PARTICIPANT INFORMATION SHEET

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AIguided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

We are writing to inform you about a research study in which you are invited to take part in. The study has been approved by the centre's Research Ethics Committee, in accordance with current legislation, Law 14/2007, 3 July on Biomedical Research. Our aim is that you receive sufficient accurate information to make an informed decision on whether or not to participate in this study. Please take the time to read this information sheet carefully. You may contact us at any time to clarify any doubts that may arise. You may also discuss this project with others if you wish. Additionally, you may request further explanations about any aspect of the study and its implications by contacting the project's principal investigator, Name, by telephone onXXXXXXXX.

1. Voluntary participation

You have been invited to participate in this study because you require a gastroscopy (a process in which a camera is inserted into your stomach via a scope through your mouth and down your throat) due to a suspected diagnosis of chronic gastric inflammation or because you were previously diagnosed with an infection by the *Helicobacter pylori* bacterium (a bacteria that infections the stomach). You should know that your participation in this study is voluntary and that you may decide NOT to participate. If you decide to participate, you can change your decision and withdraw consent at any time – your choice will not alter your relationship with your doctor or negatively affect the health care you receive. Your acceptance to participate in this study implies your consent to treat some of your personal data, in the manner described below.

2. Justification and Objective of the study

This study is carried out to better understand how inflammation over a long period of time may cause changes in the cells that line the stomach (gastric epithelium) and can eventually develop into cancer. Understanding the changes that occur before cancer develops allows for patients at risk to be identified early and to be guided with strict follow-ups as a prevention strategy.
The main objective of this study is to develop a tool that will be assisted by artificial intelligence (AI), and will combine clinical data, risk factors such as Helicobacter pylori infection (a common bacterial infection of the stomach), and pathological and molecular risks of inflammation of the stomach tissue in order to apply more effective prevention measures of gastric cancer, in the future.

3. Description of the study

This study is part of the strategy of the project: "European Consortium for the development of a tool assisted by artificial intelligence for the diagnosis and management of chronic gastric inflammation".

The study will be carried out in 2 parts:

<u>First phase</u>
Participating patients will be classified into one of 3 risk levels (high, medium-low), based on their health status, pre-existing conditions, history of Helicobacter pylori infection, history of changes in the gastric epithelium, or family history of cancer and will receive health recommendations based on their risk, which will be calculated based on the literature, in order to provide recommendations aligned with the clinical best practice guidelines.

A health questionnaire will be completed, and biopsy samples will be collected during the gastroscopy indicated by your treating physician, which will be analysed according to the protocol of the study to complete your individual risk profile.
Your participation will also consist of a dynamic monitoring process where your quality of life and your state of health. Additionally, the *Helicobacter pylori* eradication status (in the event that you received eradication treatment) will be measured to assess if the treatment was effective or not. Adherence to the established guidelines for follow-up in your case will be also monitored.
The expected number of patients to be recruited in this project is 450 patients (150 cases and 150 healthy controls as well as 150 gastric cancer patients to train the system).

Second phase
During the second phase of the project, the risk prediction capabilities of the AI-assisted tool will be established and improved, after integrating the data of the patients recruited in the initial phase, the recommendations given to the patient cohort will be reviewed. You will be informed of this update by your attending physician.

This is an international multicentre study in which 9 hospitals across Europe will participate. Participating countries include Spain, Portugal, France, Latvia, Lithuania, and the Netherlands, and recruitment is expected to take place in 3 years.

This study seeks to develop a clinical tool that is useful in the prevention of gastric cancer.

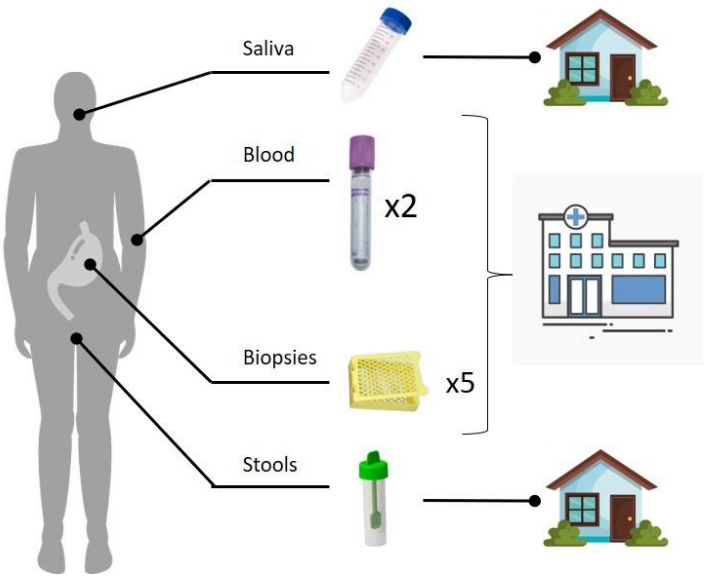
4. Study activities

The entire project will last 4 years.

Your participation, should you agree, will consist of answering questions about your state of health approximately every 2 months throughout the duration of the study, and the analysis of your gastric biopsy samples, with 5 additional biopsies, which would also be performed as part of the diagnosis process. In the event that you participate in the multiomic study (which involves analyzing the samples in greater depth including a molecular study, and analysis of the immune microenvironment and the microbiome), 5 more biopsies will be collected, in addition to two samples of blood (5 mL EDTA tubes-– EDTA is an anticoagulant and keeps the blood from clotting), and saliva and fecal samples (see the figure).

Collection of these samples will not involve any modification to your treatment.

The biopsy samples will be sent to I3S (Portugal) for characterization and classification, accompanied by the local pathology report.



In addition, to analyze the influence of exposure to different risk factors between cases, you will be asked simple questions related to your diet, anthropometry (physical measures including weight and height), physical activity, socioeconomic status, tobacco, alcohol, and salt consumption, as well as medical history related to gastritis and your family history of cancer.

The data from your medical history will be included in an electronic database, exclusive to the project, in an encrypted or coded form so that you cannot be directly identified; this will be shared and analyzed by the entire research team. The conclusions will be published and disseminated to the scientific community and the general population.

The data collected will undergo validation processes that will guarantee its integrity, consistency, and reliability.

5. Risks and inconveniences derived from your participation in the study

The risks and discomfort will be those derived from the indicated gastroscopy, a process in which a camera is inserted into your stomach via a scope through your mouth and down your throat. You may have some throat and stomach pain from the gastroscopy, as well as a little bleeding resulting from the biopsies. This is normal and should pass within a few hours. Should it persist, please contact the project's principal investigator.

For most people, needle sticks to draw blood are not a problem. However, on occasion, they can cause bleeding, bruising, discomfort, infection and/or pain at the point of blood extraction. You may also feel dizzy. Should you feel any of these symptoms, please notify the nurse performing the blood draw.

6. Possible benefits

It is very possible that you will not gain any benefit to your health from participating in this study, but it may help to better understand your disease and improve the prognosis and treatment of future patients.

7. Protection of personal data

The processing of your personal data related to this study will be carried out in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (GDPR). And it is carried out under the co-responsibility of the following institutions:

Institution	Country	Id. code		Contact
IIS INCLIVA	Spain	ESG96886080		www.incliva.es
I3S	Portugal			
UniversityofLatvia	Latvia			
Hospital La Princesa	Spain			
Hospital Clinic Barcelona	Spain			
CHU Nantes	France			
LithuaniaUniversity	Lithuania			
Instituto Portugués de Oncologia	Portugal			
Erasmus Medical Center	TheNetherlands			

The personal data that this study requires will be taken from questionnaire that you will complete, existing data in your clinical records and the results of the testing you will undergo, which will be included in an electronic database specific to the project, in an encrypted format, without directly identifiable data, for subsequent analysis by the entire research team. The conclusions will be published and disseminated to the scientific community and the general public. Your identity will not be revealed to any person, with the exceptions of medical emergency or legal requirement. This study's data can be transmitted to third parties and to other countries, but in no case containing information that can identify you directly. If data transfer takes place, it will be for the study purposes previously described or for use in scientific

publications, but always maintaining confidentiality and identity protection in accordance with current legislation. Information and updates on the progress of this study can be found on the following website:……..

If data obtained in this study may be clinically or genetically relevant to you, and of interest and importance to your health or that of your family, it may be requested that you be informed by your study doctor. In the instance that you should express your refusal to be informed, and in the opinion of the doctor in charge, the information obtained is necessary to avoid serious damage to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting the centre's Ethics Committee. This information will be communicated by professionals who are able to explain its relevance and the options that may be open to you. In case of clinically relevant genetic information, you may receive the necessary genetic counselling.

Although it is unlikely, genetic information may be obtained that is not directly related to the primary objective of the analysis, but that is considered clinically relevant to your health, or that of your family in case of heritable alterations. If so, ask your doctor about the implications of this information. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant for your family members. It is your personal decision to inform them, something we strongly recommend, so that if they wish they may seek further medical advice and guidance at a specialized clinic for family cancer or clinical genetics, where they will be informed about the clinical significance of the identified disorder.

In accordance with data protection legislation, you may exercise your right to access, modify, oppose and cancel data by contacting your study doctor. If you decide to withdraw consent to participate in this study, no new data will be added to the database, but the existing data will be used. Additionally, you can limit the processing of incorrect data, and may request a copy or transfer to a third party (portability) of any data you have provided for the study. To exercise your rights, contact your study doctor or the centre's Data Protection Officer at protecciondatos@incliva.es. Also, please note that if you are not satisfied with the way your request is handled, you have the right to contact the Spanish Data Protection Agency at www.aepd.es/agencia/contacto.

It is quite likely that you will not see any benefit to your health from participating in this study, but it could help you to understand your disease better and improve prognosis and treatment of future patients.

8. Information relating to biological samples

Your participation in this study entails obtaining and using biological samples for research purposes, which will be carried out in accordance with the provisions of Law 14/2007 on biomedical research and Royal Decree 1716/2011 on Biobanks, regulations that guarantee the Respect for the rights that assist you.

By signing this document, you agree that your samples will be used for the purposes of this study.

During this study, biopsy samples will be collected during the gastroscopy that will be performed for the diagnosis of your disease, blood, saliva and stools as described in section 4, study activities.

The biological samples will be processed by the different clinical centres included in the table in section 7. And if you allow it, the surplus of biological material will be stored in the IIS INCLIVA Biobank for use in subsequent research projects.

8.1 Sample Collection Procedures, Discomfort, and Potential Risks
The samples will be obtained as described in section 4, titled Study activities and obtaining them could cause you the inconvenience described in section 5, titled Risks and inconveniences derived from your participation in the study.

The samples will be associated with a code that can only be related to their identity by authorized personnel, in the same way that has been previously explained with the data obtained during the study.

The data derived from the use of these samples will be treated in the same way as the rest of the data obtained during this study in terms of data protection.

The samples and associated data will be kept under adequate security conditions, and it is guaranteed that the subjects cannot be identified through means considered reasonable by persons other than those authorized.

Some additional data or samples may be required. In this case, your doctor will contact you to request your collaboration again. You will be informed of the reasons and your consent will be requested again.

8.2 Expected benefits
You will not receive any economic benefit from the donation of the samples and the transfer of the data provided, nor will you have rights to possible commercial benefits of the discoveries that may be achieved because of the research carried out.

8.3. Place of analysis and storage of samples
The study biopsy samples will be sent to I3s (Portugal). I3s will distribute part of the samples to CHU Nantes and the University of Lithuania to jointly carry out the necessary determinations for the study.

8.4. Implications of the information obtained when analysing the samples
If you request it, you may be provided with information about the general objectives of this study.

If this study obtains data that could be clinically or genetically relevant to you, and of interest to your health or that of your family, you may request that they be communicated to you by your study doctor.

In the instance that you should express your refusal to be informed, and according to the criteria of the responsible doctor, the information obtained is necessary to avoid serious harm to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting to the Healthcare Ethics Committee of the centre. The communication of this information will be carried out by professionals who are able to adequately explain its relevance and the options that could be considered. In the case of clinically relevant genetic information, you may receive the mandatory genetic counselling.

Although unlikely, genetic information obtained that is not directly related to the primary objective of the analysis, may be considered clinically relevant to your health, or that of your family in case of heritable disorders. If so, discuss the implications of this information with your doctor. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant to your biological relatives. It is your personal decision to inform them, something that we recommend, so that if they so wish, they can seek out a specialized consultation in family cancer or clinical genetics, where they will be informed about the clinical significance of the identified alteration.

8.5. Future use of samples
Once the study is finished, the remaining samples will be destroyed, unless you consent to storage in a Biobank regime to be used in future research. In this case, the samples will be stored in the INCLIVA Biobank. From there they will be transferred for projects provided there is a favourable opinion from the scientific committee and the Ethics committee of the Biobank.

You can contact the INCLIVA biobank to biobanco@incliva.es to obtain information on the projects in which your samples have been used.

Said authorization can be granted by signing the corresponding consent of the INCLIVA Biobank. If you change your mind, you have the right to request its destruction or anonymization, this can be done through your study doctor or through direct communication to the biobank. However, it is important that you understand that the data obtained in the analyses carried out up to that moment may be used for the requested purposes and may be kept in compliance with the corresponding legal obligations.

Should you request it, the biobank will provide you with information about the research projects in which your samples have been used.

INFORMED CONSENT

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AIguided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<participant's name and surname>>
(Name in handwriting by the patient)
have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by the patient)
I understand that my participation is voluntary.
I understand that I am free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting my medical care.

I freely give my consent to participate in the study.
I consent to the use and processing of my personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

☐YES ☐NO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Participant's Signature
Date: ____/____/____
(Signature and date in handwriting by patient)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT LEGALREPRESENTATIVE

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AIguided app as a strategy for gastric cancer prevention".	
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CENTER	To be completed

I, _____ <<representative's name and surname>>
(Name in handwriting by representative)
In my capacity as _____ <<relationship to the participant>>, of _____<<participant's name and surname >>
(Name in handwriting by representative)

have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by representative)
I understand that his/her participation is voluntary.
I understand that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.
I freely give my consent to his/her participation in the study.
I consent to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

☐YES ☐NO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Signature of legal representative, relative or related party
Date: ____/____/____
(Signature and date in handwriting by representative)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT BEFORE WITNESSES

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DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<witness's name and surname>>
(Name in handwriting by witness)
as a witness, state that in my presence _____<< participant's name and surname >>
(Name in handwriting by witness)

has been informed and has read the information sheet about the study, and therefore:

He/she has read the information sheet that has been given to him/her about the study.
Was able to ask questions about the study.
Has received enough information about the study.
Has spoken to _____<<name of investigator>>
(Name in handwriting by witness)
Understands that his/her participation is voluntary.
Understands that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.

Freely gives his/her consent to participate in the study.
Consents to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

Consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

Would like the study doctor to inform him/her about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to his/her health or that of his/her family members:

☐YES ☐NO Contact telephone or email _____

Consents to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

Will receive a signed and dated copy of this informed consent form

Signature of witness
Date: ____/____/____
(Signature and date in handwriting by witness)

Investigator's Signature
Date: ____/____/____

PARTICIPANT INFORMATION SHEET

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1. Voluntary participation

You have been invited to participate in this study because you have been diagnosed with gastric cancer and you will undergo an endoscopy, as a strategy for managing your disease. By agreeing to participate in this study you grant us your consent to access and process some of your personal data in the ways described below, and to take extra biopsies or samples of the tissue from the gastric mucosa which makes up the inner lining of the stomach, and also to collect of a sample of blood (2 EDTA tubes 5 mL each – EDTA is an anticoagulant and keeps the blood from clotting), saliva and faecal samples. Collection of these samples will not involve any modification to your treatment. You should know that your participation in this study is voluntary and that you can decide NOT to participate. If you decide to participate, you may change your mind and withdraw your consent at any time- your choice will not affect your relationship with your doctor or negatively affect the health care you receive.

2. Justification and Objective of the study

This study is carried out to better understand how inflammation over a long period of time may cause changes in the cells that line the stomach (gastric epithelium) and can eventually develop into cancer. Understanding the changes that occur before cancer develops allows for patients at risk to be identified early and to be guided with strict follow-ups as a prevention strategy.
The main objective of this study is to develop a tool that will be assisted by artificial intelligence (AI), and will combine clinical data, risk factors such as *Helicobacter pylori* infection (a common bacterial infection of the stomach), and pathological and molecular risks of inflammation of the stomach tissue in order to apply more effective prevention measures of gastric cancer, in the future.

3. Description of the study

This study is part of the strategy of the project: "European Consortium for the development of a tool-assisted by artificial intelligence for the diagnosis and management of chronic gastric inflammation".

A health questionnaire will be completed, and biopsy samples will be collected during the gastroscopy indicated by your treating physician, your participation will allow the project to develop the AI-assisted tool.
The expected number of patients to be recruited in this project is 450 patients (150 cases, 150 controls 150 gastric cancer controls to train the system).

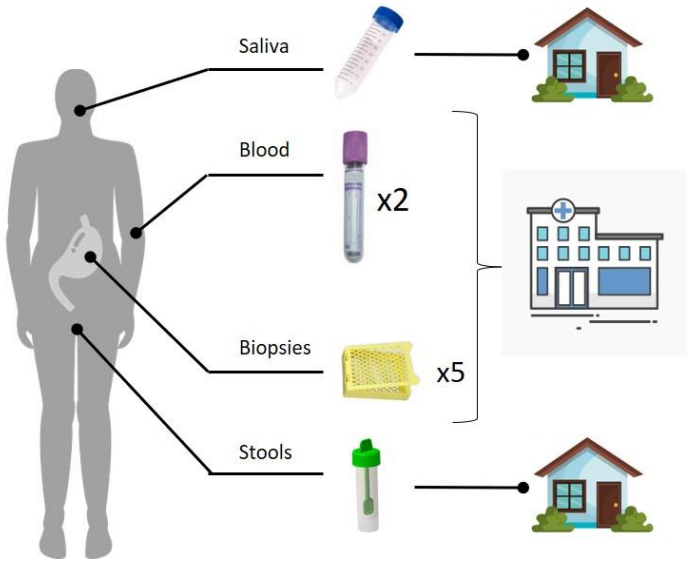
This is an international multicentre study in which 9 hospitals in Europe will participate. Participating countries include Spain, Portugal, France, Latvia, Lithuania, and the Netherlands, and recruitment is expected to take place in 3 years.

This study seeks to develop a clinical tool that is useful in the prevention of gastric cancer.

4. Study activities

The entire project will last 4 years.

Your participation, should you agree, will consist of the analysis of your gastric biopsy samples, 5 additional biopsies, two samples of blood (5 mL EDTA tubes), saliva and fecal collection (see the figure). It will not imply any modification of your treatment.
The biopsy samples will be sent to I3S (Portugal) for characterization and classification, accompanied by the local pathology report.



In addition, to analyze the influence of exposure to different risk factors between cases, you will be asked simple questions related to your diet, anthropometry (physical measures including weight and height), physical activity, socioeconomic status, tobacco, alcohol, and salt consumption, as well as medical history related to gastritis and your family history of cancer.

The data from your medical history will be included in an electronic database, exclusive to the project, in an encrypted or coded form so that you cannot be directly identified; this will be shared and analyzed by the entire research team. The conclusions will be published and disseminated to the scientific community and the general population.

The data collected will undergo validation processes that will guarantee its integrity, consistency, and reliability.

5. Risks and inconveniences derived from your participation in the study
The risks and discomfort will be those derived from the indicated gastroscopy, a process in which a camera is inserted into your stomach via a scope through your mouth and down your throat. You may have some throat and stomach pain from the gastroscopy, as well as a little bleeding resulting from the biopsies. This is normal and should pass within a few hours. Should it persist, please contact the project's principal investigator.

For most people, needle sticks to draw blood are not a problem. However, on occasion, they can cause bleeding, bruising, discomfort, infection and/or pain at the point of blood extraction. You may also feel dizzy. Should you feel any of these symptoms, please notify the nurse performing the blood draw.

6. Possible benefits

It is very possible that you will not gain any benefit to your health from participating in this study, but it may help to better understand your disease and improve the prognosis and treatment of future patients.

7. Protection of personal data

The processing of your personal data related to this study will be carried out in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (GDPR). And it is carried out under the co-responsibility of the following institutions:

Institution	Country	Id. code	Contact
IIS INCLIVA	Spain	ESG96886080	www.incliva.es
I3S	Portugal		
University of Latvia	Latvia		
Hospital La Princesa	Spain		
Hospital Clinic Barcelona	Spain		
CHU Nantes	France		
Lithuania University	Lithuania		
Instituto Portugués de Oncologia	Portugal		
Erasmus Medical Center	TheNetherlands		

Your identity will not be revealed to any person, with the exceptions of medical emergency or legal requirements. This study's data can be transmitted to third parties and to other countries, but in no case containing information that can identify you directly. If data transfer takes place, it will be for the study purposes previously described or for use in scientific publications, but always maintaining confidentiality and identity protection in accordance with current legislation. Information and updates on the progress of this study can be found on the following website:.....

If data obtained in this study may be clinically or genetically relevant to you, and of interest and importance to your health or that of your family, it may be requested that you be informed by your study doctor. In the instance that you should express your refusal to be informed, and in the opinion of the doctor in charge, the information obtained is necessary to avoid serious damage to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting the centre's Ethics Committee. This information will be communicated by professionals who are able to explain its relevance and the options that may be open to you. In case of clinically relevant genetic information, you may receive the necessary genetic counselling.

Although it is unlikely, genetic information may be obtained that is not directly related to the primary objective of the analysis, but that is considered clinically relevant to your health, or that of your family in case of heritable alterations. If so, ask your doctor about the implications of this information. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant for your family members. It is your personal decision to inform them, something we strongly recommend, so that if they wish they may seek further medical advice and guidance at a specialized clinic for family cancer or clinical genetics, where they will be informed about the clinical significance of the identified disorder.

In accordance with data protection legislation, you may exercise your right to access, modify, oppose and cancel data by contacting your study doctor. If you decide to withdraw consent to participate in this study, no new data will be added to the database, but the existing data will be used. Additionally, you can limit the processing of incorrect data, and may request a copy or transfer to a third party (portability) of any data you have provided for the study. To exercise your rights, contact your study doctor or the centres Data Protection Officer at protecciondatos@incliva.es. Also, please note that if you are not satisfied with the way your request is handled, you have the right to contact the Spanish Data Protection Agency at www.aepd.es/agencia/contacto.

It is quite likely that you will not see any benefit to your health from participating in this study, but it could help you to understand your disease better and improve prognosis and treatment of future patients.

8. Information relating to biological samples

Your participation in this study entails obtaining and using biological samples for research purposes, which will be carried out in accordance with the provisions of Law 14/2007 on biomedical research and Royal Decree 1716/2011 on Biobanks, regulations that guarantee the Respect for the rights that assist you.

By signing this document, you agree that your samples will be used for the purposes of this study.

During this study, biopsy samples will be collected during the gastroscopy that will be performed for the diagnosis of your disease, blood and saliva as described in section 4, study activities.

The biological samples will be processed by the different clinical centres included in the table in section 7. And if you allow it, the surplus of biological material will be stored in the IIS INCLIVA Biobank for use in subsequent research projects.

8.1 Sample Collection Procedures, Discomfort, and Potential Risks
The samples will be obtained as described in section 4, titled Study activities and obtaining them could cause you the inconvenience described in section 5, titled Risks and inconveniences derived from your participation in the study.

The samples will be associated with a code that can only be related to their identity by authorized personnel, in the same way that has been previously explained with the data obtained during the study.

The data derived from the use of these samples will be treated in the same way as the rest of the data obtained during this study in terms of data protection.

The samples and associated data will be kept under adequate security conditions, and it is guaranteed that the subjects cannot be identified through means considered reasonable by persons other than those authorized.

Some additional data or samples may be required. In this case, your doctor will contact you to request your collaboration again. You will be informed of the reasons and your consent will be requested again.

8.2 Expected benefits
You will not receive any economic benefit from the donation of the samples and the transfer of the data provided, nor will you have rights to possible commercial benefits of the discoveries that may be achieved because of the research carried out.

8.3. Place of analysis and storage of samples
The study biopsy samples will be sent to I3s (Portugal). I3s will distribute part of the samples to CHU Nantes and the University of Lithuania to jointly carry out the necessary determinations for the study.

8.4. Implications of the information obtained when analysing the samples
If you request, you may be provided with information about the general studies of this study.

If this study obtains data that could be clinically or genetically relevant to you, and of interest to your health or that of your family, you may request that they be communicated to you by your study doctor.

In the instance that you should express your refusal to be informed, and according to the criteria of the responsible doctor, the information obtained is necessary to avoid serious harm to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting to the Healthcare Ethics Committee of the centre. The communication of this information will be carried out by professionals who are able to adequately explain its relevance and the options that could be considered. In the case of clinically relevant genetic information, you may receive mandatory genetic counselling.

Although unlikely, genetic information obtained that is not directly related to the primary objective of the analysis, may be considered clinically relevant to your health, or that of your family in case of heritable disorders. If so, discuss the implications of this information with your doctor. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant to your biological relatives. It is your personal decision to inform them, something that we strongly recommend, so that if they so wish, they can seek out a specialized consultation in family cancer or clinical genetics, where they will be informed about the clinical significance of the identified alteration.

8.5. Future use of samples

Once the study is finished, the remaining samples will be destroyed, unless you consent to storage in a Biobank regime to be used in future research. In this case, the samples will be stored in the INCLIVA Biobank. From there they will be transferred for projects provided there is a favourable opinion from the scientific committee and the Ethics committee of the Biobank.

You can contact the INCLIVA biobank to biobanco@incliva.es to obtain information on the projects in which your samples have been used.

Said authorization can be granted by signing the corresponding consent of the INCLIVA Biobank. If you change your mind, you have the right to request its destruction or anonymization, this can be done through your study doctor or through direct communication with the biobank. However, it is important that you understand that the data obtained in the analyses carried out up to that moment may be used for the requested purposes and may be kept in compliance with the corresponding legal obligations.

Should you request it, the biobank will provide you with information about the research projects in which your samples have been used.

INFORMED CONSENT

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<participant's name and surname>>
(Name in handwriting by the patient)
have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by the patient)
I understand that my participation is voluntary.
I understand that I am free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting my medical care.

I freely give my consent to participate in the study.
I consent to the use and processing of my personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

ϒYES ϒNO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

ϒYES ϒNO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

ϒYES ϒNO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Participant's Signature
Date: ____/____/____
(Signature and date in handwriting by patient)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT LEGAL REPRESENTATIVE

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<representative's name and surname>>
(Name in handwriting by representative)
In my capacity as _____ <<relationship to the participant>>, of _____<<participant's name and surname >>
(Name in handwriting by representative)

have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by representative)
I understand that his/her participation is voluntary.
I understand that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.

I freely give my consent to his/her participation in the study.
I consent to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

ϒYES ϒNO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

ϒYES ϒNO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

ϒYES ϒNO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Signature of legal representative, relative or related party
Date: ____/____/____
(Signature and date in handwriting by representative)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT BEFORE WITNESSES

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<witness's name and surname>>
(Name in handwriting by witness)
as a witness, state that in my presence _____<< participant's name and surname >>
(Name in handwriting by witness)

has been informed and has read the information sheet about the study, and therefore:

He/she has read the information sheet that has been given to him/her about the study.
Was able to ask questions about the study.
Has received enough information about the study.
Has spoken to _____<<name of investigator>>
(Name in handwriting by witness)
Understands that his/her participation is voluntary.
Understands that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.

Freely gives his/her consent to participate in the study.
Consents to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

Consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

ϒYES ϒNO

Would like the study doctor to inform him/her about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to his/her health or that of his/her family members:

ϒYES ϒNO Contact telephone or email _____

Consents to be contacted if there is a need for further information or additional biological samples.

ϒYES ϒNO Contact telephone or email _____

Will receive a signed and dated copy of this informed consent form

Signature of witness
Date: ____/____/____
(Signature and date in handwriting by witness)

Investigator's Signature
Date: ____/____/____

PARTICIPANT INFORMATION SHEET

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

We are writing to inform you about a research study in which you are invited to take part in. The study has been approved by the centre's Research Ethics Committee, in accordance with current legislation, Law 14/2007, 3 July on Biomedical Research. Our aim is that you receive sufficient accurate information to make an informed decision on whether or not to participate in this study. Please take the time to read this information sheet carefully. You may contact us at any time to clarify any doubts that may arise. You may also discuss this project with others if you wish. Additionally, you may request further explanations about any aspect of the study and its implications by contacting the project's principal investigator, Name, by telephone onXXXXXXXX.

1. Voluntary participation

You have been invited to participate in the study because you require a gastroscopy (a process in which a camera is inserted into your stomach via a scope through your mouth and down your throat) for diagnosis purposes and because your profile meets the healthy control criteria for the disease under study. By agreeing to participate in this study you consent for us to access and process some of your personal data in the ways described below. As well as, extra biopsies from gastric mucosa (tissue from the stomach lining), in addition to – blood, saliva and faecal samples.

Collection of these samples will not involve any modification to your treatment.
You should know that your participation in this study is voluntary and that you may decide NOT to participate. If you decide to participate, you can change your decision and withdraw consent at any time – your choice will not alter your relationship with your doctor or negatively affect the health care you receive. Your acceptance to participate in this study implies your consent to treat some of your personal data, in the manner described below.

2. Justification and Objective of the study

This study is carried out to better understand how inflammation over a long period of time may cause changes in the cells that line the stomach (gastric epithelium) and can eventually develop into cancer. Understanding the changes that occur before cancer develops allows for patients at risk to be identified early and to be guided with strict follow-ups as a prevention strategy.
The main objective of this study is to develop a tool that will be assisted by artificial intelligence (AI), and will combine clinical data, risk factors such as Helicobacter pylori infection (a common bacterial infection of the stomach), and pathological and molecular risks of inflammation of the stomach tissue in order to apply more effective prevention measures of gastric cancer, in the future.

3. Description of the study

This study is part of the strategy of the project: "European Consortium for the development of a tool assisted by artificial intelligence for the diagnosis and management of chronic gastric inflammation".

The study will be carried out in 2 parts:

<u>First phase</u>

Participating patients will be classified into one of 3 risk levels (high, medium-low), based on their health status, pre-existing conditions, history of Helicobacter pylori infection, history of changes in the gastric epithelium, or family history of cancer and will receive health recommendations based on their risk, which will be calculated based on the literature, in order to provide recommendations aligned with the clinical best practice guidelines.

A health questionnaire will be completed, and biopsy samples will be collected during the gastroscopy indicated by your treating physician, which will be analysed according to the protocol of the study to complete your individual risk profile.

The expected number of patients to be recruited in this project is 450 patients (150 cases, 150 healthy controls and also 150 cancer controls).

Second phase
During the second phase of the project, the risk prediction capabilities of the AI-assisted tool will be established and improved, after integrating the data of the patients recruited in the initial phase, the recommendations given to the patient cohort will be reviewed. You will be informed on to this update by your attending physician.

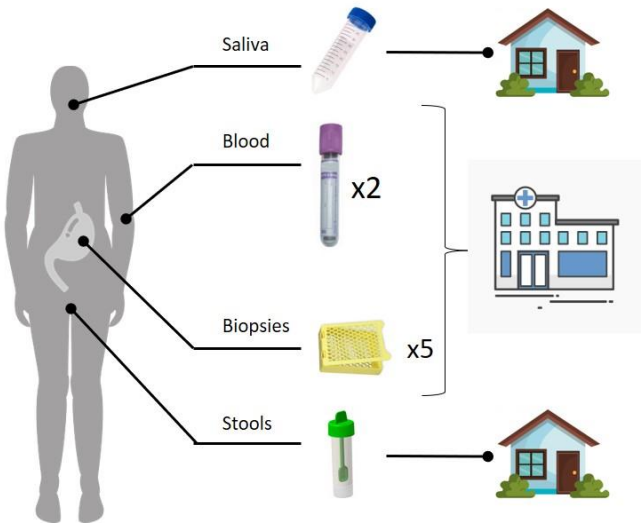
This is an international multicentre study in which 9 hospitals across Europe will participate. Participating countries include Spain, Portugal, France, Latvia, Lithuania, and the Netherlands, and recruitment is expected to take place in 3 years.

This study seeks to develop a clinical tool that is useful in the prevention of gastric cancer.

4. Study activities

The project will last 4 years.

Your participation, should you agree, will consist of answering questions about your state of health approximately every 2 months throughout the duration of the study, and the analysis of your gastric biopsy samples, with 5 additional biopsies, which would also be performed as part of the diagnosis process. In the event that you participate in the multiomic study (which involves analyzing the samples in greater depth including a molecular study, and the analysis of the immune microenvironment and the microbiome), 5 more biopsies will be collected, as well as the collection of two samples of blood (5 mL EDTA tubes– EDTA is an anticoagulant and keeps the blood from clotting), and saliva and fecal samples. Collection of these samples will not involve any modification to your treatment.
The biopsy samples will be sent to I3S (Portugal) for characterization and classification, accompanied by the local pathology report.



In addition, to analyze the influence of exposure to different risk factors between cases, you will be asked simple questions related to your diet, anthropometry (physical measures including weight and height), physical activity,

socioeconomic status, tobacco, alcohol, and salt consumption, as well as medical history related to gastritis and your family history of cancer.

The data from your medical history will be included in an electronic database, exclusive to the project, in an encrypted or coded form so that you cannot be directly identified; this will be shared and analyzed by the entire research team. The conclusions will be published and disseminated to the scientific community and the general population.

The data collected will undergo validation processes that will guarantee its integrity, consistency, and reliability.

5. Risks and inconveniences derived from your participation in the study

The risks and discomfort will be those derived from the indicated gastroscopy, a process in which a camera is inserted into your stomach via a scope through your mouth and down your throat. You may have some throat and stomach pain from the gastroscopy, as well as a little bleeding resulting from the biopsies. This is normal and should pass within a few hours. Should it persist, please contact the project's principal investigator.

For most people, needle sticks to draw blood are not a problem. However, on occasion, they can cause bleeding, bruising, discomfort, infection and/or pain at the point of blood extraction. You may also feel dizzy. Should you feel any of these symptoms, please notify the nurse performing the blood draw.

6. Possible benefits

It is very possible that you will not gain any benefit to your health from participating in this study, but it may help to better understand your disease and improve the prognosis and treatment of future patients.

7. Protection of personal data

The processing of your personal data related to this study will be carried out in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (GDPR). And it is carried out under the co-responsibility of the following institutions:

Institution	Country		Id. code	Contact
IIS INCLIVA	Spain		ESG96886080	www.incliva.es
I3S	Portugal			
UniversityofLatvia	Latvia			
Hospital La Princesa	Spain			
Hospital Clinic Barcelona	Spain			
CHU Nantes	France			
LithuaniaUniversity	Lithuania			
Instituto Portugués de Oncologia	Portugal			
Erasmus Medical Center	TheNetherlands			

The personal data that this study requires will be taken from questionnaire that you will complete, existing data in your clinical records and the results of the testing you will undergo, which will be included in an electronic database specific to the project, in an encrypted format, without directly identifiable data, for subsequent analysis by the entire research team. The conclusions will be published and disseminated to the scientific community and the general public. Your identity will not be revealed to any person, with the exceptions of medical emergency or legal requirement. This study's data can be transmitted to third parties and to other countries, but in no case containing information that can identify you directly. If data transfer takes place, it will be for the study purposes previously described or for use in scientific publications, but always maintaining confidentiality and identity protection in accordance with current legislation. Information and updates on the progress of this study can be found on the following website:……..

If data obtained in this study may be clinically or genetically relevant to you, and of interest and importance to your health or that of your family, it may be requested that you be informed by your study doctor. In the instance that you should express your refusal to be informed, and in the opinion of the doctor in charge the information obtained is necessary to avoid serious damage to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting the centre's Ethics Committee. This information will be communicated by professionals who are able to explain its relevance and the options that may be open to you. In case of clinically relevant genetic information, you may receive the necessary genetic counselling.

Although it is unlikely, genetic information may be obtained that is not directly related to the primary objective of the analysis, but that is considered clinically relevant to your health, or that of your family in case of heritable alterations. If so, ask your doctor about the implications of this information. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant for your family members. It is your personal decision to inform them, something we strongly recommend, so that if they wish they may seek further medical advice and guidance at a specialized clinic for family cancer or clinical genetics, where they will be informed about the clinical significance of the identified disorder.

In accordance with data protection legislation, you may exercise your right to access, modify, oppose and cancel data by contacting your study doctor. If you decide to withdraw consent to participate in this study, no new data will be added to the database, but the existing data will be used. Additionally, you can limit the processing of incorrect data, and may request a copy or transfer to a third party (portability) of any data you have provided for the study. To exercise your rights, contact your study doctor or the centre's Data Protection Officer at protecciondatos@incliva.es. Also, please note that if you are not satisfied with the way your request is handled, you have the right to contact the Spanish Data Protection Agency at www.aepd.es/agencia/contacto.

It is quite likely that you will not see any benefit to your health from participating in this study, but it could help you to understand your disease better and improve prognosis and treatment of future patients.

8. Information relating to biological samples

Your participation in this study entails obtaining and using biological samples for research purposes, which will be carried out in accordance with the provisions of Law 14/2007 on biomedical research and Royal Decree 1716/2011 on Biobanks, regulations that guarantee the Respect for the rights that assist you.

By signing this document, you agree that your samples will be used for the purposes of this study.

During this study, biopsy samples will be collected during the gastroscopy that will be performed for the diagnosis of your disease, blood, saliva, and stools as described in section 4, study activities.

The biological samples will be processed by the different clinical centres included in the table in section 7. And if you allow it, the surplus of biological material will be stored in the IIS INCLIVA Biobank for use in subsequent research projects.

8.1 Sample Collection Procedures, Discomfort, and Potential Risks
The samples will be obtained as described in section 4, titled Study activities and obtaining them could cause you the inconvenience described in section 5, titled Risks and inconveniences derived from your participation in the study.

The samples will be associated with a code that can only be related to their identity by authorized personnel, in the same way that has been previously explained with the data obtained during the study.

The data derived from the use of these samples will be treated in the same way as the rest of the data obtained during this study in terms of data protection.

The samples and associated data will be kept under adequate security conditions, and it is guaranteed that the subjects cannot be identified through means considered reasonable by persons other than those authorized.

Some additional data or samples may be required. In this case, your doctor will contact you to request your collaboration again. You will be informed of the reasons and your consent will be requested again.

8.2 Expected benefits

You will not receive any economic benefit from the donation of the samples and the transfer of the data provided, nor will you have rights to possible commercial benefits of the discoveries that may be achieved because of the research carried out.

8.3. Place of analysis and storage of samples

The study biopsy samples will be sent to I3s (Portugal). I3s will distribute part of the samples to CHU Nantes and the University of Lithuania to jointly carry out the necessary determinations for the study.

8.4. Implications of the information obtained when analysing the samples

If you request it, you may be provided with information about the general objectives of this study.

If this study obtains data that could be clinically or genetically relevant to you, and of interest to your health or that of your family, you may request that they be communicated to you by your study doctor.

In the instance that you should express your refusal to be informed, and according to the criteria of the responsible doctor, the information obtained is necessary to avoid serious harm to your health or that of your biological relatives, a close relative or a representative will be informed, after consulting to the Healthcare Ethics Committee of the center. The communication of this information will be carried out by professionals who are able to adequately explain its relevance and the options that could be considered. In the case of clinically relevant genetic information, you may receive the mandatory genetic counselling.

Although unlikely, genetic information obtained that is not directly related to the primary objective of the analysis, may be considered clinically relevant to your health, or that of your family in case of heritable disorders. If so, discuss the implications of this information with your doctor. In case you prefer not to be informed, your decision will be respected. The information obtained may also be relevant to your biological relatives. It is your personal decision to inform them, something that we recommend, so that if they so wish, they can seek out a specialized consultation in family cancer or clinical genetics, where they will be informed about the clinical significance of the identified alteration.

8.5. Future use of samples

Once the study is finished, the remaining samples will be destroyed, unless you consent to storage in a Biobank regime to be used in future research. In this case, the samples will be stored in the INCLIVA Biobank. From there they will be transferred for projects provided there is a favourable opinion from the scientific committee and the Ethics committee of the Biobank.

You can contact the INCLIVA biobank to biobanco@incliva.es to obtain information on the projects in which your samples have been used.

Said authorization can be granted by signing the corresponding consent of the INCLIVA Biobank. If you change your mind, you have the right to request its destruction or anonymization, this can be done through your study doctor or through direct communication to the biobank. However, it is important that you understand that the data obtained in the analyses carried out up to that moment may be used for the requested purposes and may be kept in compliance with the corresponding legal obligations.

Should you request it, the biobank will provide you with information about the research projects in which your samples have been used.

INFORMED CONSENT

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<participant's name and surname>>
(Name in handwriting by the patient)
have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by the patient)
I understand that my participation is voluntary.
I understand that I am free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting my medical care.

I freely give my consent to participate in the study.
I consent to the use and processing of my personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

☐YES ☐NO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Participant's Signature
Date: ____/____/____
(Signature and date in handwriting by patient)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT LEGALREPRESENTATIVE

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<representative's name and surname>>
(Name in handwriting by representative)
In my capacity as _____ <<relationship to the participant>>, of _____<<participant's name and surname >>
(Name in handwriting by representative)

have read the information sheet that has been given to me about the study.
I was able to ask questions about the study.
I have received enough information about the study.
I have spoken to _____<<name of investigator>>
(Name in handwriting by representative)
I understand that his/her participation is voluntary.
I understand that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.
I freely give my consent to his/her participation in the study.
I consent to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

I consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

I would like the study doctor to inform me about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to my health or that of my family members:

☐YES ☐NO Contact telephone or email _____

I consent to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

I will receive a signed and dated copy of this informed consent form

Signature of legal representative, relative or related party
Date: ____/____/____
(Signature and date in handwriting by representative)

Investigator's Signature
Date: ____/____/____

INFORMED CONSENT BEFORE WITNESSES

STUDY TITLE: "Interventional study focused on providing personalised health recommendations to the general population through an integrated AI guided app as a strategy for gastric cancer prevention".	
STUDY CODE	**101095359 – AIDA**
PRINCIPAL INVESTIGATORS	To be completed
DEPARTMENT	To be completed
CENTER	To be completed

I, _____ <<witness's name and surname>>
(Name in handwriting by witness)
as a witness, state that in my presence _____<< participant's name and surname >>
(Name in handwriting by witness)

has been informed and has read the information sheet about the study, and therefore:

He/she has read the information sheet that has been given to him/her about the study.
Was able to ask questions about the study.
Has received enough information about the study.
Has spoken to _____<<name of investigator>>
(Name in handwriting by witness)
Understands that his/her participation is voluntary.
Understands that he/she is free to withdraw from the study:
- At any time.
- Without giving a reason.
- Without this affecting his/her medical care.

Freely gives his/her consent to participate in the study.
Consents to the use and processing of his/her personal data for this investigation under the conditions explained in this information sheet.

Use of Samples

Consent to the storage and use of the samples and associated data for this research under the conditions explained in this information sheet.

☐YES ☐NO

Would like the study doctor to inform him/her about information generated from the research (genetic or non-genetic, depending on the case) that may be relevant and applicable to his/her health or that of his/her family members:

☐YES ☐NO Contact telephone or email _____

Consents to be contacted if there is a need for further information or additional biological samples.

☐YES ☐NO Contact telephone or email _____

Will receive a signed and dated copy of this informed consent form

Signature of witness
Date: ____/____/____
(Signature and date in handwriting by witness)

Investigator's Signature
Date: ____/____/____