Process Curate Analyse Link Normalize
Integrity	veracity vigilance	Process Curate Analyse Link Normalize Delete

8. The RRI Framework for COMFOCUS – analysis of COMFOCUS related activities and their ethical and legal implications / RRI

Our first task was to engage reflexively with the ethical, legal and societal considerations for all aspects of COMFOCUS. This was done through WP8 Workshop held on the 17th of November 2021. During the workshop, the COMFOCUS consortium reflected about the core challenges that we are facing within the project and engaged in reflective and transparent approaches to these challenges. A framework of decision-making was provided to stimulate scientists and innovators within COMFOCUS to think reflectively about their activities. We detail this thinking in Table 5 as it pertains to WP2-7, as JRI within the project. Table 5 (below) should be utilised by WP leaders as an initial set of challenges associated with ethical, legal and social issues identified through the process of co-production by the COMFOCUS consortium as a whole. The analysis presented within the table is organised around three components: the specific issue/challenge; the description of the issue as it manifests itself within COMFOCUS; possible steps to resolve it. This table does not cover a complete set of issues nor is it a finite set of recommended actions and steps that the Consortium should undertake as part of RRI and FAIR. It is intended as a stimulus for further engagement of all Consortium members responsible for delivering the project both in terms of raising awareness about these issues, but also in terms of providing ideas and stimulating thinking about how to address ELSI within the specific areas of work in COMFOCUS. We suggest that each WP leader takes forward the identified challenges and has ELSI as a standing item within their working packages. Each WP leader must report back to the MC meetings on Fridays on how they have addressed and progressed discussions on ELSI within their WPs.

Table 5. Analysis of COMFOCUS related activities and their ethical, societal and legal implications / RRI by work package.

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9. Conclusions and future direction

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