MICROB-PREDICT

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

D8.7 Checklist for participants to assure informed consent / other mechanisms for those unable to give a written consent

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Table of Contents

1. Objective of this document

The following is a proposal of checklist for participants and for researchers in biomedical research focused on participant information and the consent process to ensure that the project complies with the ethical and legal standards applicable. It is designed to assure the free, informed and voluntary consent of participants including those unable to consent and who need a legal representative. This proposal could be used by institutions, research centres, sponsors and research ethics committees. It is the result of the analysis of the ethical and legal guidelines and conventions that are considered as cornerstones in research (Part A). It includes the template designed by the Bioethics Commission of the University of Barcelona published in open access and available in English and Spanish. There are suggested models that could serve as guidance for the MICROB-PREDICT Consortium and for any research project and H2020 Consortium in the field of biomedical research when recruiting participants, using human biological samples and/or personal data (Part B). This checklist is part of the MICROB- PREDICT policy on Information and Informed Consent template for participation of human beings for using biological samples of human origin in research and for the use of personal data in research. More information on ethics and MICROB-PREDICT are available at: https://microb-predict.eu/for-scientists/more-results/. The proposal is not intended to be a *numerus clausus* list of issues that should be part of a checklist but to highlight the most relevant issues for participants to assure informed consent and for researchers to review at any step of the process of information and at any stage of the project to assure that it is following the ethical and legal standards agreed at European and international level. Finally, we suggest to researchers to follow the UKRIO resources (PART C):

- The recommended checklist for researchers that lists the key points of good practices in research applicable to all subjects (https://ukrio.org/publications/checklist-for-researchers/)
- The Researcher Checklist of Ethics Applications for Research with Human Beings dedicated to the general issues a research ethics committee may consider when reviewing a research project about the methodological, ethical, legal and societal issues that should be analysed as previous and compulsory step to conduct research with humans (https://ukrio.org/publications/researcher-checklist-of-ethics-applications).

UKRIO is an independent charity providing advice and support to the public, researchers and organisations to further good practice in academic research, scientific and medical research. It has been identified as an organization of reference in the field after a comprehensive study to build the MICROB-PREDICT policy on Codes of conduct applicable and research integrity policy including publications in journals. This document analyses 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. At the end, there are 10 recommendations of useful points that each code of conduct should include. More information on ethics and MICROB-PREDICT are available at: https://microb-predict.eu/for-scientists/more-results/.

2. PART A:

	Checklist	Yes	No	Notes (Supporting information if applicable)
For compliance with the EU Clinical Trials Regulation:				
For subjects capable to give free, informed and voluntary consent:				
1	Informed consent of subject is in writing			
	- If writing not possible: it is recorded in audio or visual means			
	- The subject has been given a copy of the document (or recording)			
2	The Subject has received all appropriate information in appropriate language, understandable by a layperson:			
	- The Subject has been explained the nature, objectives, benefits, implications, risks and inconveniences and possible compensations, if any for his/her participation of the clinical trial/biomedical research (his/her participation and the use of human biological samples and personal data)			
	- The Subject has been informed about the exploitation of the results of the research and its possible commercialization			
	- The Subject has had the opportunity to ask questions to the researcher in charge of the project			
	- The Subject has had adequate time to consider his/her decision			
	- The Subject is aware of the treatment alternatives and any planned follow-up care for trial participants			
3	The subject, or their legal representative is aware that they may withdraw from the clinical trial at any time without providing a justification			
4	Researchers have considered all subject circumstances (economic, social, institutional etc.) that could potentially influence their decision			

	Checklist	Yes	No	Notes (Supporting information if applicable)
5	In the case of a minor who is capable of forming an opinion, their assent has been obtained in addition to the informed consent given by the legally designated representative *not applicable for MICROB-PREDICT but included for general uses in biomedical research			
For subjects unable to give consent:				
6	His or her legally designated representative has given informed consent considering the same points listed above (1-5)			
	- The legal representative has contact details of a designated member of the investigation team in case of further information			
	- The subject unable to consent has received information adequate to their ability to understand it			
7	The subject unable to consent has been involved as far as possible in the informed consent procedure			
8	If the subject unable to consent is capable of forming an opinion, and they have explicitly refused to partake or have expressed a wish to withdraw from the clinical trial, this has been respected by all parties			
9	The subject unable to consent and/or their legally designated representative has received no incentives or financial inducements			
10	It is essential to involve subjects unable to consent in this clinical trial as comparable data cannot be obtained using persons able to give informed consent or alternative research methods			
11	This clinical study is directly related to the medical condition of the subject unable to consent			
12	There is a scientific basis for the clinical trial that has led to the expectation that a positive result for the subject unable to consent or group that they represent, and will impose minimal risk and burden			

	Checklist	Yes	No	Notes (Supporting information if applicable)
For compliance with the General Data Protection Regulation:				
13	The EU General Data Protection Regulation has been considered and respected with regards to personal data treatments and subject rights			
14	In the event of withdraw of consent by the subject and their legally designated representative all GDPR rights are respected following the moment of withdrawal			
15	Regarding data obtained before consent was withdrawn, this is not affected in either its usage or storage, with respect to the basis of the informed consent in which it was obtained			
For compliance with the Declaration of Helsinki, World Medical Association (2013) and the Convention on Biomedicine and Human Rights, Council of Europe (1997)				
16	The proposed intervention will be of direct benefit to the subject			
17	All information on the proposed procedure has been given including the potential benefits and risks			
18	Subject is a minor – his/her assent has been obtained in relation to their capacity of understand the information given and their maturity *not applicable for MICROB-PREDICT but included for general uses in biomedical research			
19	Subject is an incapacitated adult – All interventions have been approved by the legally designated representative			
20	If the subject is an incapacitated adult – they have participated as much as possible in the consent process			
21	The subject is fully aware that they have the right to withdraw at any time with no justification			
22	There are no alternatives to compare the efficacy of the treatment using other research subject able to consent themselves			
23	The risks to the subject do not outweigh the potential benefits			
24	The research has been approved by a competent REC for its scientific and ethical validity			

	Checklist	Yes	No	Notes (Supporting information if applicable)
25	The participant and their legal representative have been fully informed of their rights in the law of the country in which they reside			
26	The person has not objected			
27	If the research potential is not for the direct benefit of the participant, it aims to significantly contribute to the scientific understanding of the participants condition which will benefit that community and the research is minimal risk (all within national/international law)			

3. PART B:

PARTICIPANT'S INFORMED CONSENT (suggested model provided by the Bioethics Commission at the University of Barcelona, available here in open access.)

Title of the research project:

The potential participant (patient /healthy volunteer) must read and answer the following questions carefully:

(Please circle the answer you deem to be correct)

Have you read all the information about this project that has been provided to you? YES / NO

Have you had the chance to ask about and discuss issues on this project? YES / NO

Have you received sufficient information about this project? YES / NO

Have you received satisfactory answers to all your questions? YES / NO

Which researcher informed about and discussed this project with you? (name and surname):
_____

Do you understand you are free to leave this project without this decision affecting you in any way?
YES / NO

At any time? YES / NO

Without giving any reason? YES / NO

Do you understand the possible risks associated with your taking part in this project? YES / NO

Do you agree to take part in it? YES / NO

Will you receive any kind of compensation for taking part? YES / NO

(Only when necessary – legal representatives)

Do you authorise the participation of the person whom you are responsible for?

YES / NO

(name and surname of the person): _____
(other details that should be included according to the nature of the project):
_____

Date, place: _____ **Signature:** _____

Name and surname of the subject participant in research:

If later you would like to ask any question or comment about this project, or you wish to revoke your participation in it, please contact:

(name of researcher) (Research Centre, Department, Faculty and address)
E-mail address:
Telephone number:

Date, place: _____ **Signature:** _____

Name and surname of the researcher responsible for the research project:

_____

Copy for the participant / Copy for the researcher

4. PART C: UKRIO resources

1) **The recommended checklist for researchers** that lists the key points of good practices in research applicable to all subjects (https://ukrio.org/publications/checklist-for-researchers/)

2) **The Researcher Checklist of Ethics Applications for Research with Human Beings** dedicated to the general issues a research ethics committee may consider when reviewing a research project about the methodological, ethical, legal and societal issues that should be analysed as previous and compulsory step to conduct research with human (https://ukrio.org/publications/researcher-checklist-of-ethics-applications)

5. Acknowledgement and Disclaimer

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