MICROBiome-based biomarkers to PREDICT decompensation of liver cirrhosis and treatment response

D8.4 Codes of conduct applicable and research integrity policy including publications in journals

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Abbreviations

EFClif	European Foundation For The Study of Chronic Liver Failure
UNIDEB	Debreceni Egyetem (University of Debrecen)
OUH	Odense Universitetshospital
SDU	The University of Southern Denmark
UCPH	University of Copenhagen
EMBL	European Molecular Biology Laboratory
CEA	Commissariat à l'Energie Atomique et aux Energies Alternatives
MPG	Max-Planck-Gesellschaft zur Foerderung der Wissenschaften e.V.
Vaiomer	Vaiomer SAS
INRA	Institut National De La Recherche Agronomique
GUF	Johann Wolfgang Goethe-Universität Frankfurt Am Main
KU Leuven	Katholieke Universiteit Leuven
LUMC	Academisch Ziekenhuis Leiden
UB	Universitat de Barcelona
Biobyte	Biobyte Solutions GmbH
ICN2	Fundacio Institut Catala De Nanociencia i Nanotecnologia
UCL	University College London
UiO	Universitetet I Oslo
ELPA	European Liver Patients Association
Concentris	concentris research management GmbH
KCL	King's College London
FCRB	Fundacio Clinic Per a La Recerca Biomedica
EASL	European Association for The Study of the Liver

H2020	Horizon 2020
APC	Article Processing Charge
ALLEA	All European Academies
CIOMS	Council for International Organizations of Medical Sciences
LERU	League of European Research Universities
DORA	Declaration on Research Assessment
GDPR	General Data Protection Regulation (EU) 2016/679
OA	Open Access
ICMJE	The International Committee of Medical Journal Editors
RCR	Responsible Conduct of Research
CoI	Conflicts of Interest
MPDL	The Max Planck Digital Library
CIRAD	French Agricultural Research Centre for International Development
GRP	Good Research Practice
COSCE	Confederation of Scientific Societies of Spain
CBUB	University of Barcelona's Bioethics Commission
COPE	Committee on Publication Ethics
OBD	UB Bioethics and Law Observatory
UKRI	UK Research Councils
UKRIO	The UK Research Integrity Office
IDIBAPS	August Pi i Sunyer Biomedical Research Institute

Table of Contents

1 Executive Summary

This document analyzes the current codes of good conduct published by each member of the MICROB-PREDICT project, discusses what is included, any references to national or international guidelines, how easily accessible the relevant information is from the home page and the general usefulness of the document for the members of the institutions themselves and the public. Institutional policies on open access publishing are also included in the discussion. At the end, there are 10 recommendations of useful points that each code of conduct should include based on the best examples extracted from the MICROB-PREDICT partners.

2 Introduction

A code of conduct is an essential document for any public or private institution. Within this document, an institution can provide clear guidance to its staff (and students) on the behavioral standards expected, and can also show to the public, in a transparent manner, what these standards are and how they are met by the institution.

While many people working in the scientific and healthcare sector would agree that their work is for the direct benefit of society, this very same society can often feel in the dark about exactly what goes on at the institutions and hospitals that they themselves fund with their tax contributions. We are now facing a rise in “the empowered citizen”, one who is autonomous in their healthcare decisions, and has a desire to know their options and what is the best healthcare plan for them and why. This has opened a new door for many medical professions that has traditionally been closed: the patient may now be aware of their options before they come to the clinic. The rise of social media and open science on the internet has enabled citizens to delve into new scientific and healthcare discoveries and has increased their curiosity to know more about exactly what goes on behind closed doors. The scientific and healthcare community must now respond to this increased demand for transparency.

Codes of good scientific practice are not a new concept. The community has long been in possession of best practice 'guidelines', from the famous Nuremburg Code[1] of 1947 to the Council for International Organizations of Medical Sciences (CIOMS) international ethical guidelines for health-related research involving humans[2], first published in 1983. Considering the great cultural, social and economic differences that affect the way each country carries out its research activity, it can be difficult to draw up one set of guidelines that will apply to every country.

Therefore instead, it is suggested that these international codes of conduct act as templates to be followed by each country to draft their own code of conduct, with rules and policies specific to their national structure and systems, that will identify with both their workforce and citizens. In the European context, the All European Academies (ALLEA), a consortium of 50 academies from almost all EU member states, has done this with their European Code of Conduct for Research Integrity[3], first published in 2017. This important document is intended to serve as a framework of self-regulation for the European research community. The ALLEA Code states four core principles of good research practice: reliability, honesty, respect and accountability, and gives recommendations on how to respond adequately to violations of these principles.

The Singapore Statement on Research Integrity[4], published in 2010, states that it is "*intended to challenge governments, organizations and researchers to develop more comprehensive standards, codes and policies to promote research integrity both locally and on a global basis*". Like the ALLEA code, the Singapore Statement also lays out four basic principles for research integrity: Honesty, accountability, professional courtesy and fairness and good stewardship. While the two documents differ slightly in their chosen principles, the

[1] The Nuremberg Code (1947). (1996). BMJ, 313(7070), 1448-1448. doi: 10.1136/bmj.313.7070.1448

[2] Revised CIOMS International Ethical Guidelines for Health-Related Research Involving Humans. (2017). JAMA, 317(2), 135. doi: 10.1001/jama.2016.18977

[3] The European Code of Conduct for Research Integrity. (2017). Retrieved 20 December 2019, from https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf

[4] Singapore Statement on Research Integrity. (2010). Retrieved 20 December 2019, from https://wcrif.org/guidance/singapore-statement

overall idea is the same: responsible research, with a solid foundation of integrity and ethical principles, is vital to all disciplines, worldwide, and will increase the validity of results and the public trust. Both the ALLEA Code and the Singapore Statement are frequently cited as the inspiration for many national and institutional codes of conduct. With regards to the MICROB-PREDICT project itself, which has received funding from the European Union's Horizon 2020 research and innovation programme, all participants are required, as stipulated in the Grant Agreement article 34, to "...*respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity*".

Regardless of the chosen 'guide code', (there are many very good, comprehensive options aside from those mentioned above), it is imperative that research institutions, and other public and private bodies associated with, or involved in research projects, have a code of conduct for research integrity or good practice. With no clear guidelines, procedures or principles, it is left to the responsibility of individuals to decide what good research practice is. In reality, many issues that may arise in this environment, whether they could be ethical dilemmas or issues with conduct, can often be "grey areas", and many researchers can be left feeling out of their depth in deciding what "the right thing to do" is. Any person working in research, irrespective of the discipline, may at some point face one of these dilemmas. Having a clear and available code of conduct and a contact person to anonymously discuss it with is fundamental to ensuring that staff feel supported and able to make good choices and speak up when they see others doing less. By attempting to regulate and eradicate research misconduct, institutions can take one step further towards valid, reproducible results, that will benefit all of society.

In addition to the researchers themselves, the public also benefits from seeing an institutional code of conduct. When made available on the website, members of society can easily access a code of conduct and be assured that this is something that is a top priority for public institutions and handled in a correct and transparent manner. In an ever more connected society, where the public are increasingly aware of high-profile misconduct cases, it is vital that instructions are clear on their policies, take research misconduct seriously and protect their reputation as public institutions of good practice. Research is a multidirectional

process with many actors, trust between them is therefore paramount for the validity of the final result.

However, research nowadays is not only made up of public institutions. The rise of large cross-border collaboration projects such as the MICROB-PREDICT programme, often include private companies, hospitals, and non-profit organizations. In addition to this, the meteoric rise in next generation technologies and big data projects has also seen the inclusion of software development and data management and protection companies. With this comes a whole host of additional privacy protection and financial issues that must be taken into account, addressed and dealt with in a transparent manner.

While not all of the actors in these large projects carry out basic scientific research themselves, they are implicated in the data processing, have access to the results, and are therefore just as responsible for the outputs as the researchers themselves. Therefore, it is recommendable that these private entities also take the time to develop a code of good conduct, relevant to the work they carry out. This may include for example, a code of conduct for non-profit organizations on ethical conduct in accepting donations and working with other private entities, transparency in their financial and governance reporting, and a clear statement on their accountability.

Advice on what to include in a code of conduct can be found in any of the documents listed above, taken as international and national frameworks, but one very useful document in this sense is that published by the league of European research universities (LERU): *Towards a Research Integrity Culture at Universities*[5]. This report is focused on ways in which research institutions can promote a culture of research integrity and trustworthy research. One very useful feature of the report is the examples given by the universities that form the LERU (some of which are partners of MICROB-PREDICT) on how they are implementing good research practices at their institutions. In addition to this, LERU have also published an

[5] Towards a Research Integrity Culture at Universities (2020). LERU. https://www.leru.org/publications/towards-a-research-integrity-culture-at-universities-from-recommendations-to-implementation

advice paper "Open Science and its role in universities: a roadmap for cultural change"[6]. The main idea highlighted here is the importance of the cultural change needed at research institutions to move to an open science model. The current system of evaluation of scientific research and publications, and the researchers themselves, based on impact factors and subscription-based publishing models is something that many research institutions are trying to move past. This, however, is a notion engrained in academia, and it will be a great effort on behalf of all of those involved to change this mentality. The document highlights eight areas of open science (the future of scholarly publishing, FAIR data, the European Open Science Cloud, education and skills, rewards and incentives, next-generation metrics, research integrity, and citizen science) and the advantages and challenges that each will pose. What is needed to bring about this change? Adequate resources and leadership; targeted measures; transparency, accountability and monitoring; and trust and confidence in the shared vision. The declaration on research assessment (DORA)[7] is a worldwide initiative developed in 2012, covering all scholarly disciplines and stakeholders, which aims to change the way scholary output is assessed. The recommendations include a decreased relianace on journal impact factors, assessment of research on its own mertits, and capitalizing on the increase in online resources and publications. Research institutions can sign the DORA declaration if they are in accordance with its principles.

For data management and software companies, the introduction of the General Data Protection Regulation (EU) 2016/679 (GDPR)[8] in the EU must also be addressed. These companies should now be compliant with these regulations and include exactly how they achieve this in a code of good practice. It is important that members of the private sector involved in large projects such as MICROB-PREDICT, are held to the same integrity standards

[6] Open Science and its role in universities: a roadmap for cultural change (2018). LERU. https://www.leru.org/publications/open-science-and-its-role-in-universities-a-roadmap-for-cultural-change

[7] The San Francisco Declaration on Research Assessment (DORA). https://sfdora.org/ (Accessed 16 March 2020)

[8] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)

https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1576845353123&uri=CELEX%3A32016R0679

as their public counterparts, to ensure that all members know which standards each one holds and how they deal with privacy issues and misconduct.

In addition to research integrity, there is also a general push in the direction of the Open Access (OA) publishing model. Currently, beneficiaries of Horizon 2020 funding "*must ensure open access to all peer-reviewed scientific publications relating to its results*", therefore all partners of MICROB-PREDICT are obliged to implement this regarding the results produced from their research under the project. The International Committee of Medical Journal Editors (ICMJE) have published their recommendations for the conduct, reporting, editing and publication of biomedical and clinical research, which have recently been updated in 2019[9]. Updates to this document include widening the concept of conflict of interest to the broader term "disclosure of relationships and activities", which includes not only those directly related to the work, but those topically related, too. This will be important for the project partners to take into consideration when disclosing their own conflict of interests in future publications, and also something to consider when defining conflicts of interest in their code of good practice. By taking a clear stance on disclosure of conflicts of interest institutions can demonstrate their commitment to transparency and building public trust in scientific research.

In the following, we present the status quo of code of conduct documents and open access policies of the MICROB-PREDICT partners.

3 UNIVERSITY OF DEBRECEN

3.1 UNIDEB Code of Conduct

The University of Debrecen (UNIDEB) has a code of conduct entitled: Code of Conduct for Research Integrity: Science ethic codes in Europe and Hungary[10]. This document was made in 2018 by UNIDEB professor Dr. László Fésüs, who was also involved in the drafting of the ALLEA report as a member of the committee. References to international organizations such

[9] Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (2019) *International Committee of Medical Journal Editors* http://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_dec19.pdf

[10] UoD Code of Conduct (2018) https://unideb.hu/en/node/3271

as the World Medical Association and UNESCO, who have previously published key documents in medical ethics guidelines, are included in the first part of the code. One very useful inclusion is that of the European maps which are color coded according to whether that country has a national framework to deal with research misconduct established by law or not, taken from The Lancet. In addition to this, the guidelines also state the year in which many countries published their guidelines. Next, the document goes on to explain the points raised in the Science Ethics Code of the Hungarian Academy of Sciences, which deals with the ethics and morals of good scientific practice and research conduct, and those in the ALLEA code. The Hungarian Academy of Sciences code and that of ALLEA appear to be the basis for the universities recommendations on good practice. Overall, the document is well prepared, in clear language and complete with appropriate references.

In addition to the code of conduct for research integrity, there are numerous links on the "General Research Methods" section of the website. The University runs a course obligatory for 1st year PhD students entitled "General Research Methods" every Friday from February to May, which covers topics such as science ethics codes in Europe and Hungary, IP protection, scientific integrity and publication. The University has uploaded numerous presentations from its professors on technology transfer, choices of publication and other topics. The code of conduct and the links mentioned above were not found on the homepage of the university, instead, these were obtained using the websites search function for "code of conduct". The section is displayed in Hungarian and English and has a host of useful and relevant documents for students and researchers alike; however, it could be positioned in a more accessible location from the homepage.

3.2 UNIDEB Open Access Policy

Regarding the university's position on open access (OA) publishing, this is very clear on the library webpage[11]. The UNIDEB will not oblige affiliated researchers to publish in OA, unless specified in their grant agreements; however, they do provide support and guidance on choosing the best outlet, identifying creditable journals and support for the payment of article processing charges (APC).

[11] UoD Open Access Support https://lib.unideb.hu/en/node/711

4 THE ODENSE UNIVERSITY HOSPITAL

The Odense University Hospital (OUH) abides by the national Danish Code of Conduct for Research Integrity[12], as do all public Danish research institutions. This document was developed by the Ministry of Higher Education and Science and the organisation Universities Denmark. In addition, all eight Danish universitites were involved, as well as the national research councils. Finally, before publication, public consultation and conference discussion of the code was carried out. This is the best way to ensure that the code resonates with all actors involved: the institutes, governing bodies and the public. Published in 2014, the code begins by listing the three ethical principles of research integrity: honesty, transparency and accountability, stating "*Researchers and institutions should be aware of their responsibilities to the research community, to the funders of research activities and to society at large*". Like other codes of conduct, the Danish guide lists the Singapore statement on research integrity, the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013)[13] and the ALLEA code as of particular importance. The Danish code for research integrity then lists six basic standards for conducting responsible research, as follows:

1. Research planning and conduct
2. Data management
3. Publication and communication
4. Authorship
5. Collaborative research
6. Conflicts of interest

The sections are very clearly laid out and are scattered with helpful definition boxes and recommendations, making the code easy to follow and implement. The following sections deals with research integrity in training, teaching and supervision, and finishes with how cases of research misconduct should be handled. Overall, this is a very succinct and informative code of conduct, which covers all the necessary points in a concise and easy to

[12] The Danish Code of Conduct for Research Integrity (2014) https://ufm.dk/publikationer/2014/the-danish-code-of-conduct-for-research-integrity (Accessed 17 March 2020)

[13] The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013) http://ethics.iit.edu/codes/WCRI%202013.pdf (Accessed 27 March 2020)

understand manner. All Danish public institutions must follow this code of conduct but have local control over how it is implemented.

The SDU library provides information on the university OA policy[14] and offers explicit courses on responsible conduct of research[15]. Regarding OA, SDU states that all research output should be deposited in the institutional repository. Furthermore, SDU states its support for the national OA plan, which stipulates that all publicly funded research output should be made publicly available through the Green OA route. SDU also advises all researchers to be sure of the quality of any OA jurnal that they are considering publishing with. It would be recommendable to include some of this information on the OUH webpage.

5 THE UNIVERSITY OF COPENHAGEN

5.1 The University of Copenhagen Responsible Conduct of Research

The University of Copenhagen (UCPH) is a great example of how to clearly show that research integrity and good practice are a priority for your university. On the homepage of the faculty of health and medical sciences, under the research tab, there is an entire section "Responsible Conduct of Research (RCR)"[16]. This section begins with an introduction to the named person and all of their contact information. There is complete and easy to understand information on all of their courses in this area for PhD students, postdocs and principle investigators. For postdocs and assistant professors, it is mandatory to attend the three-hour workshop on RCR, which are held monthly. Following this, there is a section linking the Danish Code of Conduct for Research Integrity[17], the responsible conduct of research at UCPH (only accessible for members of the university), the Vancouver guidelines,

[14] Open Access at SDU

https://www.sdu.dk/en/forskning/forskningspublicering/open+access/open+access+paa+sdu (Accessed 27 March 2020)

[15] SDU RCR Course for PhD students

https://www.sdu.dk/en/bibliotek/forskere/responsibleconduct/rcrcoursephdstudents

[16] KU Responsible Conduct of Research https://healthsciences.ku.dk/research/responsible-conduct-of-research/

[17] The Danish Code of Conduct for Research Integrity (2014) https://ufm.dk/publikationer/2014/the-danish-code-of-conduct-for-research-integrity

as well as various documents related to scientific misconduct and how this is handled by the practice committee at UCPH. While it is reasonable that some documents on internal university procedure will only be accessible for members of the institution for privacy reasons, it may be useful for the European and international community to have access to a version of these documents for reference e.g., the responsible conduct of research at UCPH.

5.2 The University of Copenhagen Open Access Policy

Similar to the University of Debrecen, there are also clear guidelines on UPCH's position regarding OA publishing on their library website[18], and again, it is strongly encouraged, but not obligatory, for affiliated researchers to publish in OA. Journal APCs appear to be supported in the form of discount schemes, but further information is only accessible for members of the UPCH community.

6 THE EUROPEAN MOLECULAR BIOLOGY LABORATORY (EMBL)

6.1 EMBL Code of Good Practice

The European Molecular Biology Laboratory (EMBL) has a very clear and easily accessible code of good practice in relation to donations. This code details how the institute will handle donations and what they will be used for. Additionally, the institute is clear on its diversity policy with webpages dedicated to its equality and diversity policy when hiring personnel.

The EMBL has a code of conduct, and additional policies on equality and diversity and an anti-harassment policy. Individuals interested in having access to this information may contact the EMBL (events@embl.de). There is a training course entitled "Biomedical data: Ethical, legal and social implications"[19] which was developed during a previous EU project (BioMedBridges), however, this course is not mandatory for EMBL researchers..

[18] KU Open Access https://culis.ku.dk/usethelibrary/researchers/open-access/

[19] EMBL Biomedical data: Ethical, legal and social implications https://www.ebi.ac.uk/training/online/course/biomedical-data-ethical-legal-and-social-implicati

6.2 EMBL Open Access Policy

The EMBL's policy on OA is very clear[20]. They published their OA policy in 2015, which states that all EMBL affiliated researchers must deposit their articles in Europe PubMed Central ithin six months of publication, and it is strongly recommended that research articles are published in OA with a Creative Commons attribution (CC-BY) license. Where the APC has been paid by the EMBL, this is mandatory. The EMBL also has a number of deals with various publishers for discounts to the APC.

7 FRENCH ALTERNATIVE ENERGIES AND ATOMIC ENERGY COMMISSION

The French Alternative Energies and Atomic Energy Commission (CEA) is a center of excellence for research in renewable energy and technology for the physical and life sciences. They have published documents on sustainable radioactive waste management and their annual and financial reports.

8 THE MAX PLANCK SOCIETY FOR THE ADVANCEMENT OF SCIENCE

8.1 MPG Code of Conduct

The Max Planck Society (MPG) has an in-house code of conduct[21], which begins by stating their core values: "We treat each other with respect; We act honestly, ethically and with integrity; We communicate transparently and respectfully both internally and externally". Following this are eight principles of good practice, which the society insists upon for "all staff, scientists, directors, and guests". The first principle relates to "high-risk high reward fundamental research" which the MPG is committed to, but states that despite this, the benefit of all humankind is the primary interest. Secondly, science as a diverse workplace, that does not tolerate any form of discrimination. Next, maintaining the highest quality of scientific research with regular evaluations from external experts to uphold these high standards. The MPG states here that it values scientific quality over quantity. The fourth point explicitly states that all issues within the society will be discussed and solved openly

[20] Open Access at EMBL https://www.embl.de/services/library/open-access-information/open-access-at-embl/index.html

[21] Max Planck Society Core Values (Code of Conduct) https://www.mpg.de/14172230/code-of-conduct.pdf

and respectfully. Following this, the MPG states that it aims for a collaborative workplace where the achievements of all are celebrated. The sixth point relates to the competitiveness of sciences, something that is recognized by the MPG. Despite this, the society is clear that they respect individual capabilities and needs and aim to build a "nurturing work environment based on trust and mutual respect". The penultimate point relates to respect for work colleagues, to the public who fund the research and to the environment. Lastly, the MPG make it clear that they will communicate with each other and the public openly and with transparency, using a variety of channels for public outreach.

The code of conduct is written in clear, plain language, accessible to all, and is located in the "About us" section on the homepage under procedures and regulations. In relation to the other codes of conduct, which often relay general ethical principles laid out in the European and international guidelines, the MPG code of conduct is personalized to their society and workforce, while still retaining the most important points of good practice.

8.2 Other Useful MPG Documents

In addition to the code of conduct, there is a multitude of other documents and resources on good research practice[22], including MPG procedures, IT security guidelines and policies on discrimination and harassment.

The society has also published rules for research groups, scientific advisory boards and group leaders. One especially relevant document by the society is the "Rules of Good Scientific Practice"[23] last amended in 2009. This document gives a detailed analysis of the principles and conditions for good scientific conduct, and includes guidelines for junior scientists, scientific publications, conflicts of interest (CoI) and whistleblower protection. It is very clear from this document that any form of miscount will not be tolerated at the MPG. This section on good practice should serve as an example to other institutions on how to make your stance on misconduct clear. It is evident that the MPG puts good scientific practice at the forefront of its vision.

[22] MPG Procedures and Regulations https://www.mpg.de/about_us/procedures

[23] MPG Rules of Good Scientific Practice (Adopted 2000, updated 2009) https://www.mpg.de/197494/rulesScientificPractice.pdf

8.3 MPG Open Access Policy

Regarding its policy on OA publishing, the MPG is equally clear. Relevant information on OA models and publishing can be found on the main menu of the library webpage[24]. The Max Planck Digital Library (MPDL) has a number of agreements with publishers to waive article charges or provide discounts. The MDPL does not cover the "hybrid" publication model. Their stance is well defined, and they have plenty of information and a very clear PDF explaining their position on OA.

9 VAIOMER

Vaiomer is a biotechnology company founded by two French researchers, Rémy Burcelin (Inserm) and Jacques Amar (CHU Toulouse), in 2011. It is a Contract Research Organization and with expertise in tissue and blood microbiota. Since it is not a research centre it has no code of conduct for research. The company website mentions and names their scientific advisory board and gives plenty of information on their research and publications. Some of their recent articles have been published in OA journals.

10 NATIONAL INSTITUTE OF AGRICULTURAL RESEARCH (INRA)

10.1 INRA Code of Conduct

Like the MPG, the National Institute of Agricultural Research (INRA) also has a wealth of information on good practice on their homepage under the objectives tab. There is a section entitled: Promoting ethics and a code of conduct, where one can find all of the relevant codes of conduct and ethics information. The INRA have published a professional ethics charter[25] where they have detailed 14 principles on ethics and research practices for managers and team members, data protections, publication, evaluation and transparency. Important documents such as the Singapore Statement on Research Integrity and the French law no. 83-634 (Rights and Obligations of Officials) are mentioned as the basis for this text, which states "*INRA's central management promotes ethical principles in research*

[24] MPG Open Access Publishing https://www.biochem.mpg.de/877897/publishing

[25] INRA Ethics Charter (Published 2013, updated 2015) http://institut.inra.fr/en/Objectives/Promoting-ethics-and-a-code-of-conduct/All-reports/Ethics-Charter/Professional-Ethics-Charter

practices: objectivity, impartiality and independence, honesty and reliability, integrity and transparency". The ethical watch committee is also mentioned in the text as a body which can provide advice, support and training for all members of the INRA. The layout is clear and all points are well-explained.

The French National Charter for Research Integrity[26] published by the INRA, was signed in 2015 by a number of large French research institutes and is based on the ALLEA Code, the Singapore Statement and the European Charter for Researchers, and in line with the HORIZON 2020 framework. All researchers at the involved institutes are advised to comply by the principles mentioned in the Charter, which include compliance with legislation, communication, impartiality, collaboration and training.

The INRA ethics committee is joint with the French Agricultural Research Centre for International Development (CIRAD) and the French Research Institute for Exploitation of the Sea (IFREMER)[27]. The core principles of the INRA-CIRAD-IFREMER Ethics Committee are published online, are very clear and accessible, and begin with the following sentence "*The Joint Ethics Committee holds the recognition of human dignity as a fundamental value*" citing the Universal Declaration of Human Rights of 1948. Following this are five more guidelines pertaining to the sustainable development and environmental research conducted at the three institutes.

10.2 INRA Open Access Policy

Concerning the OA policy of INRA, this is very clear. The institute released a position paper on open access and open data policy in 2016[28]. The document begins with the goals of INRA relating to open access, which are as follows:

[26] French National Charter for Research Integrity (2015) http://institut.inra.fr/en/Objectives/Promoting-ethics-and-a-code-of-conduct/All-the-news/National-Charter-for-Ethics-in-Research-Activities

[27] Joint Consultative Ethics Committee: INRA, CIRAD and IFREMER. Retrieved 25 March 2020, from https://www.inrae.fr/en/ethics-committee

[28] INRA Open Access and Open Data Policy (Published 2016, updated 2017)

http://institut.inra.fr/en/Overview/Documents/Position-papers/INRA-releases-official-open-access-guidelines#

- By **making data open access**, the institute is increasing the transparency of its research and improving the dissemination of its results to the general public, journalists, stakeholders in civil society, and non-governmental organizations and encouraging citizen science.
- By **encouraging data reuse**, the institute seeks to create additional value from research investments and fuel innovation.

INRA then proceeds to explain the seven principles that will help them achieve these two goals. The guideline state that research coming from the INRA should be OA wherever possible. Additionally, the guidelines explain that publications should be deposited in ProdInra, the institutions digital repository. The publication list of each researcher in this database alone will be used for promotion and hiring purposes, thus further encouraging researchers to publish in an OA model. Each research project is obliged to help pay for APCs and data sharing and archiving processes.

11 GOETHE UNIVERSITY FRANKFURT

11.1 GU Code of Conduct

Goethe University Frankfurt (GU) has published a course related to the training of its doctoral students entitled "good academic practice"[29]. This tool is advised for junior researchers and is intended to familiarize them with the principles of good academic practice and with "*possible situations and constellations where these standards will come under pressure*".

In addition to this, GU also has a policy on good scientific practice, published in PDF form[30]. The senate approved this document in 2005. In the preamble, it is stated that scientific misconduct "*undermines the public's trust in science, as well as among scientists themselves*" and that the document aims to raise awareness of good practice and limit the potential for misconduct. Included in the first part of document are numerous subsections dealing with

[29] Johann Wolfgang Goethe University eLearning "Good Academic Practice during Doctoral Studies" http://www.goethe-university-frankfurt.de/54293778/Good_Academic_Practice_during_Doctoral_Studies?)

[30] Johann Wolfgang Goethe University policy regarding good scientific practice (Approved 2003, updated 2005) http://www.uni-frankfurt.de/39848797/good_scientific_practice.pdf?

general principles, collaborations, supervision of junior scientists, the criteria for measuring achievement and performance, data storage and scientific publications. The second part of the document deals with avoiding scientific misconduct and outlines the universities procedure in dealing with misconduct. Importantly, the document states that university departments are "*expressly encouraged*" to teach the university's code of conduct in their curriculums.

While the code is written in clear language and is well laid out, it was not found via any of the links on the homepage, but rather by a search of "good practice" in the webpage search bar, which brings up the PDF only. It is not clear where on the website this document can be found, or if there is anymore information regarding the GU policy on good research practice. It would be recommended that this document is made more visible from the homepage, for example, under the "Research" or "About the University" tabs.

11.2 GU Open Access policy

The GU OA policy itself is in German, however, there is plenty of other information on the website where one can find information on the different modes of OA publishing and the requirement of the EU funded projects to be in OA[31].

12 THE KATHOLIEKE UNIVERSITEIT LEUVEN (KU Leuven)

12.1 KU Leuven Code of Conduct

Another great example of how to clearly display a university's good research practice policy is from the Katholieke Universiteit Leuven (KU Leuven). From the homepage, it is only two clicks and one is taken to a webpage of the KU Leuven research policy plan[32], which displays its top five agendas for 2018-2020, the fifth being: *KU Leuven wants to pursue a responsible ethical and integer research agenda completely in line with Rector Sels' vision in "Integrity and trust: absolutely vital for a university"*. Below this, one can find links to the homepages for research integrity and the KU Leuven OA policy.

[31] GU Open Access for Publications http://www.goethe-university-frankfurt.de/60764153/Open_Access

[32] KU Leuven Vision and Policy https://www.kuleuven.be/english/research/policy/index

On the homepage for Research Integrity, in large text, KU Leuven makes it clear that their objective is "*the research at KU Leuven should meet the highest standards and correct scientific behavior is the norm at KU Leuven*".

The university follows the Belgian code of conduct[33] for research integrity nationally, and on the European level, the ALLEA code. The "Code of Ethics for Scientific Research in Belgium" was produced jointly by "*the Académie Royale des Sciences, des Lettres et des Beaux Arts de Belgique, the Académie Royale de Médecine de Belgique, the Koninklijke Vlaamse Academie van België voor Wetenschappen en Kunsten and the Koninklijke Academie voor Geneeskunde van België, supported by the Federal Public Planning Service Science Policy*". The introduction of this ethics code states that it "*demonstrates to citizens, who finance the majority of research and reap the benefits, that the world of research is developing its own tools to guarantee responsible research*", and that it should be applied to all research disciplines. The code emphasizes how important ethical behavior and self-reflection are for researchers, and that particular attention must be given to this when training the next generation of young researchers. Next, there are three sections, each elaborating on a pair of keywords as follows: Rigor and caution; Reliability and verifiability; Independence and impartiality. Splitting the code into these three sections, renders the information well-presented and easily digestible. Overall, the code promotes scientific knowledge and rationale above any personal reason or interest, and that all tasks be carries out in the most rigorous way possible without any cutting corners.

12.2 KU Leuven Good Practice

Next, a brief elaboration on the other useful resources in the KU Leuven section of Good Practices[34]. The section Supervision and Mentoring contains a link to the charter of the PhD researcher and the supervisor. Here, one can find principles that should be abided by, by both the student and supervisor on issues such as good scientific conduct, handling

[33] Codes of Ethics for Scientific Research in Belgium (2009)
https://www.kuleuven.be/english/research/integrity/practices/belspo-code

[34] KU Leuven Good Practices https://www.kuleuven.be/english/research/integrity/practices

misconduct and publication ethics. Additionally there is a checklist[35] for fair and honest scientific conduct for doctoral researchers and their supervisors, in which there are links to ethics codes, KU Leuven policy on authorship, conflicts of interest etc. This checklist contains all relevant university policies and would serve as a great example to other universities looking for a way to organize their policies in a simple way for students and staff. The university has also linked a great infographic on five ways supervisors can promote research integrity[36], by the US Office of Research Integrity, which can be printed and hung in the office or lab.

The next section of the webpage deals with publication and authorship, and KU Leuven clearly states that they encourage staff to adhere to best practices and guidelines. The KU Leuven policy on authorship cites the COPE guidelines and those of Harvard University and the University of Melbourne. Affiliations, journal quality and peer review (coming soon), are also expanded upon in their own sections.

KU Leuven have published their own guidelines for good management of research data in the data life cycle under the good practice webpage (only available for KU Leuven personnel). Regarding image processing, KU Leuven has also published six principles detailing image filtering, adjustment and enhancement to make clear what is acceptable and what is not. They have also published a PDF of some examples of western blots and microscopy images that have been misrepresented[37]. Finally, KU Leuven have also dedicated a section to conflicts of interest, which state that a conflict of interest is not always a bad thing but should always be disclosed to the correct body at the correct time. Reference is also made to the KU Leuven conduct on conflicts of interest and conflicts of commitment concerning spin-offs document, which is published in Dutch only.

[35] KU Leuven CHECKLIST for doctoral researchers and their supervisors
https://www.kuleuven.be/english/research/integrity/Checklist

[36] US Office of Research Integrity - 5 ways supervisors can promote research integrity
https://www.kuleuven.be/english/research/integrity/practices/SupervisorTips

[37] KU Leuven Guidelines for Laboratory and Clinical Image Processing
https://www.kuleuven.be/english/research/integrity/practices/image-processing

12.3 KU Leuven Open Access Policy

KU Leuven supports OA publishing[38] both the green and gold (non-profit) models, and also has its own institutional repository, Lirias (Leuven Institutional Repository and Information Archiving System). The costs of OA publishing are supported by the Fund for Fair OA. There is abundant information on which institutes KU Leuven support, and help to personnel is also provided.

13 LEIDEN UNIVERSITY MEDICAL CENTER (LUMC)

13.1 LUMC Code of Conduct

Good research practice and integrity are to be found easily under the research tab on the main website for the Leiden University Medical Center (LUMC). The university states that all employees, PhD students, and those using LUMC facilities are expected to conduct their activities "*according to the highest ethical and professional scientific standards*". The LUMC research code[39] is published in Dutch and English and both contain a separate reading guide. The reading guide is a unique and useful supplement to the code itself as it contains points on the scope of the code (impossible to be exhaustive), for whom it is intended (all staff and students) and when and how it will be reviewed (once a year, all invited to contribute). Additionally, the reading guide details where to contact in the case of further questions and names two specific people that can be of help.

The code itself was drafted in accordance with three important reference documents: the Singapore Statement on Research Integrity, the OECD (Organisation for Economic Co-operation and Development) Best Practices for Ensuring Scientific Integrity and Preventing Misconduct and the ALLEA code. It was last reviewed in May 2019 and contains four sections.

The first section deals with creating a climate of research integrity. This section gives a detailed profile of the ethical and responsible researcher who is: Respectful, scrupulous, honest and verifiable, Independent, impartial and transparent and responsible and reliable.

[38] KU Leuven OA Policy https://bib.kuleuven.be/english/research/open-access/OApolicy

[39] LUMC Good Research Practice & Integrity https://www.lumc.nl/research/grp-and-integrity/research-codes/

It is highlighted that team leaders and principle investigators are looked upon as an example to their team members and junior faculty members and should act accordingly.

The second section gives an overview of the laws and regulation of research involving human subjects; Research using human tissue and patient data; Research involving animal subjects; Research data; Publication and Ethics in EU projects. In the introduction to this section, they introduce the e-learning module 'Basic course on Regulations and Organisation for clinical investigators'[40] which "*teaches researchers what the specific laws and regulations are that govern research involving human subjects*". It is mandatory that all researchers at LUMC using human subjects take this course and pass the exam. The rest of the section is a detailed review of the university's principles on research in the six specified areas. It also highlights all the relevant national laws and guidelines and those of other countries, and international guidelines. Regarding ethics, there is a section dedicated to the ethics self-assessment for all projects funded under the EU Horizon 2020.

The third section of the code deals with suspected breaches of research integrity. Firstly, a brief overview is given of ten points the LUMC Committee Scientific Integrity considers unethical behavior at the minimum e.g. falsifying data, misinterpreting results, plagiarism etc. there are named individuals who act as confidential advisors, and all those affiliated with LUMC are encouraged to report any suspected breaches of research integrity.

The fourth section gives links to the LUMC guidelines, which are in Dutch only and on the intranet. A very useful addition to the code is the annex at the end, which gives all the links mentioned in the code in the form of a table, organized by chapter.

13.2 LUMC Good Research Practice & Integrity

In addition to the code of conduct, LUMC also has a webpage entitled Good Research Practice (GRP) & Integrity[41], which explains that the university "*…is performing research in such a way that it fulfills all aspects of clean and integer research. Respect for patients, volunteers and animals being subject of scientific research and objectivity and honesty in*

[40] LUMC Training Course "Basic course on regulations and organization for clinical investigators" https://www.lumc.nl/research/leading-fellows/training-and-courses/

[41] LUMC Good Research Practice & Integrity https://www.lumc.nl/research/grp-and-integrity/grp/

reporting research results are the main pillars". This GRP committee provides services to support faculties performing clinical research. They state that they have provided advisors on GRP, a committee of science for every department, data management strategies, GRP audits, monitoring courses etc. A committee such as this one is a very useful resource for an institution to have, which shows how good practice has been implemented in the management and running of the institution.

13.3 LUMC Open Access Policy

Regarding their policy on publishing OA, again the LUMC supports OA publisher with several agreements for discounts and waivers[42].

14 THE UNIVERSITY OF BARCELONA (UB)

14.1 Ethics and Research at the UB

Ethics and research at the University of Barcelona (UB) is very easily accessible from the homepage under the "Research at the UB" tab. The section begins with the following statement "*The University of Barcelona considers that it is extremely important for all members of the university community to be aware of the ethical implications of research in all areas of knowledge*"[43]. The first link on the page is to the UB's policy on openness in animal research, which has signed an agreement with the Confederation of Scientific Societies of Spain (COSCE). The agreement comprises of four agreements:

- *Speak clearly of when, how and why animals are used in research.*
- *Make information on the conditions of animal use in research available publicly, and in proportionate language.*
- *Promote initiatives that generate a better understanding in society about the use of animals in scientific research.*

[42] LUMC Open Access
https://www.lumc.nl/org/walaeus/wegwijzers/openaccess/?setlanguage=English&setcountry=en

[43] UB Ethics and Research
https://www.ub.edu/web/ub/en/recerca_innovacio/recerca_a_la_UB/etica_recerca/etica_recerca.html

- *Make yearly reports on the progress of this and share the information and experiences.*

Next, one can access the homepage of the University of Barcelona's Bioethics Commission (CBUB)[44]. Here, you can find information of the committee, which evaluates research projects from the University of Barcelona community and "*elaborates protocols and check-lists useful for preparing research projects and to improve understanding of the methodological and ethical-legal issues related to different types of research*". The CBUB has published a PDF document online detailing its regulations in three sections: Functions, composition and general working rules. In the first section, in addition to evaluating research projects, the committee is also responsible for disseminating information on bioethical issues and promoting public debate, promoting research integrity and good practice and examining UB members' complaints regarding research integrity, good scientific practices and research ethics.

In addition to the regulations, the CBUB has published numerous other documents of interest[45]. One of these is a document regarding the possible ethical problems that may arise in scientific publications, which cites the ICMJE and the Committee on Publication Ethics (COPE). Here, the issues of authorship in publication and what is ethically considered acceptable or not is discussed.

Under the section Documents and Rules are numerous other documents regarding ethics and good practice procedures followed by the UB. Included is the EU's Ethics and Data protection document form 2018, which outlines best practices following the introduction of the GDPR, emphasizing that although "*your research is legally permissible does not necessarily mean that it will be deemed ethical*". The CIOMS Guidelines for Health-Related Research Involving Humans, the Declaration of Helsinki and the EU Additional protocol to the convention on human rights and biomedicine concerning biomedical research are other prominent ethics documents included in this section.

[44] The University of Barcelona's Bioethics Commission (CBUB) http://www.ub.edu/comissiobioetica/en

[45] CBUB Communiques http://www.ub.edu/comissiobioetica/en/comunicats

14.2 UB Code of Good Research Practices

The UB has written its own code of good practices in house, which was published in 2010 in three languages (Catalan, Spanish and English). To begin, the code states its objectives as: "to improve the quality of research in all fields; set up mechanisms for ensuring honesty, responsibility and rigor in research; ensure that researchers-in-training acquire good scientific practice". It states that the code is directed at all members of the UB group who carry out research. The UB code includes the principles: honesty, responsibility, rigor and conflicts of interest as its first four points of discussion. The emphasis here is on being honest in the review of one's own work, reviewing all data and results, and transparency with any conflicts of interest. Next, the code discusses research team leadership and organization, focusing on good leadership and the establishment of a clear organizational structure. In addition to this, the code also recommends the minimum requirements for a good project proposal, such as stating the human/animal materials needed, the schedule of work, a risk assessment and the implementation of monitoring for these activities. Safe working conditions, adequate staff training and supervision, research procedures and methods are also discussed in relation to research projects. The following sections focus on equipment facilities, recording and storage of data and materials, publication of research results and research on human and animal subjects. The unique feature of this code compared with other good practice codes is the practical element. This document will be a very useful tool for any research group, as it gives solid practical advice on how to carry out research projects in a sound ethical manner, without just listing ethical principles that need to be abided by in theory. Recommendations of updates to the code of good research practice were recently published, which include suggestions such as: the creation of a research integrity office to deal with cases of alleged fraud, integrated integrity training based on real practical cases, and educating researchers on the importance of research integrity as a vital part of their day to day activity and not merely a box to tick. In addition to this, the article also recommends the inclusion of a data management plan in accordance with the EU FAIR data management principles.

14.3 Code of Ethics on Integrity and Best Practices

In addition to the Code of Good Research Practice, the UB Ethics committee also published the Code of ethics on integrity and best practices in 2018. The purpose of the ethics code is "to provide guidelines for action that guide and support the rights and obligations of the members of the University of Barcelona community in the exercise of their freedom and responsibility". This ethical code consists of the following nine sections: Academic freedom, professional responsibility, scientific and academic integrity, honesty, equal rights, respect, privacy and confidentiality, sustainability and solidarity and risk behaviors. This code is aligned with the principles and practices laid out in other codes of conduct of MICROB-PREDICT partners.

Regarding ethics training, the UB doctoral school has also implemented training programmes related to good practice with courses[46] of four hours in ethical aspects of research, publication in scientific journals and research disclosure among other diverse topics. All these courses are offered in three languages (Catalan, Spanish and English) by the doctoral school. Again, this is a great way to ensure that all students have the same level of knowledge surrounding good research practice and research ethics.

Lastly, there is a link to the UB Bioethics and Law Observatory (OBD)[47], a research center that specifically focuses on the ethical, legal and social implications of biotechnology and biomedicine. The OBD has published a report where it detailed all of its activities, which include bioethical research on big data and health, two master degrees (Bioethics and Law and Food Ethics and Law), and an OA scientific journal, *The Bioethics and Law Journal*. In addition to all of this, the OBD also publishes techno-scientific documents on issues of public debate, written by internal members and external experts. One such document, published in 2016 is the "*Declaration on research integrity in responsible research and innovation*"[48]. Here, research integrity is defined as encompassing the following three points:

[46] UB Doctoral School Training Activities http://www.ub.edu/escola_doctorat/en/capsules-formatives

[47] UB Bioethics and Law Observatory (OBD) http://www.bioeticayderecho.ub.edu/ca

[48] Declaration on research integrity in responsible research and innovation (2016) http://hdl.handle.net/2445/103268 (Accessed 13 March 2020)

- honesty, in the commitment to truth
- independence, in the preservation of freedom of action in relation to pressures outside the profession
- impartiality, neutrality of professional practice in relation to private interests outside of the research

The document also includes an analysis of what constitutes an infringement of scientific integrity, organised by each stage of the scientific process: the research objectives, research methodology and impact of the research. The cause of ethically abjectable behaviour are also discussed, such as individual beliefs and organizational factors, and finally, some of the consequences of research malpractice on researchers, participants and institutions.

14.4 UB Open Access Policy

The UB library states in its institutional policy on OA[49], that it encourages all UB staff to publish in OA journals, and requires that all articles produced form the UB be deposited in the institute's internal repository.

In 2019 the UB updated its institutional policy on OA publishing[50], in which it reiterated it commitment to OA, aiming to evertually achieve complete free open access to all of its scientific production in the coming years. Additionally, the university will also achieve all levels of OA requested by major funding bodies, such as H2020, by setting annual reviews of its policies and achievements in this regard. The approval of the Research Data Management Policy also states that data accompanying open scientific publication must also made available in order to validate publications and improve reproducibility. This will involve correct data management systems to ensure the integrity of data in the long term.

The UB library (CRAI) has published a valuable presentation explaining the research data cycle, the different types of data and how to manage them correctly. The CRAI has also published a webpage with support on research data management, which includes sections

[49] UB CRAI Open Access policies and guidelines https://crai.ub.edu/en/crai-services/open-access-ub/policies

[50] UB policies on open access and management of research data https://crai.ub.edu/ca/Noticies-butlleti/politiques-de-la-ub-sobre-acces-obert-i-dades-de-recerca (Accessed 16 March 2020)

on data and projects funded by Horizon 2020, disseminating the data and resuing and citing the data[51].

Overall, the UB resources are abundant, clear and of high quality and detail. One recommendation would be to have clear links to the resources mentioned here in the initial homepage of the university. Currently, these documents need to be sourced through the UB depository and there is no mention of the English versions of them on the Bioethics Commission webpage.

15 BIOBYTE SOLUTIONS

Biobyte solutions is a bioinformatics services company and will be responsible for developing and maintaining the central data repository of the MICROB-PREDICT project. In general terms, Biobyte provides data management and visualisation solutions being used in various large-scale collaborative projects. The Biobyte privacy policy[52] begins by clearly defining important terms such as “Third-party Social Media Service” and “Personal Data”. It then describes how the data is used, retained and transferred, all according to the terms set out in the privacy policy.

16 THE CATALAN INSTITUTE OF NANOSCIENCE AND NANOTECHNOLOGY (ICN2)

16.1 ICN2 Code of Conduct

The Catalan Institute of Nanoscience and Nanotechnology (ICN2) offers a session to first year candidates on their PhD programme called “Ethics in research”. No further information on what this programme entails could be found from their website. The center does not yet have a code of conduct or ethics, however, in their document “Human resources strategy for researchers: Internal Audit” from 2017, the institute states that they are setting up an ethics committee and developing a code of ethics with legal advisory services. This code is not yet available on their website and there is no information on the ethics committee

[51] CRAI Support on research data management https://crai.ub.edu/en/crai-services/support-researchers/research-data (Accessed 17 March 2020)

[52] Biobyte Solutions Privacy Policy https://www.biobyte.de/privacy.html (Accessed 30 March 2020)

16.2 ICN2 Open Access Policy

Although there is no information on the institute's policy regarding OA publishing that could be found from their website, there are many of their recent publications in OA format.

17 UNIVERSITY COLLEGE LONDON (UCL)

17.1 UCL Code of Conduct

Once inside the research section of the website, it is very easy to find the section dedicated to research integrity[53]. University College London (UCL) states here that it is "*fundamental that research should be conducted, and the results of research disseminated, honestly, accurately and in accordance with professional standards*". There are several sections following this, each with its own dedicated web space, including The UCL Statement on Research Integrity[54], The Nagoya Protocol, Policies and Guidelines and Training, among others. The link to the UCL code of conduct[55] is clear and once clicked, is accessible along with the institutional policy for handling misconduct[56]. The code itself was published in 2013 and starts with a statement saying that it should be understood in conjunction with the Research Councils UK Policy and Guidelines on Governance of Good Research Conduct[57]. Five main areas are covered in the code:

- Professional and personal integrity of researchers
- Process of research design
- Publication process
- Leadership responsibilities

[53] UCL Research Integrity https://www.ucl.ac.uk/research/integrity/

[54] UCL Statement on Research Integrity (2015)

https://www.ucl.ac.uk/research/integrity/sites/research_integrity/files/UCL-Statement-on-Research-Integrity.pdf

[55] UCL Code of Conduct for Research (2013) https://www.ucl.ac.uk/srs/sites/srs/files/code-of-conduct-research.pdf

[56] UCL Research Governance https://www.ucl.ac.uk/srs/governance-and-committees/research-governance

[57] UK Research and Innovation Policy and Guidelines on Governance of Good Research Conduct. (2013, updated 2017). Retrieved 25 March 2020, from https://www.ukri.org/files/legacy/reviews/grc/rcuk-grp-policy-and-guidelines-updated-apr-17-2-pdf/

- Institutional responsibilities

Personal integrity is highlighted as very important for UCL researchers in the second section, with the ability to perceive conflicts of interest and being honest and transparent in all stages of the research process. Principles relating to the storage of data, external collaborations, risk assessments and responsibility of principle investigators are covered in section three. Section four involves publication ethics, copyright and authorship. Next, research group leaders are said to be responsible for compliance with safety, ethics and any other legal standards, risk assessments, checking the work of the group and regular reviews. The code states that these tasks can be delegated to members of the team, as long as this is clear. Finally, institution responsibilities in the code seek to foster a culture of good practice among staff and include continually strengthening the ethics code and committee, providing training and a clear procedure for dealing with allegations of research conduct. The code finishes by providing a list of links to other UCL documents on issues such as misconduct allegations, copyright and health and safety, to be read together with the code of conduct. Overall, the code is clear, well written and accessible to staff and the public.

17.1.1 UCL Code of Ethical Principles

UCL have also written a general Code of Ethical Principles[58], with an annex of useful information, and some example questions a researcher may want to ask themselves when dealing with a situation, for example:

- Have you considered all those who might be affected by your decision and those who might criticize your decision…?
- Have you considered what could go wrong as a result of your decision…?
- How would you defend your actions if publicized in the media?

17.1.2 UCL Code of Conduct for Students

The Code of Conduct for Students[59] is part of the UCL Academic Manual 2019-20, and comprises its own chapter detailing how a UCL student should behave (honest, respectful of

[58] UCL General code of ethical principles https://www.ucl.ac.uk/students/policies/conduct/ethical-principles

themselves, others and the environment, no drunken behavior etc.), the duty of care that UCL will show for its students and the disciplinary code.

Overall, while the information is abundant, accurate, and very informative and clear, the 'Research' section of UCL is difficult to find from the general homepage, so much so, that only a google search for "UCL ethics" brought the user to the correct location..

17.1.3 UCL Research Funding Ethics Policy

UCL have also written an ethics code regarding their research funding (UCL Research Funding Ethics Policy[60]). The policy, written in 2014, lays out the terms for research funding and states a commitment to "*focus the impact of UCL education and research on improving the lot of people around the world and respect for human rights, and countering ignorance, poverty ,ill-health and political tyranny*". UCL will not accept any funding from the tobacco Industry. It is clear in the guidelines that cases will be evaluated by the ethics committee.

17.1.4 UCL Sensitive Research

There is also a specific section dedicated to Sensitive Research[61], which UCL says "carries with it particular risks that need to be managed". UCL gives 10 points that make research sensitive, including research into 'risky' topics, research into terrorism or national security, culturally sensitive research, research in countries with strict law and dual use research. The university then goes on to give information and links to important internal and EU documents on how to evaluate and manage sensitive research. Misuse of research, data storage, ethical approval and UCL safety services are all included in this section. This is a very useful and informative resource for UCL personnel and those from other universities, who may be undertaking this type of research, or who just want to know more about it.

[59] UCL Code of Conduct for Students 2019-2020 https://www.ucl.ac.uk/academic-manual/chapters/chapter-6-student-casework-framework

[60] UCL Research Funding Ethics Policy (2014) https://www.ucl.ac.uk/research/integrity/ucl-research-funding-ethics-policy

[61] UCL Sensitive Research https://www.ucl.ac.uk/research/integrity/sensitive-research

17.1.5 UCL Research Integrity Training

Regarding training in research integrity, UCL has a very comprehensive training plan[62] comprising four levels, the first two being mandatory for new staff and students, and the last two being dependent on the type of researcher and their needs. The university states that while it will not be mandatory for experienced researchers to do the basic courses (what is ethical research etc.), they will be required to train on UCL specific codes of conduct and ethical standards. According to UCL, the Research Integrity Training Framework will generate "*a culture of research integrity at UCL*" which will equip all staff with the means to ensure their research is ethical "*(e.g. appropriate research methods, thorough research data management, consideration of ethical issues, etc.)*".

17.2 UCL Open Access Policy

UCL declare on their OA homepage that they '*strongly support*' this model of publishing[63]. They have an internal repository and their own OA publishing serve *UCL Press*. Regarding OA funds, UCL has deals with various funding bodies, such as the Wellcome Trust and UK Research Councils (UKRI) to help pay APCs, but does state that the university itself has limited institutional funds for OA publishing, and allocates this on a first come first serve basis. Regarding Plan S[64] (an initiative to make all publicly funded research OA by 2020), UCL have announced their support for the movement, but were critical of its viability in their 2019 town hall discussion.

18 THE UNIVERSITY OF OSLO

18.1 UiO Code of Conduct

The University of Oslo (UiO) ethical guidelines can be found easily from the homepage, under the 'About UiO > Regulations' section. While they do state that many of their important and official documents are in Norwegian, they provide a very wide selection of

[62] UCL Research Integrity Training Framework https://www.ucl.ac.uk/research/integrity/research-integrity-training-framework

[63] UCL Open Access https://www.ucl.ac.uk/library/open-access/open-access-ucl

[64] Plan S https://www.coalition-s.org/

English translations for the most important ones. The ethical guideline page[65] covers the following topics: Governing Rules of UiO, individual responsibilities, all forms of bullying, dual relations, research ethics, academic cooperation, human rights and specific guidelines. It is under this final section that one is directed to the research ethics page, which contains the UiO's 10 commandments for ethical practice in research[66]. The 10 commandments were approved by the university board in 2007 and focus on honesty, transparency and responsibility.

Further to this, the university also published ethical guidelines for supervisors[67] in 2011, which state in the introduction that supervisors should "*carry out his or her activity in an academic and kindly way with a high standard of professional ethics*". These guidelines not only point out issues of conflict resolution, authorship and respect, but also place great emphasis on how the professional relationship between a student and supervisor should be respected. In this regard, there are many rules on how the supervisor should behave and what is and is not appropriate in the workplace.

18.2 UiO Open Access Policy

The UiO policy on OA is similar to that of other universities in that it is strongly recommended. The university also has its own institutional repository. The Norwegian Government has set a goal that by 2024 all research articles funded by the public will be made publicly available[68], and has released a document from the Norwegian Ministry of Education and Research, stating that research communities should promote OA and "*convert important journals within their subject areas from closed subscription based journals to*

[65] UiO Ethical guidelines https://www.uio.no/english/about/regulations/ethical-guidelines/index.html

[66] UiO 10 commandments for ethical practice in research (2007) https://www.uio.no/english/for-employees/support/research/ethics/10-commandements.html

[67] Ethical guidelines for supervisors at UiO https://www.uio.no/english/about/regulations/ethical-guidelines/ethical-guidelines-supervisors/index.html

[68] Norwegian Ministry of Education and Research: National goals and guidelines for open access to research articles (2017) https://www.regjeringen.no/contentassets/ae7f1c4b97d34806b37dc767be1fce76/national-goals-and-guidelines-for-open-access-to-research-articles.pdf

open access titles". At the institutional level, the UiO guidelines[69] state that researchers are strongly encouraged to publish in OA, but it is only obliged that they submit a full version to the internal repository. The webpage then goes on to explain specific guidelines from funding bodies such as the Research Council of Norway and the EU.

19 EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EFClif)

The European Foundation for the study of Chronic Liver Failure (EFClif) is a private non-profit organization aimed to promote research and education in Chronic Liver Failure, and the coordinating institution of the MICROB PREDICT research project. The website provides information on how personal data is handled according to the GDPR guidelines.

20 CONCENTRIS RESEARCH MANAGEMENT

Concentris carries out non-scientific tasks of funded research projects and provides support and consultancy services for scientists and researchers at universities, in businesses and research institutes from the first project idea to the successful completion. Since concentris is focused on project management, financial management and in the organisation of meetings of the MICROB-PREDICT Consortium, there is no need to have a code of conduct as in the case of research institutions. Regarding personal data treatments and protection, concentris has an updated policy according GDPR[70].

21 KING'S COLLEGE LONDON (KCL)

21.1 KCL Code of Conduct

King's College London (KCL) have published numerous codes of practice on many different themes on their website, under the Governance Zone[71]. Here, you can search their documents by type or from A-Z, therefore they are all easily accessible. Under the theme 'Research Policies', there are codes of conduct for contracted services, external

[69] UiO Open Access Policy https://www.ub.uio.no/english/writing-publishing/open-access/open-access-policy.html

[70] Concentris Data Protection and Privacy Statement https://concentris.de/en/imprint/

[71] KCL Governance Zone: Research Documents https://www.kcl.ac.uk/governancezone/research/research

collaborators, intellectual property etc. Regarding a KCL code of good research practice, there is a Core Code of Practice for Postgraduate Research Degrees 2017-18[72]. In this document, the roles of supervisor and student are specified, the rules and responsibilities of both made clear, and the procedure for complaints and appeals is included.

21.1.1 The UK Research Integrity Office (UKRIO) Code of Practice for Research: Promoting good practice and preventing misconduct

KCL have stated that while they are in the process of drafting a College Code of Good Conduct in Research, they have adopted the The UK Research Integrity Office (UKRIO) Code of Practice for Research: Promoting good practice and preventing misconduct[73]. This document was first published in 2009 and the organization states that institutes may use it as a reference point for their own code of conduct (as UCL have done with UKRI) or adopt it in full, as KCL have done. The UKRIO code of conduct begins with a short checklist for researchers to consider at all stages of their projects, which includes questions such as:

- Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organizations and/or countries if relevant?
- Has your research undergone any necessary ethics review, especially if it involves animals, human participants, human material or personal data?
- Have any changes to the agreed research design been reviewed and approved if applicable?
- Will your research and its findings be reported accurately, honestly and within a reasonable timeframe?

These checklists are a great resource for researchers as they give a quick overview of all of the issues they need to consider before, during and after their research projects. Standards for organizations are then described in detail, starting with eight core principles that should

[72] KCL Core Code of Practice 2017-18: Postgraduate Research Degrees https://www.kcl.ac.uk/governancezone/research/postgraduate-research-degrees-core-code-of-practice-2017-18

[73] UKRIO Code of Practice for Research (2009) http://ukrio.org/publications/code-of-practice-for-research/

be followed by researchers: Excellence, honesty, integrity, cooperation, accountability, training and skills and safety. The document also offers central guidance on good practice in research, such as ensuring good practice is an integral part of their research strategy, that all personnel are aware of the procedures and institutional policies and that adequate training on the subject is provided. Recommendations on conflict of interest, research involving human subjects and animals, finances, publication and misconduct is also given in detail, among others. The UKRIO have provided an exhaustive and very well-prepared document which covers all of the essential elements of good research practice and ethical conduct.

21.2 KCL Research Conduct Offices

KCL also has three offices to deal will all issues related to research integrity: The Research Governance Office[74], the Research Ethics Office[75] and the Research Integrity Office[76]. Together, these departments are responsible for ensuring that "*all research conducted is safe, lawful, and of the highest standards of integrity and rigour*". The research governance office provides support with GDPR compliance, Human Tissue Act requirements, Registration of Research on Public Databases, and research ethics and integrity among many more. The research ethics office provides support on applying for and obtaining ethical clearance. Finally, the research integrity office provides support to the university community on how to ensure transparency in their research while adhering to the relevant disciplinary codes and procedures. This section lists honesty, rigor, transparency and care/respect as the key principles for research integrity at King's. Additionally, KCL has also signed the 2019 Concordat to Support Research Integrity[77] by Universities UK, a collective of 136 universities in England, Scotland, Wales and Northern Ireland. This concordant is an agreement by these institutions to:

1. uphold the highest standards of rigor and integrity in all aspects of research

[74] KCL Research Governance Office https://www.kcl.ac.uk/research/support/research-governance/index

[75] KCL Research Ethics Office https://www.kcl.ac.uk/research/support/research-ethics/index

[76] KCL Research Integrity Office https://www.kcl.ac.uk/research/support/rgei/research-integrity

[77] Universities UK: Concordat to Support Research Integrity https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf

2. ensure that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards
3. support a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers
4. use transparent, timely, robust and fair processes to deal with allegations of research misconduct should they arise
5. work together to strengthen the integrity of research and to review progress regularly and openly

The Concordat states that the principles listed are applicable to any research discipline, provide guidance and accountability and are a complement to already existing standards and governance. Additionally, the concordat states that it aims to be a framework through which the principles outlined in the Singapore statement, the Montreal Statement on Research Integrity and the ALLEA code can be understood in the UK context. All employers of researchers stated in the concordat must publish an annual statement on research integrity.

21.3 KCL Open Access Policy

The KCL policy on OA publishing is very easy to access through their library website. Once in the OA section[78], one can find a wealth of information on OA policy, funding and different publishing models. As with many of the other universities involved in MICROB-PREDICT, KCL has an institutional repository, in which researchers must deposit a full text version of their work, as soon as is possible. In addition to this, researchers must also abide by the KCL Publication Policy[79]. Regarding payment of APCs for Gold OA publishers, KCL directs authors to refer to their funding agency and publisher membership schemes, and states that in the case of researchers having no funding, they should source departmental funds or a waiver.

[78] KCL Open Access https://www.kcl.ac.uk/library/researchsupport/openaccess/index

[79] King's College London Research Publications Policy
https://www.kcl.ac.uk/governancezone/Assets/Research/Research-Publications-Policy.pdf

22 THE CLINIC FOUNDATION FOR BIOMEDICAL RESEARCH (FUNDACIÓ CLÍNIC)

The Clinic Foundation for Biomedical Research (FCRB) is a non-profit organization founded by members of the Hospital Clínic and the University of Barcelona, which is "*dedicated to promoting, managing and conducting biomedical research and innovation and teaching activities related to healthcare sciences*". Also included is the August Pi i Sunyer Biomedical Research Institute (IDIBAPS), which is the research centre. From the website homepage, all of the important documents can be found in the 'Transparency Portal'[80], which is located at the bottom of the homepage. This location is not intuitive and would be easier to find under their 'Research' or 'About us' tabs. Once in the transparency portal, users will find three links to the transparency portals of Hospital Clínic, IDIBAPS and the FCRB. All three portals are in Catalan, with no English translations neither in the website nor in any of the documents. These three portals will be analyzed separately below:

22.1 Transparency Portal IDIBAPS and Clinic Foundation for Biomedical Research at Hospital Clínic de Barcelona

IDIBAPS has written their own code of good practice[81] for their board members, published in 2016. This centers around 13 points as follows: diligence, loyalty, fidelity, independence, confidentiality, information, transparency, abstention due to conflict of interest, selection of investments, dedication, compliance with legislation and law and self-evaluation. The code then goes on to describe the rights of the board members, such as that to oppose any votes, the right to all of the information among others. To finish the code, IDIBAPS then describes how all governance documents and information shall be made public through the website and in a way that is intelligible to any citizen. Although this code is very complete for the board of governors, it is recommendable that IDIBAPS, as a research institute, have a code of good scientific practice to complement this.

[80] Fundació Clínic Transparency Portal https://www.clinicbarcelona.org/portal-de-transparencia

[81] IDIBAPS Code of Good Governance (2016)
https://transparencia.idibaps.org/sites/transparencia.idibaps.org/files/general/codi_bon_govern_0.pdf

The code of good governance for the FCRB[82] is the same as that of IDIBAPS[83]. In the IDIBAPS and Fundació Clínic annual report[84], there are mentions of ethical review in the transversal research groups section. One of the main lines of research for the clinical pharmacology group, which provides support activities in pharmacovigilance and pharmacoepidemiology, is ethics in clinical research. The Research Ethics Committee at Hospital Clínic is entitled to review research protocols.

23 THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER (EASL)

23.1 EASL Code of Conduct

The European Association for the Study of the Liver (EASL) have published an in-house code of conduct (found at the 'Compliance and Policies' tab[85]), which has been approved by the EASL ethics committee and the governing board in 2017. The document aims to provide guidance on "*the standards of conduct required by the organization*". The document starts by listing the EASL mission, which is to promote research of liver disease, and then goes on to explain the mission of the governing board, including managing the business of the association and their finances. The mission of the ethics committee is defined as supporting the governing body to promote the highest ethical standards in the hepatology field and educate members on ethical issues. EASL states that "*public trust in EASL's integrity, ethical standards and credibility, are of paramount importance*" and to accomplish that all members will abide by five ethical standards, paraphrased below:

1. The EASL committee will abide by the EASL code of conduct and all other European and national law and regulations
2. The EASL leadership will conduct the business affairs of the association in good faith and with honesty, integrity, due diligence, and judicious competence

[82] Hospital Clínic Barcelona Transparency Portal https://transparencia.clinic.cat/

[83] IDIBAPS Transparency Portal https://transparencia.idibaps.org/

[84] IDIBAPS and Fundació Clínic annual report https://www.clinicbarcelona.org/en/idibaps/about-us/scientific-memories

[85] EASL Compliance & Policies (Here one can find the 2017 EASL Code of Conduct, Use of Images and EASL Equality and Diversity policy statement) https://easl.eu/easl/compliance-policies/

3. No EASL leadership member shall share, copy, reproduce, transmit, divulge or otherwise disclose any confidential information related to the affairs of the association, its meetings and communications
4. The EASL leadership will exercise proper authority and good judgement in their dealings with association staff, suppliers, members and the general public
5. No member of the EASL leadership will use any information provided by the association or acquired as a consequence of their service to the association in any manner other than in furtherance of his or her position duties

The next section convers conflicts of interest, which are defined in the code as “any circumstances that create a risk that professional judgements or actions regarding a primary interest, as stated in the mission of EASL, will be unduly influenced by a secondary financial or non-financial interest”. The code states that they have based their criteria for assessing CoI on that of the American Association for the Study of Liver Diseases, which uses five questions; the first three pertaining to the impairment of impartial decision-making and the last two to the possible harm to EASL:

1. What is the financial value of the secondary interest involved?
2. What is the scope of the relationship(s) of the individual being assessed, with the party or parties associated with the secondary interest?
3. Does the circumstance involve the sole discretion of the individual being assessed?
4. What is the value (and risk) (either direct financial or “in-kind”) to EASL of the interest that could be affected by a conflict?
5. What are the consequences to EASL that could ensue from broad public disclosure of the conflict?

The result of the CoI evaluation will be made by the EASL ethics committee, which consists of five members independent from the governing board. The code then goes on to give a table which describes where CoI are permitted, not permitted, permissible but need to be disclosed etc. for members of the EASL governing board, editors of the Journal of Hepatology, and Clinical Practice Guidelines Panel members. This is a very useful resource, which can be quickly utilized by members without having to read pages of documents and

could serve as a good example to other similar organizations when they are unsure of their own position regarding CoI.

23.2 EASL Equality and Diversity Policy Statement

The EASL has also published the EASL Equality and Diversity policy statement. Within this document, the EASL have laid out their goals regarding diversity in the organization, stating, "*EASL is therefore dedicated to equal opportunities and has zero tolerance for discrimination or harassment*". Regarding gender equality, the document asserts that there should be minimum of two females and two males on the scientific committee (currently two females and four males). Additionally, a minimum of three females and three males within eight named senior EASL positions (of which women fill the following four positions: Editor in chief of JHEP Reports, European Policy Councillor, Chair of the Scientific Committee and the European Policy Councillor). EASL also states that it "*strives for equal opportunities and diversity across membership, grants, prizes, honorary titles, publications from EASL journals, and access and participation in conferences and events*".

23.3 EASL Open Access

EASL do not have specific codes for OA and publish Clinical Practice Guidelines, the Journal of Hepatology and JHEP Reports. The Journal of Hepatology is a hybrid journal, meaning while subscriptions are paid, authors can choose to publish in OA and pay the corresponding APC if they wish. Thecompanion journal JHEP Reports is fully OA, with EASL members receiving a 50% APC discount.

24 EUROPEAN LIVER PATIENTS' ASSOCIATION

Like the EASL, the European Liver Patients' Association (ELPA) also has a code of conduct[86] for their board members and staff and a separate code of conduct for the ELPA and its relations with the pharmaceutical industry. Both are easily accessible form the ELPA homepage under the 'Discover' section. Although neither are available in PDF format, they are both clearly sectioned, short and concise.

[86] ELPA Code of Conduct (link includes: Code of Conduct of ELPA Board Members and Code of conduct between the Pharmaceutical Industry and ELPA) https://elpa.eu/codes-of-conduct/

24.1 Code of Conduct of ELPA Board Members

The code of conduct for the board members is divided into four sections: purpose, principles, professional and ethical conduct, communications and proper practice and finally, guidelines for conflicts of interest. The first section states that the code of conduct is intended to define the "*standard of professional and ethical conduct, communications and proper practice of the ELPA Board Members and staff*". The next section outlines four principles of good practice such as: the commitment of ELPA members the professional code of conduct, honesty and openness, conflicts of interest and misconduct procedure. The third section, Process and Guidelines for Professional and Ethical Conduct, Communications & Proper Practice, issues 12 points and a final discussion, and convers the following topics: professional, ethical conduct, attendance to board meetings, disclosure of confidential information and protecting the reputation of ELPA. The section on CoI defines what this could be for an ELPA board or staff member and when and how they should declare any potential conflict of interest.

24.2 Code of conduct between the pharmaceutical industry and ELPA

The second code of conduct is that of the relation between ELPA and the pharmaceutical industry, which is laid out in five principles: Area of application, respect, independence, transparency and promotion. Importantly, the code states "*the independence of ELPA, its health policy objectives, its communication and public relation activities must always be preserved during all interactions and relationships between patient associations and the pharmaceutical industry*", and that any employee or director of a pharmaceutical company cannot become a member of a patient organization, and can only participate when specifically invited to consult. Lastly, the promotion of any prescription medicines is also prohibited. This second code of conduct is a very welcome addition to the codes of good practice for patient associations and is recommendable for other patient associations who would like to make their stance on this issue public and clear.

25 MICROB-PREDICT PUBLICATION POLICY

In this section the reader will find the contractual requirements of publications and internal authorship rules. This publication policy is coordinated by Dr. Ameli Schwalber, project

manager of the MICROB PREDICT research project as part of the Work Package 10 and author of this part. This is a transversal issue applicable to all partners and has been developed following international and European agreed standards by the scientific community in a wide sense. The main goal is to understand the different (contractual) requirements of publications in MICROB-PREDICT and what this means in practice.

25.1 Different sources for requirements of publications

There are different sources for requirements to publications: 1) Grant Agreement: a) Obligation to publish; b) Obligation to protect; c) Open access and d) EU Acknowledgement 2) Consortium Agreement: Ownership of results and 30 days prior notice of publications and) Dissemination Plan: Principle of authorship and Review and approval procedures

25.1.1Grant Agreement:

a) Obligation to publish: The European Commission Publication rules establish the obligation to publish; unless it goes against their legitimate interests, each beneficiary must — as soon as possible — 'disseminate' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium). *Source: EC-GA: Art. 29.1*

b) Obligation to protect: Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited;

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries. *Source: EC-GA: Art. 27.1*

c) Open Access (*Source: EC-GA: Art. 29.2)*

- Gold: immediately open access, APC paid by author;

- Green: author archives (deposits) the article in an online repository, embargo may apply
- Open access to publications must be applied:

- on publication, if an electronic version is available for free via the publisher, or

- within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

- open access to the bibliographic metadata that identify the deposited publication.

- Open access to research data:

- deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — …data, including associated metadata…

- provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves). *Source: EC-GA: Art. 29.3*

d) Europen Union Acknowledgement: The mandatory text to be used in every publication is the following: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.This reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains". Plus, if possible, EU Emblem:

25.1.2 Consortium Agreement: Ownership of results and 30 days prior notice of publications

The publications rules are the following: Throughout the duration of MICROB-PREDICT, partners will publish their research output in OA. Other parties involved must be informed of any planned publication at least 30 days before publication. Furthermore, each party will have 20 days for objection for any of the following reasons:

- The results or background of the objecting party would be adversely affected by the publication.
- The legitimate interests of the objecting party would be harmed in the event of publication.
- Confidential information of the objecting party is contained in the publication.
- There are ethical issues in the proposed publication.

The objecting party must then include a specific request for modification, and there must be a discussion over the objections. There should be no unnecessary continuation of the objection and it must not exceed 60 calendar days. In the case of no objection, within 20 days the publication can be accepted for continuation to publication.

25.1.3 Dissemination Plan: Principle of authorship and review process

The MICROB-PREDICT Consortium aligns itself with the ICMJE rules for authorship[87], which have been recently updated (2019), and aim to act as a guideline for responsible and ethical publishing, not just for the the scientific and publishing community, but also for members of the public. Public documents such as these serve as a great resource for researchers and journals to provide clarity on many complex issues like authorship, retractions, fees etc., that can often lead to misunderstandings and (often unintended) unethical practices. Furthermore, they serve as proof to society of ethical and transparent publishing procedures.

The ICMJE defines an author as someone who meets all four of the following criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published;

[87] Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (2019) International Committee of Medical Journal Editors http://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_dec19.pdf

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

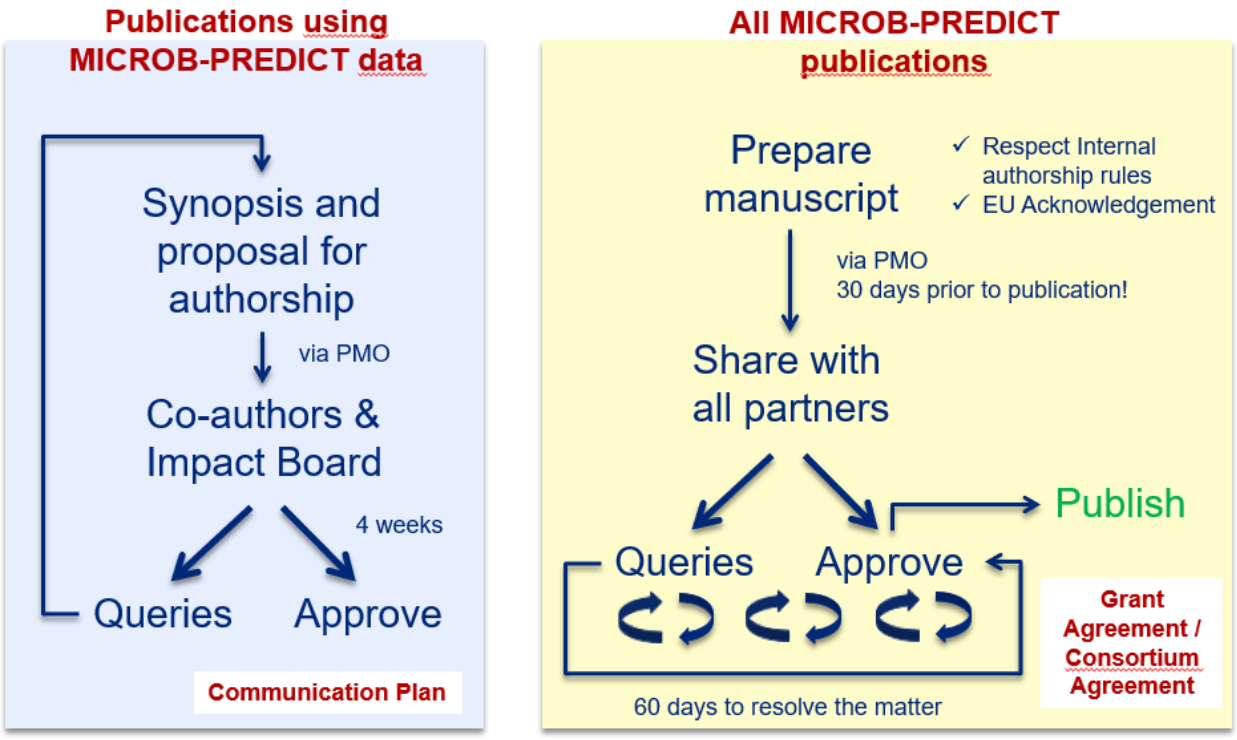
In addition, the consortium agrees amongst its members the following general rules:

- Main papers (analyses, drafting, etc.) published under directorship of the work package leader (WPL).
- Authors must meet ICMJE authorship criteria.
- Ultimate responsibility for deciding authorship (order): WP leader.
- In case of conflict: WP10 / coordinator mediate and take ultimate decision.
- For main papers (deliverables): one author per consortium partner and all consortium members, including students, to be acknowledged.
- If limited number of authors permitted, publication "on behalf of the MICROB-PREDICT study group".
- The coordinating centre EFCLIF under scientific coordination of Jonel Trebicka and the European Commission funding and grant number must be recognised in all papers.

Regarding the ICJME rules commented above, and taking into account the ICJME reccomendations on **conflicts of interest**[88], all MICROB PREDICT partners are obligued to declare any potential conflicts of interest of any kind. Usually the tendency is to focus only on conflicts of interest of economic or financial nature but there could be conflicts of interest of a different nature such as personal, hierachical, etc. The need to declare it is an ethical and legal requirement grounded in research integrity.

[88] ICMJE Conflicts of Interest http://www.icmje.org/conflicts-of-interest/(Accessed 25 March 2020)

MICROB-PREDICT publications: Review process



Publication rules: When are they to be applied?

MICROB-PREDICT Publication

- Results from any output from MICROB-PREDICT (data, knowledge, information…)
- Serves the objectives of MICROB-PREDICT
- Respects rules from GA, CA and Dissemination Plan
  - Open Access
  - EU Acknowledgement
  - Pre-submission review (30 days)
  - Authorship

➔ Will be reported as MICROB-PREDICT output to the EU

Non-MICROB-PREDICT Publication

- May emerge from work done by MICROB-PREDICT partners, but work not done directly as a task from MICROB-PREDICT
- Work not funded by MICROB-PREDICT
- Usual procedure
- May mention MICROB-PREDICT in conflict of interest statement

➔ Will not be reported as MICROB-PREDICT output

26 RECOMMENDATIONS

After the analysis of the 22 MICROB-PREDICT partners codes of conduct, good practices and related references in the field of ethics, we recommend:

26.1 Have a named person

Firstly, as was demonstrated very clearly with UPCH and LUMC, it is useful to show the named person for ethical issues and to display how they can be contacted. For students, researchers or even members of the public, this may inspire confidence and a sense of transparency, that they can contact an institutional expert directly with any queries they may have.

26.2 Mandatory training for staff and students

Next, it was noted in several institutions (i.e. UNIDEB, UPCH, LUMC, UCL) that they published an ethics and good research practice training course online or in person and stated that this was mandatory for staff and post-graduate students. Again, this is a great way to show that an institute takes these matters seriously and has implemented them as part of the core staff training. Mandatory training on good practice, ethics and university regulations is also the best way to ensure that all staff have the same base level of knowledge. Leaving this training down to the PI of the group or the department, or even the staff and students themselves, will result in a very varied level of knowledge and understanding across staff, as some will consider these issues of prior importance and will seek out the information and training themselves, and others may not if it is not obligatory.

26.3 Easy to access code of conduct

One of the best and most obvious ways to advertise an institute's code of good practice is to make it easily accessible from the homepage. Many of the institutes in this report have chosen to put this information in either the "About us" or "Research" tabs on the homepage. The further away this information is from the homepage, and the more difficult it is to access, the less people will have the indication to find it, and many may give up before they reach what they were looking for. Furthermore, an institution with a difficult to access, hidden, or even no code of conduct or mention of good research practice, may give the impression that this is not important to them, although in many cases this will be

unintended. The best way to avoid this is to place a quick link directly on the homepage, or a popular tab, to the good practice site.

26.4 List the key principles

A helpful inclusion seen in a handful of the documents above is the addition of core principles, ethical or otherwise, in the code of good practice. Notably, The Netherlands code of conduct for research adopted by LUMC, the UCL Statement on Research Integrity and the UKRIO Code of Practice for Research. All these documents explicitly state ethical principles, some of which in common include honesty, transparency, responsibility/accountability, respect and integrity. Laying out these principles clearly to define the institutional position of what good practice is, makes it clear for the reader to relate and understand, and also gives a clear link to the ethical principles mentioned in important international guidelines such as the Declaration of Helsinki and the European Code of Conduct for Research Integrity. This will help to build trust between the institute and the public.

While it is important to be clear about which ethical/ good practice principles ones code is trying to emit, it is important to be vigilant that the code is useful on a practical level for those that are going to use it, and does not err into the philosophical realm. One recommendation would be to first list the principles and give recommendations on how they should be implemented through good practices within a research context. One very good example of how to do this is seen in the Code of Good Research Practice by the University of Barcelona.

26.5 Cite other important reference documents

As seen at the INRA, UPCH, KCL and LUMC, it can be a good idea to cite other codes of conduct aside from the institutional one. The most popular documents mentioned by the partners of MICROB-PREDICT were the ALLEA Code and the Singapore statement. Other institutes went beyond this and published their in-house institutional code of conduct alongside the code of good practice for their country (if applicable), and other European and international reference documents. Readers of these codes of conduct will get a good idea of the national context, principles and basis of the codes when read alongside these international ones, and it may help them to level the document in place with the national,

EU and international standards for good practice. Additionally, it is good practice for staff to be familiar with not only their institute's regulations, but those of the wider community. With the introduction of the GDPR, institutions and the public are more aware of issues surrounding data protection and are increasingly asking for more transparency and protection. A good resource of reference for institutions wanting to incorporate data protection into their research projects and good practice policies, is the EU's FAIR Data Management document[89]. Here, the EU have provided guidelines for researchers on how to make their data findable, accessible, interoperable and reusable. Further to this, the LUMC has also developed a reading guide for their code of conduct. This document begins by stating the intended scope of the code of conduct and encouraging any feedback or missing parts be relayed to two named persons (including the Directorate of Research Policy). The reading guide also explains how the university is ensuring that its code is complied with, by electronic lab journals, a research support desk, the Medical Ethical and Good Research Practice committees etc. This is a very welcome and unique supplement to a code of conduct, and is reassuring to see that, not only has the LUMC gone to the effort of creating their code of conduct but is actively ensuring that it is in practice.

26.6 Checklist

One of the best resources seen by partners of MICROB-PREDICT was a good practice or ethical checklist. Copenhagen University, UCL and the UKRIO as adopted by KCL, all included this resource either in their code of conduct or as a supplement. While all staff should read the entire code of conduct, a checklist is a very useful resource for all researchers to have and to go through when doing their work or while preparing a project proposal. Additionally, this could be printed and placed on the laboratory noticeboard, or in the front of lab notebooks, as a reminder to staff to keep good practice and ethics in mind. Overall, the checklist of a quick and easy summary of the main point needed for an ethical, and well-planned project which abides by an institutional code of conduct and can be used in a multitude of ways to keep these principles at the forefront of research. The UKRIO

[89] H2020 Guidelines on FAIR Data Management in Horizon 2020 (2016) https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf (Accessed 16 March 2020)

recommended checklist for researchers, adopted by KCL, provides "*key points of good practice in research for a research project and is applicable to all subject areas*" and is a great example of a resource from an independent charity that could be used by institutes that do not have the resource to provide their own. For institutes that would like to develop their own in-house checklist, a great example is that of KU Leuven, which also contains links on each point to the appropriate institutional regulation. Regarding data management, one very important checklist is that included at the end of the EU FAIR data management document. The data management plan includes an accessible list of checkpoints to make sure that data comply with the FAIR principles (findable, accessible, interoperable and reusable). As good data management is an integral part of good scientific practice, it is recommended that institutions include a data management plan like this or make reference to this one in the code of good research practice.

26.7 Revisions and updates

It is recommendable for institutions to revise their code of conduct regularly in order to keep them current, and in line with current societal demands and academic research. As the field of research ethics and good practice becomes ever more at the forefront of the demands of large consortiums such as the EU (as seen with the requirements of Horizon 2020 funding) and other national funding bodies, it is important that those responsible for the codes of conduct of the institutes mentioned regularly revise them in light of new developments. This will ensure they are up to date and in-line with each other, and with international expectations. It is highly recommened that when revising the institutional code of conduct, all members of the institute are invited to contribute. This will foster a sense of contribution and responsibility, that should translate to greater adherence with the principles themselves. Recently, we have seen the importance of data security and research misconduct become increasingly more evident for society as a whole and have also seen the implementation of the GDPR in 2018. All codes of conduct should address these topics of concern and demonstrate how they are being implemented and protected at an institutional level.

26.8 Implementation of the Code

Having an institutional code of conduct is only of finite use if it is not being read and implemented. It is important for members of the public, funding bodies and members of the institutes themselves, to show how they are ensuring that their code of conduct is being used. A good example of this is seen with the University of Barcelona and their Code of Good Research Practice, which names those exact university statutes which correspond to points in the code. This demonstrates that the university has written good practice into its statute. External monitoring is mentioned by the Max Planck Society and many of the institutions above also include mandatory training on the codes. It is important that institutions have a clear and visible approach to what they consider research misconduct, how it can be reported (anonymously if necessary), whistleblower protection, and finally, the channels the institute has put in place to deal with these cases. One approach to achieve this is to clearly state who is the officer for research integrity (or other relevant institutional office), where they are based, and how to contact them. This will provide confidence to employees, particularly younger members and graduate students, that they can speak up if necessary, and to promote a culture of transparency. A good example of this can be seen with the University of Oslo and their Speak up programme[90]. This is an online portal which provides students and staff with appropriate information and tools to report adverse events, problems in the learning environment and research misconduct. It also provides and overview of the administrative procedures that would follow for each type of report filed. This is a great research and provides staff and students with all the information they need to know about the UiO policy on research misconduct and how complaints will be handled so that they can make informed decisions. A crucial point to communicate here is that when dealing with instances of misconduct, the goal is to educate those involved and the wider community, and notto punish them. Protection for those reporting and those accused must be ensured.

[90] UiO Speak up https://www.uio.no/english/studies/contact/speak-up/

26.9 Institutional open access guidelines or policy

Open access publication of research results is becoming ever more prominent, with funding bodies such as the EU's Horizon 2020 now insisting that all research coming from these projects be published in OA format. Initiatives such as Plan S and those by institutions like the Norwegian Government are also now drawing up plans to make all applicable research outputs OA by specific dates in the future. Therefore, it is important that universities and research institutes provide clear information on what is OA publishing, the benefits it can provide for the researcher, their institute and the public, the associated fees (APCs) (if applicable), and how members of these institutes can get support when publishing OA. Some institutions have opted to include a FAQs section where they answer the most common questions on the OA model, and others provide guides online with all relevant information. The two greatest issues that appear to arise from researchers when discussing changing to an OA model are "How are we going to pay for it?" and "how do we avoid 'Predatory Publishers'?". In this regard, it is recommended that institutes provide clear information on any funds they have for OA publishing, links to funding websites etc.; and that they provide guidance on how to identify credible OA publishers (e.g., membership to the Committee on Publication Ethics (COPE), the Directory of Online Journals (DOAJ) and avoid the less credible ones. The FAQ by KCL[91] and the OA information from LUMC[92] could serve as good examples for institutions wanted to prepare their own OA section for staff.

26.10 Clear policy on publications and internal authorship rules promoting open access

In addition to having a clear OA policy, it is also recommended that institutions participating in EU-funded projects make clear what policy is in place regarding any research publications, output or dissemination coming from the project. This should be communicated to all involved parties from the beginning. Further to this, all partners should be in agreement about the standards of publication and dissemination activities, both from their own institutions and within the grant agreement. National and international laws and

[91] KCL Open Access FAQs https://www.kcl.ac.uk/library/researchsupport/openaccess/faqs

[92] LUMC Open Access https://www.lumc.nl/org/walaeus/wegwijzers/openaccess/?setlanguage=English&setcountry=en

recommendations on publcation may vary, especially in cross border collaborations, which further reinforces the need to agree on a unanimous stardard from the start of the project, with all parteners involved and informed. In the case of MICROB-PREDICT, the ICJME guidelines are followed as the standard for publication activities. Ensuring that all partners in large consortium projects have a stong, transparent and ethical stance on publishing is the best way forward, and will save time and discussion in the long run regarding results output and dissemination.

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