PICCOLO

Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support

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Abstract:

This document is the first version of Deliverable 7.4 that includes the activities belonging to task 7.3.

D7.4 includes the Data Management Plan (DMP) for the PICCOLO project to assure a proper use of all generated data in accordance with the Guidelines of FAIR Data Management in Horizon 2020. The final version including all ethical items related to the use of data during the project will be submitted in M30.

Dissemination level		
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V0.4	08/12/2017	Integrated version (send to WP members)
V0.5	11/12/2017	Updated version (send to Quality Manager)
V0.5	11/12/2017	Updated version (QM send to project internal reviewers)
V0.6	18/12/2017	Reviewed version sent to QM
Sign off		Signed off version (for approval to EB members)
V1.0		Approved Version to be submitted to H2020 office

Table of contents

Document Info....4

Executive summary....9

1. Introduction....10

1.1 Objective of this document....10

1.2 Structure of this document....10

1.3 Relationships with other deliverables....10

1.4 Acronyms and abbreviations....11

2. Data Summary....12

2.1 Description....12

2.1.1 What is the purpose of the data collection/generation and its relationship to the objectives of the project?....12

2.1.2 What types of formats of data will the project generate/collect?....12

2.1.3 Will you re-use any existing data and how?....12

2.1.4 What is the origin of the data?....12

2.1.5 What is the expected size of the data?....16

2.1.6 To whom might the data be useful (‘data utility’)?....17

3. FAIR data....18

3.1 Making data findable, including provisions for metadata....18

3.1.1 Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?....18

3.1.2 What naming conventions do you follow?....19

3.1.3 Will search keywords be provided that optimize possibilities for re-use?....19

3.1.4 Do you provide clear version numbers?....19

See 3.1.2....19

3.1.5 What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how. 19

3.2 Making data openly accessible 19

3.2.1 Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions. 19

3.2.2 Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out. 20

3.2.3 How will the data be made accessible (e.g. by deposition in a repository)? 20

3.2.4 What methods or software tools are needed to access the data? 21

3.2.5 Is documentation about the software needed to access the data included? 21

3.2.6 Is it possible to include the relevant software (e.g. in open source code)? 21

3.2.7 Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible. 21

3.2.8 Have you explored appropriate arrangements with the identified repository? 21

3.2.9 If there are restrictions on use, how will access be provided? 21

3.2.10 Is there a need for a data access committee? 21

3.2.11 Are there well described conditions for access (i.e. a machine readable license)? 22

3.2.12 How will the identity of the person accessing the data be ascertained? 22

3.3 Making data interoperable 23

3.3.1 Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organizations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)? 23

3.3.2 What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable? 23

3.3.3 Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability? 23

3.3.4 In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies? 23

3.4 Increase data re-use (through clarifying licenses) 23

3.4.1 How will the data be licensed to permit the widest re-use possible? 23

3.4.2 When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible. 23

3.4.3 Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why. 24

3.4.4 How long is it intended that the data remains re-usable? 24

3.4.5 Are data quality assurance processes described? 24

4. Allocation of resources 25

4.1.1 What are the costs for making data FAIR in your project? 25

4.1.2 How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions). 25

4.1.3 Who will be responsible for data management in your project? 25

4.1.4 Are the resources for long term preservation discussed (costs and potential value, who decides how and what data will be kept, and for how long)? 25

5. Data security 26

5.1.1 What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)? 26

5.1.2 Is the data safely stored in certified repositories for long term preservation and curation? 26

6. Ethical aspects 27

6.1.1 Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA). 27

6.1.2 Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data? 27

7. Other 28

7.1.1 Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones? 28

8. Conclusions/Further work 29

References 30

Disclaimer 31

Executive summary

Work package 7 focuses on the ethical, legal, regulatory and safety issues associated to the development of the PICCOLO diagnosis medical device that will accelerate the road to market process in an ethical and safe way.

Data Managment plans (DMPs) are a key element for a good data management. A DMP describes the data management life cycle for the data to be collected, processed and/or generated by a Horizon 2020 project. As part of making research data findable, accessible, interoperable and re-usable (FAIR), a DMP should include information on:

- The handling of research data during and after the end of the project;
- What data will be collected, processed and/or generated;
- Which methodology and standards will be applied;
- Whether data will be shared/made open access;
- How data will be curated and preserved (including after the end of the project).

The definition, analysis and evaluation of the ethical use of health data described in T7.3 are gathered in this document. For this aim, the FAIR Guidelines Guideline on FAIR Data Management in Horizon 2020 described in D7.1 has been followed.

This deliverable is the first version of the Data Management Plan (DMP) of the PICCOLO project. At this stage of the project not all the ethical issues are solved, thus the final ethical aspects and conclusions related to the health data usability will be included in the final update of this deliverable D7.4 in M30.

1. Introduction

1.1 Objective of this document

The objective of this document is to gather all the ethical aspects related to the definition and evaluation of proper use of all generated databases during the PICCOLO project according the Guideline on FAIR Data Management in Horizon 2020.

This version of the deliverable includes main ethical aspects agreed among the consortium members at this stage of the project.

1.2 Structure of this document

This document, which is expected to be a living document delivering updates in M24 and M36, is structured based on the set of questionnaires listed in the Guideline on FAIR Data Management in Horizon 2020. The first section introduces the document and explains its aims in the context of related deliverables from other work packages. The second section describes the health data used in the PICCOLO project. The third and fourth section list a set of questions related to the management of the data in a findable, accessible, interoperable and reusable (FAIR) way. The fifth section is about the data security issues and the last section gathers ethical aspects that should be taken into account throughout the project.

1.3 Relationships with other deliverables

Since the early stages of the project, PICCOLO gives special attention to identify and monitor the particular challenges related to ethical issues associated to the development of the PICCOLO medical device.

D7.4 will directly be related to the following deliverables:

- D3.1 Image Database acquisition protocol
- D3.2 Photonic Database
- D5.1 Validation plan on animal models
- D5.2 Laboratory tests report
- D5.3 System validation & evaluation report on animal models
- D6.1 Human tissue validation plan
- D6.2 System validation & evaluation report on human tissues
- D7.1 Ethical, regulatory and DMP protocols and copies of the ethical approvals of the competent national/local committees/bodies
- D7.2 Ethical and regulatory dialogues and minutes
- D7.3 Safety, efficacy criteria and patient risks report
- D10.1 H-POPD – Requirement No. 1 (Ethical requirements)
- D10.2 HCT-A – Requirement No. 2 (Ethical requirements)

1.4 Acronyms and abbreviations

FAIR	Findable, Accessible, Interoperable and Reusable	DICOM	Digital Imaging and Communication in Medicine
MPT	Multi-photon tomography	JSON	JavaScript Object Notation
OCT	Optical coherence tomography	OME	Open Microscopy Environment
.mxf	Material Exchange Format	XML	Extensible Markup Language
H&E	Hematoxylin and Eosine	NBI	Narrow Band Imaging
MB	MegaByte	GB	Gigabyte
FTP	File Transfer Protocol	DPO	Data Protection Officer
DMP	Data Managment Plan		

2. Data Summary

2.1 Description

2.1.1 What is the purpose of the data collection/generation and its relationship to the objectives of the project?

The PICCOLO project will produce an extensive digital database of images representing colonic neoplastic and hyperplastic lesions. The necessity of generating a stratified and fully annotated digital database for the identification and validation of the imaging biomarkers in the project will provide unprecedented information on OCT and MPT imaging. This information will serve the research community as a boost for OCT/MPT imaging biomarkers discovery, analysis of the capabilities of OCT/MPT technology for diagnosis, further analysis on clinical prognosis related to the OCT/MPT biomarkers, and lesion grading studies among others.

White light recordings and images from murine model will be also stored in the database. These will allow for tracking of lesion development, which is not feasible in human patients.

2.1.2 What types of formats of data will the project generate/collect?

OCT/MPT imaging data will follow lossless standard formats such as DICOM or conventional lossless image compression with associated JSON format for metadata. Histology imaging will be comprised of lossless OME (open microscopy environment) standard (OME-JPEG) and metadata will be offered in standard XML format.

White light recordings will be stored in Material exchange Format (.mxf), a container format for professional digital media not decided yet.

2.1.3 Will you re-use any existing data and how?

Existing data that was generated in the project BIOPOOL FP7 could be re-used in the PICCOLO project. BIOPOOL FP7 project constructed a digital repository of digital histology that allows researchers to access histological data. An innovative software was developed to search and gather digital pathology slides with associated data from multiple biobanks and pathology archives. The software is based on an innovative Content-Based Image Retrieval system. BIOEF (Project Coordinator) and TECNALIA (Technical Coordinator) were partners in this project and have an outsourcing contract that allows TECNALIA to use data generated by BIOEF.

2.1.4 What is the origin of the data?

The database will contain datasets with different origins:

- Stratified imaging database of murine model (healthy and diseased): ~400 samples
- Imaging database of human samples (healthy and diseased): ~400 samples
- Database of white light colonoscopy videos of human samples: ~50 samples

- Database of white light colonoscopy videos of murine model: ~100 samples

The PICCOLO database will contain the following datasets:

- Imaging database of murine model (healthy and diseased): This dataset contains imaging data from white light, OCT and MPT imaging systems of genetically modified murine models. This set of data contains specific assays related to model the degradation of the acquired signal during the biopsy tissue processing protocol. This will be performed in order to check when is the best state of the sample biopsied (from fresh to ready-to-histopathology stage) to be analyzed suffering the minimum changes possible in structural and functional characteristics. After imaging data is acquired, conventional histopathological analysis is performed over the tissue to serve as gold standard. Metadata on each acquired image and its acquisition conditions will be also included (~50 samples).

- Stratified imaging database of murine model (healthy and diseased): This dataset contains in vivo white light and OCT/MPT imaging data from stratified murine model obtained during laparotomy. After imaging data is acquired, conventional histopathological analysis is performed over the tissue to serve as gold standard. Due to the temporal precision of murine models for developing neoplastic lesions, this database will offer a stratified lesion grading to the database. This dataset will include the white light, OCT and MPT images of each sample, their corresponding high resolution histological microscopy images (provided by BIOEF) and the anatomopathological diagnosis report including lesion grading. This will serve researchers to analyse the limits of the technology and to enhance imaging biomarkers to allow early diagnosis (100 subjects/~400 samples).

- Imaging database of human samples (healthy and diseased): This dataset contains data from real patients included in the WP6 studies and will be performed under strict ethical and safety conditions defined in WP7. The data will include ~400 white light and OCT/MPT imaging data gathered immediately after tissue resection. Comparative histology high resolution microscopic imaging will be included as well as pathological diagnosis report.

- Database of white light colonoscopy videos of human samples: This dataset contains data from real patients and will be performed under strict ethical and safety conditions. Thus all the video will be collected once signed, informed consent is provided by the patient (see annex 4). It will include videos collected during routine colonoscopy procedures in order to analyse polyp optical detection. It has been estimated 50 cases/videos as a first stage, if it is necessary more cases will be captured.

- Database of white light colonoscopy videos of murine model: This dataset contains data from white light videos of murine models collected during colonoscopy or laparotomy procedures. It has been estimated 100 videos as a first stage. If it is necessary, more videos will be captured.

The table below (Table 1) shows the data that will be associated to the images captured with the PICCOLO device from murine samples:

Table 1. Data associated to images obtained from murine samples

MURINE METADATA	
CODE	SAMPLE ID_SAMPLE_ORIGIN_ID_MODALITY

SAMPLE_ID	ID stating the acquisition identification to map sample among different imaging modalities.
SAMPLE_ORIGIN_ID	ID indicating the source of the tissue (rat) [1]
SEX	Male/Female
GROUP	G0 – control, G1 – hyperplasic, G2 – Neoplasic 2 months, G3 – Neoplasic 4 months, G4 – Neoplasic 8 months
SAMPLE STATE	In-vivo, Ex-vivo-fresh, Ex-vivo-paraffin
COLONOSCOPY DATE_TIME	DD/MM/YYYY
FOLLOW-UP NUMBER	
IMAGING MODALITY	White light / MPT / OCT / H&E Histopathology/ METADATA
POLYP SIZE	(mm)
POLYP LOCALIZATION	Ascending colon/Transverse colon/Descending colon/Sigmoid colon/Rectum
KUDO´S PIT PATTERN	Non-neoplastic: I, II Non-invasive: IIIs, IIIL, IV Invasive pattern: Vi, VN
PARIS CLASSIFICATION	Protruded lesions: Ip, Ips, Is Flat elevated lesions: 0-IIa, 0-IIa/c Flat lesions: 0-IIb, 0-IIc, 0-IIc/a
NICE CLASSIFICATION (NBI Vascular pattern)	Type 1, Type 2, Type 3
MORPHOLOGIC DIAGNOSIS	SNOMED Code
TOPOGRAPHIC DIAGNOSIS	SNOMED Code
LITERAL DIAGNOSIS	
HISTOLOGICAL STRATIFICATION	No dysplasia/Low grade dysplasia/High grade dysplasia/Invasive adenocarcinoma/Hyperplasia/Serrated morphology
ADDITIONAL FINDINGS	

The table below (Table 2) shows the data that will be associated to the images captured with the PICCOLO device from human samples:

[1] Murine specimens will be identified with a unique ID. This code will be used to trace the origin of the sample if required and for the definition of the training and test sets during the evaluation of the algorithms to be developed in WP3.

Table 2. Data associated to images obtained from human samples

HUMAN METADATA	
CODE	SAMPLE ID_SAMPLE_ORIGIN_ID_MODALITY
SAMPLE_ID	ID stating the acquisition identification to map sample among different imaging modalities.
SAMPLE_ORIGIN_ID	Anonymized ID indicating the source of the tissue (patient) [2]
AGE	(years)
SEX	Men/Women
IMAGING MODALITY	White light / MPT / OCT / H&E Histopathology/ METADATA
REASON FOR COLONOSCOPY	Screening colonoscopy/Urgent colonoscopy for altered bowel habit/Surveillance/therapy
COLONOSCOPY DATE_TIME	DD/MM/YYYY
NUMBER OF FOUND POLYPS	
POLYP SIZE	(mm)
POLYP LOCALIZATION	Ascending colon/Transverse colon/Descending colon/Sigmoid colon/Rectum
KUDO´S PIT PATTERN	Non-neoplastic: I, II Non-invasive: IIIs, IIIL, IV Invasive pattern: Vi, VN
PARIS CLASSIFICATION	Protruded lesions: Ip, Ips, Is Flat elevated lesions: 0-IIa, 0-IIa/c Flat lesions: 0-IIb, 0-IIc, 0-IIc/a
NICE CLASSIFICATION (NBI Vascular pattern)	Type 1, Type 2, Type 3
BOSTON BOWEL PREPARATION SCALE	0, 1, 2, 3
MORPHOLOGIC DIAGNOSIS	SNOMED Code
TOPOGRAPHIC DIAGNOSIS	SNOMED Code
LITERAL DIAGNOSIS	
HISTOLOGICAL STRATIFICATION	No dysplasia/Low grade dysplasia/High grade dysplasia/Invasive adenocarcinoma/Hyperplasia/Serrated morphology

[2] Patients will be identified with a unique ID defined exclusively for the project. From this ID, it won't be possible to identify the patients or access any information of them. Only clinicians at IC and BIOEF will know the real patient information under this codified ID. In this respect, the European regulation on general data protection (Regulation (EU) 2016/679) will be applied. Since the implementation date of this new regulation is the 25 of May 2018, until then, current directive on data protection (95/46/EC) will be followed.

PREVIOUS TREATMENT	Yes/No
RECURRENCE	Yes/No
ADDITIONAL FINDINGS	

2.1.5 What is the expected size of the data?

Following a brief summary of the expected data size at this stage of the project, however this information will be specified better in M30.

Description	Number of samples	Expected size	Type
Imaging database of murine model	~50 samples MPT/OCT images Associated histological data	 10-30 image acquisition/sample., 10MB/3D OCT + MPT image < 15GB 50 samples x 300Mb/each sample < 15GB	 Uncompressed 16bit images. For quality purposes only JPG2000
Stratified imaging database of murine model	~400 samples MPT/OCT images Associated histological data	 10-30 image acquisition/sample., 10MB/3D OCT + MPT image < 120GB 400 samples x 300Mb/each < 120GB	 Uncompressed 16bit images. JPG2000
Imaging database of human samples	~400 samples MPT/OCT images Associated histological data	 10-30 image acquisition/sample., 10MB/3D OCT + MPT image < 120GB 400 samples x 300Mb/each < 120GB	 Uncompressed 16bit images. For quality purposes only JPG2000
Associated clinical text data	~400 samples	100MB	JSON based data

Human colonoscopy videos	~50 samples	50GB, ~10min/sample	Annotated videos
Murine models colonoscopy videos	~100 samples	480MB, ~2min/video	Annotated videos
Associated clinical text data (video)	~50 samples	50GB, ~10min/sample	Annotated videos

2.1.6 To whom might the data be useful ('data utility')?

As a first stage, the dataset created in the PICCOLO project might be useful mainly for researchers and developers of the project, as well as for consortium members with clinical profiles. The detailed data sharing among the members would allow the development of the Multimodal highly-sensitive PhotonICs endoscope, PICCOLO's final product.

At the end of the project, once anonymization of the data is ensured, the captured images will be open-access for the research community. Moreover, in order to ensure the right use of human data (images and associated minimum clinical data) a risk assessment and impact evaluation will be carried out by the external legal agency and included in the update of this deliverable D7.4 in M30.

3. FAIR data

3.1 Making data findable, including provisions for metadata

3.1.1 Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

The files exchanged in the PICCOLO project will be uniquely identifiable and versioned by using the following naming convention (based on the institutions where images are collected). This will help tracing the origin/source of the data:

- PICCOLO_CCMIJU_ YYYY-MM-DD_#CODE.
- PICCOLO_IC_YYYY-MM-DD_#CODE.
- PICCOLO_BIOEF_YYYY-MM-DD_#CODE.

The term CODE is explained in detail in Table 3. The dataset will be stratified by SAMPLE_ID key. A SAMPLE_ID describes a single biological sample that belongs to a specimen identified as SAMPLE_ORIGIN_ID. A biological sample can be acquired by different modalities (White light, OCT, MPT, HISTOPATHOLOGY_IMAGE) and can also have related metadata.

Table 3. Labelling of entries in the PICCOLO Dataset

CODE: SAMPLE ID_SAMPLE_ORIGIN_ID_MODALITY	
SAMPLE_ID	ID stating the acquisition identification to map sample among different imaging modalities.
SAMPLE_ORIGIN_ID	Anonymized ID indicating the source of the tissue (patient)
MODALITY	White light / MPT / OCT / H&E Histopathology/ METADATA
MODALITY SPECIFIC METADATA	Specific metadata for each imaging modality

For machine learning purposes (in WP3) it is enough to provide the zipped dataset. For other uses (e.g. clinical), it will be assessed in a future stage of the project if search key-words will be provided in order to optimize the possibilities of re-use. At present, search keywords are out of the scope of the project and data will be shared as a zipped dataset

Different versions of the database are subject to be created during the development of the multi-source endoscope. Each version of the endoscope will work with a different version of the database, as the database will growth exponentially during the development of the endoscope and the project. These database versions will be unequivocally identified and packaged. Each version generated will contain a file summarizing the samples contained.

3.1.2 What naming conventions do you follow?

During the project, naming will be detailed at WP3 and the datasets will be homogenized. Details of the dataset will be included in a scientific publication at later stages of the project.

3.1.3 Will search keywords be provided that optimize possibilities for re-use?

See 3.1.2

3.1.4 Do you provide clear version numbers?

See 3.1.2

3.1.5 What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

Details of the dataset will be included in a scientific publication at later stages of the project.

3.2 Making data openly accessible

3.2.1 Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

In the future, the intention is to make the data generated from murine samples openly accessible and it will be at the scientific community´s disposal.

Regarding data generated from human samples, a data protection impact assessment will be performed to evaluate the risk of identifying an individual considering the provided variables associated to the images. If there is no risk, anonymized data generated from human samples will be made openly accessible and will also be at the scientific community´s disposal. The detailed information related to this analysis will be included in the updated version of the deliverable (D7.4) in M30.

With the aim of providing open access to peer-reviewed scientific publications that might result from the project, TECNALIA participates in Recolecta project (Open Science Harvester), which is a platform that gathers all the Spanish scientific repositories together in one place and provides services to repository managers, researchers and decision-makers by following a ‘Green’ Open Access Model.

3.2.2 Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for *opting out.*

3.2.3 How will the data be made accessible (e.g. by deposition in a repository)?

In the PICCOLO project, data will be generated in 3 different institutions:

- BIOEF: captured images and videos with the associated information will be stored at the Basque Biobank Database/BIOCLOUD (Central sample repository of the Basque Biobank-https://www.basquebiocloud.org/). The diagnosis of the colonoscopy as well as the anatomic pathology will also be transferred to the Basque Biobank Database/BIOCLOUD.
- Imperial College: Patient data, including any endoscopic images and histopathological reports, will be stored in secure servers controlled by Imperial College Healthcare NHS Trust, accessible by members of the IC research team.
- CCMIJU: Captured images with the associated information will be stored at the CCMIJU's internal structure of data storage.

All data generated in the PICCOLO project will be anonymized and transferred to a private repository to which PICCOLO partners will have access through security codes. All data will be aggregated at LENS facilities on a unique server for internal project work. Data exchanged among partners will be always encrypted. Moreover, in order to ensure the appropriate use of the data, the following logging message with the restrictions of use, as described in PICCOLO Consortium Agreement pag. 17, will be included:

a) protect and keep strictly confidential any part of/or the whole of any Confidential Information and shall treat and use the Confidential Information with the same degree of care as it applies to its own proprietary information, but in no case with less than reasonable care;
b) protect any part of/or the whole of the Confidential Information from disclosure to anyone other than its employees who have a need to know and inform them of the confidentiality attached to such Information;
c) not disclose, copy, duplicate totally or partially, unless extremely necessary for Purpose, the Confidential Information without the prior written consent of the Disclosing Party.

Use of the Confidential Information by the Receiving Party shall be strictly limited to the carrying out of the Project.

The Receiving Party shall be responsible for the fulfillment of the above obligations on the part of their employees or third parties involved in the Project.

3.2.4 What methods or software tools are needed to access the data?

The data will be made accessible through a webpage with access restriction. Access will be given by database owner after signing the documents designed for this purpose. Access will be provided via secure FTP. Activity logging will be included.

3.2.5 Is documentation about the software needed to access the data included?

N.A. as common image data and video formats will be used.

3.2.6 Is it possible to include the relevant software (e.g. in open source code)?

N.A. as common image data and video formats will be used.

3.2.7 Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

As described in 3.2.3 all data generated along the project will be storage in each institution and at LENS facilities which will be a unique server for internal work of the project.

During the following months how to proceed after the end of the project will be agreed among the consortium members.

3.2.8 Have you explored appropriate arrangements with the identified repository?

During the following months the consortium members will think and decide about it.

3.2.9 If there are restrictions on use, how will access be provided?

Access to the publicly available data will be provided after agreement on data use contract signature.

3.2.10 Is there a need for a data access committee?

As included in the consortium agreement pag. 17 all the consortium members follow the restrictions of data use.

3.2.11 Are there well described conditions for access (i.e. a machine readable license)?

During the following months the consortium members will think and decide about it.

3.2.12 How will the identity of the person accessing the data be ascertained?

During the following months the consortium members will think and decide about it.

3.3 Making data interoperable

3.3.1 Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organizations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

PICCOLO project will use standard vocabularies for all data types present in the data set to allow inter-disciplinary interoperability. This will allow data exchange and re-use between researchers, institutions, organizations, countries, etc.

3.3.2 What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

Further information will be included in M24 and M36

3.3.3 Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

Further information will be included in M24 and M36

3.3.4 In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

Future versions we will explore and fully formalise how different data types are interrelated, as well as any hierarchies that exist.

3.4 Increase data re-use (through clarifying licenses)

3.4.1 How will the data be licensed to permit the widest re-use possible?

This information will be included once the impact evaluation of the data is done. (M30)

3.4.2 When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how

long this will apply, bearing in mind that research data should be made available as soon as possible.

It will be at the disposal of the scientific community and other interested parties after data validation and publication of the dataset informative scientific paper. Data generation will start during phase 2 of the PICCOLO project (Validation on animal models).

3.4.3 Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

If the risk assessment process is satisfactory we will also liberate all or part of human datasets.

3.4.4 How long is it intended that the data remains re-usable?

At this point of the project it has not been discussed about these aspects. This information will be included in M30 update.

3.4.5 Are data quality assurance processes described?

At this point, the data quality assurance process has not been described yet and it has not been determined how long is intended that the data remains re-usable.

4. Allocation of resources

4.1.1 What are the costs for making data FAIR in your project?

The total costs for making data FAIR have not been calculated at this stage of the project. However, just the tasks related to the Health Data Risk Assessment will need budget redistribution.

4.1.2 How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

Full information of the new reallocation action mentioned in 4.1.1 will be included in the amendment of the project that will be send to the officer in M13.

4.1.3 Who will be responsible for data management in your project?

The owner of the data will be the clinical institution where the data have been collected. Then, considering that a copy of the data will be stored in the clinical institution where data have been collected and another in a repository physically located at LENS, the responsible for the management of each database will be the hosting institution.

4.1.4 Are the resources for long term preservation discussed (costs and potential value, who decides how and what data will be kept, and for how long)?

During the kick-off meeting it was discussed, about the possibility to preserve acquired data for a longer term with respect to the duration of the project. However, we haven't yet explicitly defined the minimum amount of time after the end of project during which the data will be maintained available. During the following month all the consortium members will discuss and decide about the best option.

5. Data security

5.1.1 What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

The data generated in the PICCOLO project will be stored in secure repositories for long term preservation and curation. Regular backups (at least weekly) will be done for data security. The institution hosting the databases will manage these backups

Secure passwords will be used for accessing the databases. Logs will be automatically generated in order to keep trace of the actions performed by each user. Access to the data will be only possible for the personnel directly involved in the project. As described in 3.2.3, a logging message will remind to the partners the right use of the data.

Data exchanged between the partners will be always encrypted and secured.

5.1.2 Is the data safely stored in certified repositories for long term preservation and curation?

The data generated in the PICCOLO project will be safely stored in regularly backed-up secure databases. The created databases allow for a long term preservation of data. The duration of the preservation of data in the databases has to be decided.

6. Ethical aspects

6.1.1 Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

Personal data obtained in this project will be stored following the legal framework about data protection at national and European level. In this regard, dedicated servers will allow PICCOLO users to connect at once under controlled access. Personal data will be stored anonymized and only the research physicians (who maintain the contact with the patient) will know the identity of the patients.

Data will be kept indefinitely as long as it is not used in connection with decisions affecting particular individuals, or in a way that is likely to cause damage or distress to the patients.

The corresponding Data Protection Officer (DPO) at BIOEF and Imperial College Healthcare NHS Trust will be notified according to the Data Protection Directive (EC Directive 95/46). The DPOs will ensure, in an independent manner, the internal application of the provisions of the Regulation in their institutions and will keep a register of all the processing operations including personal data in PICCOLO. The Register, which must contain information explaining the purpose and conditions of the processing operations, should be accessible to any interested person.

Moreover, an evaluation of the data risk assessment will be done and described in M30 update.

6.1.2 Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

Ethical approvals for the PICCOLO project were obtained from the relevant Ethics Committees at the early stage of the project, as included in D7.1. However, at this phase of the project other updates/approvals have been received:

a) BIOEF: Approval from the Basque Ethics Committee related to the re-use of the histological images (base on colon disease) acquired during BIOPOOL project (see annex 1) and modification of the clinical data associated to the human samples (see annex 2). In this sense, a new clinical text datasheet focused on the description of the video, including endoscopic and pathologic diagnosis will be sent to be evaluated (update in M30).
b) Imperial College Healthcare Tissue Bank received a renewal of ethical approval (see annex 3)

Informed consents will be used in both institutions (Imperial College and BIOEF) for image and video acquisition and data collection. Only data from patients able to give informed consent will be included in the study.

7. Other

7.1.1 Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

Since institutions from different countries (UK and Spain) will generate data in the PICCOLO project, each country will carry out their research according to their Data Protection Law. The following documents will be used as reference:

- Royal Decree 1720/2007, of 21 December, which approves the Regulation implementing Organic Law 15/1999, of 13 December, on the Protection of Personal Data (Spanish Data Protection Agency).
- European Data Protection Directive.
- The Data Protection Act, 1998 (UK).

Note: Refer to Article 29 of the Grant Agreement of the PICCOLO project for **DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING**

8. Conclusions/Further work

This document delivered at M12 contains all necessary ethical aspects related to the use of health data during the project that could be fulfilled at this stage.

The data management plan has been elaborated based on the Guideline on FAIR Data Management in Horizon 2020 described in D7.1 and it is intended to be a living document in which information can be made available on a finer level of granularity through updates as the implementation of the project progresses and when significant changes occur.

Moreover, updates of the ethical approvals have been included as annexes (see 6.1.2).

References

[1] PICCOLO H2020 Project, Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support. 2017-2020. Available at: www.piccolo-project.eu

Disclaimer

This deliverable has been prepared in the context of the funded project PICCOLO. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 732111.

Annex 1

Ethical Approval to use BIOPOOL database (BIOEF)

Issued by: Euskadi Clinical Research Ethics Committee

CEIm
Euskadiko Medikamentuen gaineko Ikerkuntza Batzorde Etikoa
Comité de Ética de Investigación con medicamentos de Euskadi

EUSKO JAURLARITZA
GOBIERNO VASCO
OSASUN SAILA
DEPARTAMENTO DE SALUD

Arantza Hernández Gil
Secretaria del CEIm Comunidad Autónoma del País Vasco (CEIm-E)

CERTIFICA

1- Que el CEIm Comunidad Autónoma del País Vasco (CEIm-E) en su reunión del día 25/10/2017, acta 10/2017 ha evaluado la solicitud de cesión del biobanco en relación a la cesión de Imágenes Histológicas para el proyecto:

Título: **Título: Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cáncer diagnosis and clinical decision support - PICCOLO**
IP: Artzai Picón (Tecnalia)
Cesión de imágenes histológicas (no muestras físicas)

Código Promotor: **17-14** Código Interno: CES-BIOEF 2017-16

2- Considera que

- La cesión se ha planteado siguiendo los requisitos de la Ley 14/2007, de 3 de julio, de Investigación Biomédica y el Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica.
- Se cumplen los requisitos necesarios para la gestión de muestras.

3- Se acuerda emitir informe favorable a la solicitud de cesión de imágenes histológicas. Se recuerda que cuando se disponga de más información se debe enviar un informe con los resultados incluso publicaciones, si las hubiere.

Por lo que este CEIm, actuando como comité externo al Biobanco, y reunido el 25/10/2017 (recogido en acta 10/2017) emite el correspondiente DICTAMEN FAVORABLE

Lo que firmo en Vitoria, a 10 de noviembre de 2017

Fdo:

ARANTZAZU HERNANDEZ GIL

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Nombre de reconocimiento (DN): c=ES, o=Eusko Jaurlaritza, ou=SALUD, ou=Ziurtagiri onartua - Certificado reconocido, ou=Entitate publikoen ziurtagiri - Certificado de entidad publica, ou=Condiciones de uso en www.izenpe.com nola erabili jakiteko, dnQualifier=-dni 44678219Y -cif S4833001C, cn=ARANTZAZU HERNANDEZ GIL, givenName=ARANTZAZU, sn=HERNANDEZ, serialNumber=44678219Y
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Arantza Hernández Gil
Secretaria del CEIm Comunidad Autónoma del País Vasco (CEIm-E)

Annex 2

Amendment Ethical Approval (BIOEF), November 2017

Issued by: Euskadi Clinical Research Ethics Committee

CEIm
Euskadiko Medikamentuen gaineko Ikerkuntza Batzorde Etikoa
Comité de Ética de Investigación con medicamentos de Euskadi

EUSKO JAURLARITZA
GOBIERNO VASCO
OSASUN SAILA
DEPARTAMENTO DE SALUD

INFORME DEL COMITE ETICO DE INVESTIGACION CLINICA DE EUSKADI (CEIC-E)

Arantza Hernández Gil
Secretaria del CEIC Comunidad Autónoma del País Vasco (CEIC-E)

CERTIFICA

Que este Comité de acuerdo a la ley 14/2007 de Investigación Biomédica, principios éticos de la declaración de Helsinki, el Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica y resto de principios éticos aplicables, en su reunión del día 25/10/2017, acta 10/2017, ha evaluado la propuesta del promotor para que se realice la modificación del cuaderno de recogida de datos y documento explicativo a los donantes de la solicitud con código 17-14:

Título: Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cáncer diagnosis and clinical decision support – PICCOLO
IP: Artzai Picón (Tecnalia) en el estudio:

Título: Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cáncer diagnosis and clinical decision support - PICCOLO

Código Promotor: 17-14 Código Interno: PI+CES BIOEF 2017-03

Versión Hoja Información al Paciente evaluada: GENERAL / V3, 30/08/17
Versión Cuaderno de Recogida de datos evaluada: V2, 30/08/17

Y que este Comité ha decidido emitir INFORME FAVORABLE A LA REALIZACIÓN DE DICHA ENMIENDA.

Lo que firmo en Vitoria, a 07 de noviembre de 2017

ARANTZAZU HERNANDEZ GIL

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Arantza Hernández Gil
Secretaria del CEIC Comunidad Autónoma del País Vasco (CEIC-E)

Nota: Una vez comenzado el estudio, se recuerda la obligación de enviar un **informe de seguimiento anual** e **informe final** que incluya los resultados del estudio (si el estudio dura menos de un año, con el informe final será suficiente). Más información en la página web del CEIC-E:
http://www.osakidetza.euskadi.eus/informacion/proyectos-de-investigacion/r85-pkfarm03/es/

Annex 3

Imperial College's Tissue Bank Ethical Approval (renewal, July 2017)

Issued by: Research Ethics Committee (REC) for Wales

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Wales REC 3
Health and Care Research Support Centre
Castlebridge 4
15-19 Cowbridge Road East
Cardiff CF11 9AB

Telephone : 029 2078 5741
E-mail : helen.williams19@wales.nhs.uk
Website : www.hra.nhs.uk

25 July 2017

Professor Geraldine A Thomas
Imperial College Healthcare Tissue Bank
Room 11L04
Charing Cross Hospital
Fulham Palace Road, London
W6 8RF

Dear Professor Thomas

Title of the Research Tissue Bank:	**Imperial College Healthcare Tissue Bank**
REC reference:	**17/WA/0161**
Designated Individual:	**Professor Geraldine A Thomas**
IRAS project ID:	**229026**

Thank you for your letter of 11 July 2017, responding to the Committee's request for further information on the above research tissue bank and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the Research Tissue Bank on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all Research Tissue Banks that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the Research Tissue Bank.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation as revised.

The Committee has also confirmed that the favourable ethical opinion applies to all research projects conducted in the UK using tissue or data supplied by the tissue bank, provided that the release of tissue or data complies with the attached conditions. It will not be necessary for these researchers to make project-based applications for ethical approval. They will be deemed to have ethical approval from this committee. You should provide the researcher with a copy of this letter as confirmation of this. The Committee should be notified of all projects receiving tissue and data from this tissue bank by means of an annual report.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was 12/WA/0196.

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Duration of ethical opinion
The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the standard conditions of ethical approval for Research Tissue Banks set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research tissue bank.

Research Tissue Bank Renewals
The Research Tissue Bank has been renewed for a further five years from the end of the previous five year period. The previous five year period ran from 17 July 2012 to 17 July 2017. This Research Tissue Bank may be renewed for further periods of five years at a time by following the process described in the above paragraph.

Approved documents
The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper [Cover note]	1	12 May 2017
Covering letter on headed paper [Cover note]		11 July 2017
Human Tissue Authority licence [HTA Licence]	1	22 March 2010
IRAS Checklist XML [Checklist_12052017]		12 May 2017
IRAS Checklist XML [Checklist_15052017]		15 May 2017
IRAS Checklist XML [Checklist_18052017]		18 May 2017
IRAS Checklist XML [Checklist_11072017]		11 July 2017
Other [Annex 2]	1	03 May 2017
Other [Annex 4]	1	26 April 2017
Other [Annex 1]	1	12 May 2017
Other [Annex 10]	1	10 May 2017
Other [Annex 11]	2	10 May 2017
Other [G Thomas CV]	1	12 May 2017
Other [Annex 5]	v2	10 May 2017
Other [Annex 7]	v2	10 May 2017
Other [Annex 6]	v1.1	11 July 2017
Other [Annex 8]	1.1	20 June 2017
Other [Annex 9]	1.1	11 July 2017
Other [PIS xenografting track change]	v2	10 July 2017
Other [PIS T&GCT]	1.1	20 June 2017
Other [RIS T&GCT]	1.1	20 June 2017
Other [Health Volunteer TB-DOC-PI3]	3.1	20 June 2017
Other [Provisional opinion letter]		12 June 2017
Participant consent form [Discover PIS v1.1 track change]	1.1	11 July 2017
Participant information sheet (PIS) [Annex 3]	v1.1	11 July 2017
Protocol for management of the tissue bank [Project description]	1	12 May 2017
REC Application Form [RTB_Form_15052017]		15 May 2017
REC Application Form [RTB_Form_11072017]		11 July 2017

Thank you for providing a copy of the above licence.

Research governance
Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research tissue banks in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the research tissue bank.

Research permission is also not required by collaborators at tissue collection centres (TCCs) who provide tissue or data under the terms of a supply agreement between the organisation and the research tissue bank. TCCs are not research sites for the purposes of the RGF.

Research tissue bank managers are advised to provide R&D offices at all TCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All TCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using tissue or data supplied by a research tissue bank must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the research tissue bank has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research tissue banks.

Registration of Research Tissue Banks
It is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory. The Research Tissue Bank should be registered no later than 6 weeks after the date of this favourable ethical opinion letter or 6 weeks after the Research Tissue Bank holds tissue with the intention to provide for research purposes. Please use the following link to register the Research Tissue Bank on the UKCRC Directory: https://directory.biobankinguk.org/Register/Biobank Registration is defined as having added details of the types of tissue samples held in the tissue bank.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment or annual progress report form. We will monitor the registration details as part of the annual progress reporting process.

Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training
We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/WA/0161	Please quote this number on all correspondence

Yours sincerely

Mrs Helen Williams
Health and Care Research Wales
Research Ethics Committee Co-ordinator

Email - helen.williams19@wales.nhs.uk

pp **Mrs Monika Hare**
Vice Chair

Enclosures: Standard approval conditions

Copy to: Professor Geraldine A Thomas, Imperial College London

Annex 4

Informed Consent for wide-field colonoscopy videos (BIOEF)

MODELO DE HOJA DE INFORMACIÓN AL PACIENTE PARA PROYECTOS DE INVESTIGACIÓN QUE IMPLIQUEN LA UTILIZACIÓN DE MUESTRAS BIOLÓGICAS

Versión del modelo aprobado por el CEIC-E 30 de Abril de 2014

TÍTULO DEL PROYECTO: Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cáncer diagnosis and clinical decision support - PICCOLO

INVESTIGADOR PRINCIPAL: Artzai Picón de Tecnalia

ENTIDAD FINANCIADORA: HORIZON 2020

DESCRIPCIÓN GENERAL:

Considerando que usted o su familiar está participando en el Programa de Cribado del cáncer de colon, le solicitamos su consentimiento para participar en un estudio del que le informamos a continuación. Antes de decidir si quiere participar o no, le rogamos lea detenidamente este documento que incluye la información sobre este proyecto. Puede formular todas las preguntas que le surjan y solicitar cualquier aclaración sobre cualquier aspecto del mismo

PROPÓSITO DEL ESTUDIO: Tal y como ha leído en la hoja informativa que le han proporcionado anteriormente, el el proyecto PICCOLO pretende desarrollar un nuevo endoscopio que incorpore mejoras con respecto a los actuales con objeto de ayudar a los médicos a hacer un diagnóstico más rápido.

EXPLICACIÓN DEL ESTUDIO: Si usted accede a participar en este estudio, será necesario que acepte que se pueda utilizar el vídeo de su colonoscopia para el desarrollo de este nuevo endoscopio.
No hay contraprestación económica de ningún tipo.

DATOS A RECOGER: Como parte de este proyecto aprobado por el Comité Ético de Investigación Clínica de Euskadi se le va a solicitar autorización para utilizar el VIDEO de su colonoscopia con fines de investigación, con objeto de aumentar los conocimientos sobre el aparato objeto de estudio.

La realización de la prueba diagnóstica de la colonoscopia corresponde a la práctica clínica.

El vídeo de la colonoscopia será estudiado por los socios del proyecto PICCOLO.

BENEFICIO Y ATENCIÓN MÉDICA: No recibirá ningún beneficio por su participación en este estudio.
Su participación en este estudio es completamente voluntaria: Si usted decide no participar recibirá todos los cuidados médicos que pudiera necesitar y su relación con el equipo médico que le atiende no se verá afectada.

TRATAMIENTO DEL VIDEO Y CONFIDENCIALIDAD. Se solicita su consentimiento para la utilización del vídeo de su colonoscopia para el desarrollo de este proyecto. El vídeo se recogerá empleando un procedimiento de anonimización. Nadie podrá relacionar el vídeo con Vd.

La información será procesada durante el análisis de los resultados obtenidos y aparecerá en los informes finales. En ningún caso será posible identificarle, garantizándole la confidencialidad de la información obtenida, en cumplimiento de la legislación vigente.

DESTINO DEL VIDEO TRAS SU UTILIZACIÓN EN ESTE PROYECTO DE INVESTIGACIÓN

Una vez finalizada la investigación, se le ofrecen las siguientes opciones:

A. La **destrucción** del vídeo.

B. Su **utilización en futuros proyectos** de investigación biomédica relacionados con el APARATO DIGESTIO, o para cualquier fin de investigación (preferentemente relacionados con el APARATO DIGESTIVO). A tal fin, se le ofrece la opción de donar el vídeo al **Biobanco Vasco** de la Fundación Vasca de Innovación e Investigación Sanitaria (BIOEF) con objeto de que pueda ser conservado y destinado a futuras investigaciones. En este caso, firmará el consentimiento específico incluido en este documento, que será custodiado por el coordinador del BIOBANCO de su Hospital.

ALMACENAMIENTO DEL VIDEO EN EL BIOBANCO. Con la firma del consentimiento anexo, Vd. autoriza al Biobanco Vasco, al almacenamiento y utilización de su vídeo, para la realización de proyectos de investigación que cumplan con los principios éticos y legales aplicables.

El clínico responsable de la investigación entregará al Biobanco los datos clínicos asociados, y el vídeo, conforme a su voluntad, para su almacenamiento en las instalaciones del centro hospitalario adscritas al Biobanco, así como el documento de consentimiento informado por usted firmado. En el hospital Universitario Basurto se registrarán los datos que pudieran relacionarle con las muestras a conservar, empleando un procedimiento de anonimización. NADIE podrá relacionar estos datos con Vd.

La donación de muestras/vídeo para investigación es voluntaria y altruista. Su único beneficio es el que corresponde al avance de la medicina en beneficio de la sociedad. Su vídeo no podrá ser objeto directo de actividades con ánimo de lucro. No obstante, la información generada a partir de los estudios realizados sobre el vídeo podría ser fuente de beneficios comerciales. En tal caso, se pretende que estos beneficios reviertan en la salud de la población, aunque no de forma individual ni en el donante ni en sus familiares.

Los resultados de futuros estudios podrán ser comunicados en reuniones científicas, congresos médicos o publicaciones científicas. Siempre se mantendrá una estricta confidencialidad sobre su identidad.

La donación de su vídeo no supone ningún gasto extra.

ANEXO ACLARATORIO

SE GARANTIZA QUE LA REALIZACIÓN DE ESTE PROYECTO, EL TRATAMIENTO, ALMACENAMIENTO Y UTILIZACIÓN DEL VIDEO ALMACENADO EN EL BIOBANCO CUMPLIRÁ CON LA **NORMATIVA APLICABLE**:

Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. En observancia a esta ley los datos de carácter personal recogidos en este estudio pasarán a formar parte de un fichero automatizado que reúne las medidas de seguridad de nivel alto.

Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica

Ley 14/2007, de 3 de julio, de Investigación biomédica.

Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica

¿QUÉ ES UN BIOBANCO?

Un **biobanco** es un centro de conservación, en condiciones adecuadas, de muestras, tejidos, ADN y otros derivados, representan un valioso instrumento con destino a la investigación de enfermedades y que puede permitir la obtención de conocimientos que sirvan para el desarrollo de nuevas estrategias y terapias aplicables a pacientes.

El Biobanco de BIOEF está constituido en nodos, uno de los cuales está ubicado en el Hospital Universitario Basurto, en donde se almacenará y conservará su vídeo.

Los proyectos de investigación realizados con el vídeo almacenado en el Biobanco serán aprobados por un Comité de Ética de la Investigación, y, si procede, autorizado por la autoridad sanitaria pertinente, previo informe favorable de los comités ético y científico externos del biobanco.

Tanto el Biobanco Vasco, como el investigador al que en un futuro se pueda ceder el vídeo, son responsables del manejo de los Datos, conforme a la Ley orgánica 15/1999, de 13 de diciembre, sobre Protección de Datos de Carácter Personal. El Hospital Universitario Basruto garantiza que en ningún caso saldrá del centro dato alguno que le identifique personalmente.

CONSENTIMIENTO PARA LA REALIZACIÓN DEL PROYECTO DE INVESTIGACIÓN

Investigador/Responsable clínico: Dr. Francisco Polo

TÍTULO DEL PROYECTO: Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cáncer diagnosis and clinical decision support - PICCOLO

Yo……con DNI…..... declaro que he leído la Hoja de Información al paciente, de la que se me ha entregado una copia. He recibido información sobre las características del estudio, así como los posibles beneficios y riesgos que puedo esperar, los derechos que puedo ejercitar, y las previsiones sobre el tratamiento de datos y muestras. He recibido suficiente información sobre el estudio.

Sé que se mantendrá en secreto mi identidad y que mi video será anonimizado.

Yo doy mi consentimiento para que se utilicen mi vídeo y los datos clínicos asociados como parte de **este proyecto de investigación**. Consiento en participar voluntariamente.

Afirmo haber sido advertido sobre las opciones de destino del vídeo al finalizar el proyecto de investigación.

En este sentido: Solicito la destrucción del vídeo □

Solicito la incorporación del vídeo en el Biobanco Vasco □

Fecha …… Firma del paciente ……..

Fecha …….. Firma representante legal (si procede)……..

Nombre representante legal:

Relación con el paciente:

Constato que he explicado las características del proyecto de investigación y las condiciones de conservación, si procede, que se aplicarán al vídeo y a los datos conservados.

Nombre del Investigador o la persona designada para proporcionar la información:

Fecha …… Firma ……

CONSENTIMIENTO PARA LA DONACIÓN DEL VÍDEO AL BIOBANCO VASCO

Responsable clínico: Dr. Francisco Polo

Yo_____

He sido informado sobre la posibilidad de transferir y almacenar el vídeo junto con la información clínica relacionada al Biobanco Vasco de forma anonimizada.

He sido informado sobre la finalidad de la **conservación,** el lugar de conservación, así como sobre las garantías de cumplimiento de la legalidad vigente y de la posibilidad de ceder el vídeo para futuros proyectos de investigación. Se me ha informado que el presente consentimiento será custodiado en las instalaciones del Nodo del Biobanco en el Hospital Universitario Basurto.

Yo **DOY** mi consentimiento para que el Hospital Universitario Basurto transfiera mi vídeo y los datos de salud relevantes (excepto los que me identifiquen) del AREA DEL APARATO DIGESTIVO, al Biobanco Vasco.

Doy mi consentimiento para que:

- ☐ el vídeo se utilice sólo para **proyectos relacionados con EL APARATO DIGESTIVO**
- ☐ el vídeo se utilice para **cualquier investigación biomédica** (preferentemente relacionado con el área del aparato digestivo)

Fecha …… Firma del paciente ……

Fecha :…….. Firma representante legal (si procede)……..

Nombre representante legal:

Relación con el paciente:

Constato que he explicado las características de las condiciones de conservación y seguridad que se aplicarán al vídeo y a los datos clínicos conservados.

Nombre del clínico responsable

Fecha …… Firma ……