MICROB-PREDICT

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

D 8.2. 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

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1. MICROB-PREDICT Objective

Decompensation of liver cirrhosis and progression towards acute-on-chronic liver failure (ACLF) causes 1.2 million deaths/year. Microbiome is causally involved in cirrhosis progression and is for drugs the first interaction point with the patients. Drugs can alter the microbiome leading to unwanted effects or even facilitating their effects, but the microbiome metabolizes the drugs, shapes their effects and possibly determines the host response to drugs. As each person carries an individual microbiome, insight in these processes should help stratify or even personalize patient health care and treatment.

The aims of MICROB-PREDICT are:

1) to better understand the role of microbiome and the gut-liver axis interactome with respect to microbiome functionalities,
2) to identify and validate microbiome-based biomarkers and signatures for personalized prediction of decompensation and ACLF, and response to treatment,
3) to design three new tests as easy-to-use tools and point-of-care, smartphone-connected nanobiosensors, and
4) to validate them in a randomized controlled trial. MICROB-PREDICT will assemble existing data and samples from major microbiome initiatives in hepatology (12 international studies, >10,000 patients), and enrich them with holistic and in-depth analysis using cutting-edge multi-omics technologies of host and microbiome from different body sites in samples of >1,000 patients collected in a longitudinal manner with sequential visits and controlling for confounders.
5) MICROB-PREDICT results will foster more accurate, personalized risk stratification and significant steps towards personalized treatment of decompensated cirrhosis and ACLF. World-leading microbiome specialists, technology leaders and clinical experts make this a programme of scientific excellence; patient organisations (ELPA) and the European Association for the study of the Liver (EASL) will channel our results into a powerful dissemination, communication and exploitation programme.

2. Introduction

The MICROB-PREDICT research project has different interventions in research: clinical trials with patients and healthy volunteers, biomedical research with human biological samples from diverse origins (blood, stool, mucosa, etc.) and collection, transfer and processing of personal data. These different types of research require designing specific research protocols, information and informed consent procedures and templates to assure the protection of rights of participants, while promoting freedom of research at any stage.

This work provides a template for the MICROB PREDICT Consortium for the use of human biological samples and personal data in biomedical research. It could be used as a guidance or can be adapted to support the templates of each research institution involved. Human biological samples include personal data as valuable information for research. Personal data such as genetic data should be specially protected according to ethical and legal regulations at international, European and national level. The right to privacy and confidentiality and other related rights such integrity should be protected and promoted as well as freedom of research. In this sense, the template provided here includes the updates on information to be added about data protection due to the application the General Data Protection Regulation from May 2018.

This work should be considered as a piece of the policy of information and informed consent Informed consent policy for human subjects, human biological samples and personal data in MICROB-PREDICT. This policy describes the ethical and legal framework for the planned research interventions, the implications for research participants (patients and healthy volunteers) and obligations for those conducting research: It is about the information that potential study participants should have received in order to be able to decide whether or not to participate ('informed consent'), and the implications this decision may have for their personal situation. Our information and informed consent policy respects also the main ethical and legal guidelines on ethics in research and research integrity at international and European level that the Consortium should follow to achieve the goals of the project, while respecting research subjects.

3. Information and informed consent templates for donating human biological samples to biomedical research[1]

The use of biological samples of human origin for biomedical research is possible in different regimes within the framework of a biobank. A biobank is "a public or private, non-profit establishment that

[1] The templates proposed here are the result of the analysis of different forms and a thorough study of the ethical and legal regulations applicable. The autor is member of two research ethics committes in research: The Bioethics Commissions at the University of Barcelona and the Research Ethics Committee (REC) at Hospital Clínic de Barcelona. The first Biobank established in Spain was the Biobank of IDIBAPS – Hospital Clínic de Barcelona. In particular, to produce this proposal I have followed the example of the templates provided by the REC at Hospital Clínic and adapted to the MICROB-PREDICT Consortium taking into account its diversity and trying to find a common ground applicable to all partners. I Would like to thank to the technical secretariat at REC Hospital Clínic and to the members dedicated to review the uses of human biological samples in biomedical research for their help in providing information.

houses a collection of biological samples designed for diagnostic or biomedical research purposes and organized as a technical unit with criteria of quality, order and destination" (see Spanish Biomedical Research Act, 2007, art. 3 d)). Biobanks integrate a scientific committee and a research ethics committee in charge of reviewing and approving research protocols that request the uses of human biological samples.

a) Collection of human biological samples to do biomedical research into a specific line of research. In this case, the biological samples given altruistically for research purposes by the entitled subject, may only be used by the owner of the collection in research projects that fall within the specific line of research. Furthermore, these studies must be carried out at the research centre where consent was obtained. In the event that research with these samples should be carried in a different research setting, it is necessary to ask for the informed consent to the entitled person. In the Spanish case, as in other contexts, it is necessary to register the collection in the National Registry of Biobanks, located at the Carlos III Health Institute in Madrid. This institute is in charge in charge of coordinating the research carried out in the Spanish country. Research protocols should be reviewed and approved by the entitled research ethics committee.

b) The biobank regime is established by law for the storage of human biological samples in a broader sense and purpose. Thus, the samples are stored and available for many different purposes in research and not tight to a specific line. For this reason, informed consent includes the possibility of transferring the samples to third parties for research purposes. All research protocols should be approved by the entitled research ethics committee and for which it would not be necessary to seek consent again.

It should be taken into account that the person in charge of the collection or the biobank is the person responsible for legal purposes of the samples used for research purposes.

3.1 Collection regime

Information and informed consent template for the use of human biological samples and clinical data in research projects to be stored in a collection regime

*This template includes the uses for biomedical research purposes of human biological samples surplus from healthcare processes.

A. Information

At the **(institution) (health care assistance and/) biomedical research** it is carried out for the advancement of the scientific knowledge in biomedicine. Once human biological samples have been obtained and used for the diagnosis or control of diseases, they could be used for research purposes with the consent of the owner after being informed about the donation process, the uses of the samples and his/her rights.

In accordance with (**Law/ Regulation i.e.** Spanish Law 14/2007 on Biomedical Research) we request your authorization to store and use of clinical information and biological material left over from tests or surgical interventions that have been or will be performed on you at the **(Hospital service)**. This authorization is part of the regular healthcare process in order to allow biomedical research.

The purpose is to create a collection of human biological samples that will allow us to investigate the molecular or genetic alterations of the **(diseases/ condition to study).**

The final aim is to advance in the creation of scientific knowledge to prevent, diagnose, predict and/or treat **(disease/specific condition to study). If you give your consent, the genetic studies done could be related to your complete genome sequencing[2].**

The principles that rule the uses of human biological samples in research are: autonomy and informed consent; gratuity and solidarity; confidentiality, quality, security and traceability. The donation and uses of human biological samples will be evaluated by the entitled research ethics committee to reviewing the methodological, ethical, legal and societal issues of the research protocol involved.

Human biological samples contain personal genetic information. Personal data and health care data, included genetic data are considered as special categories of data that should be protected at any time with specific guarantees. It is the duty of researchers and research institutions and as of the biobank.

Thus, we ask you your consent to store your biological material **(indicate type of sample DNA, blood, stool, hair urine, ascites, biopsy bio specimens i.e.)** in a collection **(name of the collection and acronym) (Dr. in charge and contact)** to use it for research **(purposes)[3].** The collection is located at the Biobank **(name of the biobank**) and registered at **(national registry** i.e. Spanish National Registry Ref. number**)**.

A biobank is a public or private, non-profit establishment that houses a collection of biological samples designed for diagnostic or biomedical research purposes and organized as a technical unit with criteria of quality, order and destination. It fosters biomedical research, mainly, translational

[2] This clause could be optional.

[3] In the case of MICROB-PREDICT the purposes could be: learn about the factord that may affect the progression of cirrhosis; how biomaterials analysis can predict the progression of the disease or to study the alterations molecules found in tissues, to study on cirrhosis.

research, to improve knowledge and to move from basic knowledge to its application in order to develop treatments and interventions to improve the quality of life and health conditions.

Your samples will be under the custody of the biobank, frozen and properly stored and maintained, until the material has been left over. In the event that additional biological samples are needed for research purposes, the **(institution)** will contact again to ask you for your collaboration and informed consent.

All research protocols that include the use of human biological samples will be carried out by researchers in **(line of research)** of **(research team**) of the **(institution).** Prior to any use of human biological samples, the research protocols should be reviewed by the entitled research ethics committee **(add reference, link).**

You are free to decide to donate your human biological samples to biomedical research after being informed and having time enough to ask questions and solve doubts. You can contact with **(Dr. in charge**) in case you need more information or assistance in this process.

The Dr. in charge should explain the risks of the donation process (related to the donation process itself i.e. slight discomfort or bruising from the blood draw) and the benefits of the uses of your biological sample in research (i.e. no direct benefit from participants but to increase general knowledge about the natural history of the disease).

Here you will find the rights to be exercised in the donation process and the regulation applicable:

In compliance with the provisions of Regulation (EU) 2016/679 of 27 April on the protection of individuals with regard to the processing of personal data (known as General Data Protection Regulation) and (**national regulation**), the **(Institution**) as the data controller[4], with **(VAT XXX),** and address in **(CITY), (STREE ZIP CODE),** informs you that you can contact the Data Protection Officer at _____@_____._____ for any questions related to the donation and the exercise of the rights as donors of human biological samples in research.

1. The donation of biological samples to the **(Collection name)** for biomedical research is voluntary, free and altruistic. You will not receive any direct financial benefit from your participation in the research studies, nor will you have any property rights to possible commercial value from the discoveries as result of the biomedical research (i.e. new products, tests).

2. You can be informed on the use of your biological samples in research by contacting the person responsible for the Collection **(name)** and indicated at the bottom of this page.

3. You may refuse to participate or withdraw your consent at any time without any explanation and this situation will not adversely affect your present or future medical care.

[4] The Data controller is in charge of protecting the rights of the donors of the human biological samples, mainly privacy and confidentiality. The data controller defines the purposes and means of personal data treatments. See General Data Protection Regulation.

If you withdraw your consent your biological samples and personal data associated will be removed from the collection, except the data generated until the date of your withdrawal.

There is a specific section in this template to revoke your consent, if you wish to do so, please contact with the **(institution) (Customer Service or similar).**

If you request to revoke your consent, the person in charge of the collection **(Dr. in charge)** will provide you with information about the research protocols in which your samples have been used and its results.

4. In the case of obtaining relevant information that could affect your or your relative's health, the person in charge of the collection **(Dr. in charge),** will contact you:

- To offer you the possibility of being informed of this situation and;
- To advise you on the convenience of communicating it to your relatives, if necessary. For the purposes of any such contact, the information contained in your medical record will be used. However, your right not to be informed of the results of the research will be respected[5].

5. Your personal data, including genetic data will be:

- Codified to preserve your privacy and confidentiality at any time. A number will be assigned to your sample and personal data associated. The information provided by the research could be published in scientific journals.
- Processed for research purposes related to the abovementioned collection, based on the consent you give us by signing this document.
- Not used or disclosed by third parties except Research Ethics Committees or by public authorities according to legal regulations.
- Not transferred to third parties or transferred to third countries outside from the European Union[6].
- Kept for a period of **(_) years**. After that period samples and data will be destroyed.
- Transferred to the National Registry of Biobanks in case the activity of the biobank ceases or in the event that its authorization to operate has been revoked.

[5] This principle of respect for the right to be informed (or not) of the owners of samples and data has its limitations. Rights are not absolute and there are exceptions justified by law and by ethical and deontological regulations. In this sense if there is relevant information that should de delivered to the affected and its relatives it could be delivered even against the will of the affected due to the protection of those (third parties) that could be at risk in case of not having access to the information.

[6] If this is the case, there are specific clauses and information to be explained to participants. I.e. Agreements to protect human rights respecting the highest of protection, specially privacy and confidentiality. In this sense, the General Data Protection Regulation establishes the Privacy Shield. It is a certificate that international companies need to have for data treatments coming from Europe. It is the formula established to protect rights of the individuals based in Europe when transferring personal data to third countries.

6. You have the right to access your data, request the rectification of inaccurate data or, if appropriate, request their deletion. Likewise, you can limit the processing of your personal data, oppose and withdraw consent to their use for specific purposes.

These rights can be exercised by contacting with the **(institution)** by postal address in **(CITY), (STREET ZIP CODE),** or by email to Data Protection Officer ____@_____.edu . We also inform you of your right to complain with the **(National Authority on Data Protection** i.e. Spanish Agency on Data Protection**)** against any action taken by the **(institution)** that you consider to be in breach of your rights.

Feel free to ask for more information the person in charge of the collection and the identified personnel to do so.

Thank you very much for your cooperation.

Responsible for Collection: **(Name and surname) (Service/unit) (Institution)**

CITY), (STREE ZIP CODE). (Phone number)

B. Informed consent

After being properly informed and having understood the information provided about the implications of the donation and uses of human biological samples in biomedical research, here you will find the informed consent template to authorize the donation of your biological samples as entitled person. You have the right to have a copy of the information and informed consent template provided here signed and dated.

This information and informed consent process should have enough time and opportunities to contact with the researcher and the team in charge to provide you all information that you feel you need for solving doubts, for clarifications and for asking questions related to the donation of biological samples and the research process. Specially about possible benefits and related to the intervention associated to the donation.

Bearing in mind that the process of information and informed consent should be developed in a free way. The entitled person decides to collaborate donating his/her human biological samples and personal data associated to for the purpose of biomedical research to (institution). There should be no coercion or undue influence in the process.

I, (**name and surname)**, authorize and give my consent to the storage and use of human biological samples (including the left over from medical tests and clinical healthcare related information obtained from my medical record (**service/unit**) to the **(Collection name)** in charge of (**Dr.**), registered in the **(institution)** and in the (**National Registry of Biobanks**).

The goal is carry out biomedical research projects related to **(diseases)** by researchers in (team/group/line of research) of the **(institution) to contribute to the advancement of scientific knowledge and to develop treatments and interventions to improve healthcare.**

I have been informed that research protocols should be approved by the entitled research ethics committee **(contact).** It is an interdisciplinary body to review the methodological, ethical, legal and societal issues involved in the research and in the uses of human biological samples and personal data associated. They should approve the proposed research and review that all information has been delivered properly to the potential donor during the information process, including their rights and how to exercise them. The personal data associated to my biological sample will be protected under the duty of confidentiality of all personnel involved in the research process. Data will be codified and guarded by the **(Biobank).**

I declare that I have been properly informed and that I had the opportunity and the conditions to ask for more information about the donation process and the uses of my samples, and to solve any doubts with **(the person in charge – healthcare professional- and his/her team**.

Please indicate yes or no to the following:

- I want to be informed about the information provided by the research process with my human biological samples and personal data associated that is relevant to my health: Yes No
- I agree to be contacted in case the research justifies the donation of more biological material. To contact me, the person in charge will use the contact information provided in my medical record Yes No
- I authorize the use of these samples in projects that include the complete genome sequencing Yes No

SIGNATURES

Name surname (patient/ healthy volunteer)[7]	**Name surname (entitled personnel)**
ID	**ID**
Place, date, month, year	**Place, date, month, year**

C. Form to revoke consent

The right to revoke consent could be exercised at any time, for this reason we recommend to add a specific section in the informed consent template as follows:

CONSENT WITHDRAWAL

I **(name and surname)** hereby revoke my consent to store and use my human biological material donated for biomedical research in the **(Collection name) (Dr. in charge).** I have been informed of my rights and duties regarding the withdrawal. The information and knowledge generated until the date

[7] For subjects that are unable to consent, following the ethical an legal regulations, there should a specific template to provide all the information specified to be signed by the legal representative of the owner of the human biological sample.

of my withdrawal will remain for the sake scientific advancement as stated in the regulation. From now my biological samples and personal data associated should be eliminated from the storage facilities and the data base of the **(biobank).**

For the withdrawal of consent to the uses of human biological samples in biomedical research the entitled person should include a copy of ID card or similar documentation accepted and a contact information and address for notification purposes[8].

SIGNATURE

Name surname (patient/ healthy volunteer)

ID[9]

Place, date, month, year

3.2 Biobank regime

Information and informed consent template for the use of human biological samples and clinical data in research projects to be stored in the biobank regime[10]

A. Information

At the **(institution) (health care assistance and/) biomedical research** it is carried out for the advancement of the scientific in biomedicine. Once human biological samples have been obtained and used for the diagnosis or control of diseases, they could be used for research purposes with the consent of the owner after being informed about the donation process, the uses of the samples and his/her rights.

In accordance with (**Law/ Regulation i.e.** Spanish Law 14/2007 on Biomedical Research) we request your authorization to store and use of clinical information and biological material left over from tests or surgical interventions that have been or will be performed on you at the **(Hospital service)**. This authorization is part of the regular healthcare process in order to allow biomedical research.

The purpose is to use your human biological material and data associated for research purposes. For this reason the material will stored in the (biobank) and become part of its repository to be used by researchers in different research projects. The final aim is to advance in the creation of scientific knowledge to prevent, diagnose, predict and/or treat **(disease/specific condition to study).**

[8] It is possible to add the number of the medical record of the entitled person.

[9] It is common to ask for this evidences for withdrawing consent.

[10] *This template includes the uses for biomedical research purposes of human biological samples surplus from healthcare processes.

The principles that rule the uses of human biological samples in research are: autonomy and informed consent; gratuity and solidarity; confidentiality, quality, security and traceability. The donation and uses of human biological samples will be reviewed by the entitled research ethics committee to reviewing the methodological, ethical, legal and societal issues of the research protocol involved.

Human biological samples contain personal genetic information. Personal data and health care data, included genetic data are considered as special categories of data that should be protected at any time with specific guarantees. It is the duty of researchers and research institutions and as of the biobank.

Thus, we ask you your consent to store your biological material **(indicate type of sample DNA, blood, stool, hair urine, ascites, biopsy bio specimens i.e.)** in **(name of the biobank**) and registered at **(national registry** i.e. Spanish National Registry Ref. number**)**.

A biobank is a public or private, non-profit establishment that houses a collection of biological samples designed for diagnostic or biomedical research purposes and organized as a technical unit with criteria of quality, order and destination. It fosters biomedical research, mainly, translational research, to improve knowledge and to move from basic knowledge to its application in order to develop treatments and interventions to improve the quality of life and health conditions.

Your samples will be under the custody of the biobank, frozen and properly stored and maintained, until the material has been left over. In the event that additional biological samples are needed for research purposes, the **(institution)** will contact again to ask you for your collaboration and informed consent.

You are free to decide to donate your human biological samples to biomedical research after being informed and having time enough to ask questions and solve doubts. You can contact with **(person in charge at the biobank**) in case you need more information or assistance in this process.

The Dr./person in charge should explain the risks (related to the donation process itself i.e. slight discomfort or bruising from the blood draw) of the donation process and the benefits of the uses of your biological sample in research (i.e. no direct benefit from participants but to increase general knowledge about the natural history of the disease).

Here you will find the rights to be exercised in the donation process and the regulation applicable:

In compliance with the provisions of Regulation (EU) 2016/679 of 27 April on the protection of individuals with regard to the processing of personal data (known as General Data Protection Regulation) and (**national regulation**), the **(Institution**) as the data controller[11], with **(VAT XXX),** and address in **(CITY), (STREE ZIP CODE),** informs you that you can contact the Data Protection Officer at

[11] The Data controller is in charge of protecting the rights of the donors of the human biological samples, mainly privacy and confidentiality. The data controller defines the purposes and means of personal data treatments. See General Data Protection Regulation.

_____@_____.____ for any questions related to the donation and the exercise of the rights as donors of human biological samples in research.

The donation of biological samples to the **biobank** for biomedical research is voluntary, free and altruistic. You will not receive any direct financial benefit from your participation in the research studies, nor will you have any property rights to possible commercial value from the discoveries as result of the biomedical research (i.e. new products, tests).

2. You can be informed on the use of your biological samples in research by contacting the person responsible for the biobank (**name)** and indicated at the bottom of this page.

3. You may refuse to participate or withdraw your consent at any time without any explanation and this situation will not adversely affect your present or future medical care.

If you withdraw your consent your biological samples and personal data associated will be removed from the collection, except the data generated until the date of your withdrawal.

There is a specific section in this template to revoke your consent, if you wish to do so, please contact with the **(institution) (Customer Service or similar).**

If you request to revoke your consent, the person in charge of the biobank will provide you with information about the research protocols in which your samples have been used and its results.

4. In the case of obtaining relevant information that could affect your or your relative's health, the person in charge of the collection **(Dr. person in charge),** will contact you:

- To offer you the possibility of being informed of this situation and;
- To advise you on the convenience of communicating it to your relatives, if necessary. For the purposes of any such contact, the information contained in your medical record will be used. However, your right not to be informed of the results of the research will be respected[12].

5. Your personal data, including genetic data will be:

- Codified to preserve your privacy and confidentiality at any time. A number will be assigned to your sample and personal data associated. The information provided by the research could be published in scientific journals.
- Processed for research purposes related to the abovementioned collection, based on the consent you give us by signing this document.
- Not transferred to third parties or transferred to third countries outside from the European Union.

[12] This principle of respect for the right to be informed (or not) of the owners of samples and data has its limitations. Rights are not absolute and there are exceptions justified by law and by ethical and deontological regulations. In this sense if there is relevant information that should de delivered to the affected and its relatives it could be delivered even against the will of the affected due to the protection of those (third parties) that could be at risk in case of not having access to the information.

- Not used or disclosed by third parties except Research Ethics Committees or by public authorities according to legal regulations.
- Transferred to the National Registry of Biobanks in case the activity of the biobank ceases or in the event that its authorization to operate has been revoked.

6. You have the right to access your data, request the rectification of inaccurate data or, if appropriate, request their deletion. Likewise, you can limit the processing of your personal data, oppose and withdraw consent to their use for specific purposes.

These rights can be exercised by contacting with the **(institution)** by postal address in **(CITY), (STREE ZIP CODE),** or by email to Data Protection Officer ____@_____.edu . We also inform you of your right to complain with the **(National Authority on Data Protection** i.e. Spanish Agency on Data Protection**)** against any action taken by the **(institution)** that you consider to be in breach of your rights.

Feel free to ask for more information the person in charge of the collection and the identified personnel to do so.

Thank you very much for your cooperation.

Responsible for the Collection: **(Name and surname) (Service/unit) (Institution)**

CITY), (STREE ZIP CODE). (Phone number)

B. Informed consent

After being properly informed and having understood the information provided about the implications of the donation and uses of human biological samples in biomedical research, here you will find the informed consent template to authorize the donation of your biological samples as entitled person. You have the right to have a copy of the information and informed consent template provided here signed and dated.

This information and informed consent process should have enough time and opportunities to contact with the researcher and the team in charge to provide you all information that you feel you need for solving doubts, for clarifications and for asking questions related to the donation of biological samples and the research process. Specially about possible benefits and related to the intervention associated to the donation.

Bearing in mind that the process of information and informed consent should be developed in a free way. The entitled person decides to collaborate donating his/her human biological samples and personal data associated to for the purpose of biomedical research to (institution). There should be no coercion or undue influence in the process.

I, (**name and surname)**, authorize and give my consent to the storage and use of human biological samples (including the left over from medical tests and clinical healthcare related information obtained from my medical record to the **(biobank)** in charge of (**name and surname**), and registered in the (**National Registry of Biobanks**)

The goal is carry out biomedical research by researchers to contribute to the advancement of scientific knowledge and to develop treatments and interventions to improve healthcare.

I have been informed that research protocols should be approved by the entitled research ethics committee **(contact).** It is an interdisciplinary body to review the methodological, ethical, legal and societal issues involved in the research and in the uses of human biological samples and personal data associated. They should approve the proposed research and review that all information has been delivered properly to the potential donor during the information process, including their rights and how to exercise them. The personal data associated to my biological sample will be protected under the duty of confidentiality of all personnel involved in the research process. Data will be codified and guarded by the **(Biobank).**

I declare that I have been properly informed and that I had the opportunity and the conditions to ask for more information about the donation process and the uses of my samples, and to solve any doubts with **(the person in charge of the biobank).**

Please indicate yes or no to the following:

- I consent to the use of the surplus biological material and/or associated data for biomedical research YES NO
- I authorize the donation of blood samples for biomedical research YES NO
- I consent to receiving the information obtained, if it is relevant to my health or to the health of my relatives YES NO
- I authorize to be contacted in case of needing more information or additional biological samples for research purposes YES NO
- I authorize the use of the biological samples previously stored at **(institution)**[13] YES NO
- I want to include restrictions on the use of the biological samples and personal data associated YES NO

SIGNATURES

Name surname (patient/ healthy volunteer)[14]	**Name surname (entitled personnel)**
ID[15]	**ID**

[13] This is because, in the case of Spain, no regulation was in place until 2007. But samples have been stored and used for many years and since 2007 the persons in charge should store it in biobank (choosing the regime).

[14] For subjects that are unable to consent, following the ethical an legal regulations, there should a specific template to provide all the information specified to be signed by the legal representative of the owner of the human biological sample.

Place, date, month, year **Place, date, month, year**

C. Form to revoke consent

The right to revoke consent could be exercised at any time, for this reason we recommend to add a specific section in the informed consent template as follows:

CONSENT WITHDRAWAL*

I **(name and surname)** hereby revoke my consent to store and use my human biological material donated for biomedical research stored in **(biobank**). I have been informed of my rights and duties regarding the withdrawal. The information and knowledge generated until the date of my withdrawal will remain for the sake scientific advancement as stated in the regulation. From now my biological samples and personal data associated should be eliminated from the storage facilities and the data base of the **(biobank).**

*For the withdrawal of consent to the uses of human biological samples in biomedical research the entitled person should include a copy of ID card or similar documentation accepted and a contact information and address for notification purposes.

SIGNATURE

Name surname (patient/ healthy volunteer)

ID

Place, date, month, year

4. Acknowledgement and Disclaimer

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.

[15] It is possible to add the number of the medical record of the entitled person.