Cooper Health System
Institutional Review Board
FWA #: 00000211

Notification of Continuing Review Approval
Expedited Review

Date: May 12, 2020

To: *Principal Investigator*
Joshua DeSipio, MD
Dept/Div: The Cooper Health System - Medicine-Gastroenterology and Liver Diseases
IRB#: **17-077EX**
Submission Type: Continuing Review Submission Form
Submission Outcome: Approved
Sponsor: New Jersey Health Foundation(NJHF)
Study Title: ***Designing Evidenced-Based Strategies for Eradicating H pylori - Phase II***

This study was given expedited continuing review by an experienced IRB member based on the criteria stated in 45 CFR 46.110, 21 CFR 56.110 and the expedited review categories specified in the Federal Register/Vol. 63, No. 216 dated 11/9/98. The reviewer renewed approval of this study for 12 Months. Supporting documents along with the reviewer's recommendation will be attached to the agenda for the 06/18/2020 Committee (A) IRB meeting.

Approval Date: 05/12/2020	**IRB approval expires: 05/13/2021**
Review Period: 12 Months	**Continuing review report due: 03/13/2021**

Comments: 1. This study qualifies for expedited review because the reviewer of the original application determined that it involves no more than minimal risk and it fits expedited review categories (3) prospective collection of biological specimens for research purposes by non-invasive means, (5) research involving materials that have been or will be collected solely for non-research purposes and (7) research on individual or group characteristics or behavior or research employing surveys, interviews, etc. as specified in the Federal Register. There have been no changes to the study since initial approval that changed the original determination regarding its expedited review status. This study is open to accrual and approved through investigator initiated study application version 1.6. This study is approved for collection of data from 6/01/2017 to 12/31/2021. At CHS, 42 subjects were enrolled and all have completed study participation. A combined consent form/HIPAA authorization was submitted for online stamp approval.
The Reviewer renewed approval of this study for one year with the combined consent form/HIPAA authorization submitted with this report.

Please be reminded that for investigator-initiated studies, you must report to the IRB **ALL** serious adverse events whether they are expected or unexpected, **AND** whether they are related or unrelated to the study drugs or procedures.

This approval is for a period of 12 Months. You should receive electronic notification 60 days prior to the expiration of this project's approval. However, it is your responsibility to insure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a final report of findings at the completion of the project.

Consent Form (if applicable)**:** All subjects must use the approved and stamped consent form. You are responsible for maintaining signed consent forms for a period of at least three years after study

completion. **Print out and use the currently approved and stamped consent form and HIPAA authorization when enrolling subjects.** Please note that the expiration date is stamped on consent and HIPAA authorization forms as well as the approval date.

Research Modifications: Please note that you are responsible for informing the IRB of any and all protocol modifications prior to implementing those changes; serious or unexpected adverse events, IND safety reports, and additional information pertinent to the risk, benefit, or desire for subjects to continue to participate.

Sincerely,
Deborah LoPresti
IRB Analyst

Cooper University Health Care

Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information

TITLE OF STUDY: Designing Evidenced-Based Strategies for Eradicating *H. pylori* – Phase II

DEPARTMENT: Department of Medicine - Gastroenterology

INVESTIGATOR: Joshua DeSipio, MD

PHONE NUMBER: (856) 642-2133

CO-INVESTIGATORS: Thomas Judge, MD, Anjali Mone, MD, Imad Awan, Hansol Chung, Zoya Grigoryan, Harpreet Singh, Sangita Phadtare, Sanket Patel, DO, Robert Cooper, DO

SPONSOR: None

SUBJECT'S NAME: _____

What does informed consent for a research study involve?

You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and his staff will discuss with you what is involved in this research study. If you decide to take part, you and the study doctor, or a member of the study team will sign this Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are suspected to have *H. pylori* infection and will be treated by the physicians at the Cooper Digestive Health Institute.

Why is this study being done?

H. pylori is a common type of bacteria that usually infects the stomach. *H. pylori*

normally infect your stomach during childhood. While infections from these bacteria typically don't cause symptoms, they can lead to diseases in some people, including peptic ulcers and cancers, and an inflammatory condition inside your stomach known as gastritis.

In order to diagnose *H. pylori* infection the physician may perform a test on your bowel movement; perform a breath test, or an endoscopy. During the breath test, you will be asked to exhale into a balloon-like bag. The air you breathe into this bag is tested to provide a basis for comparison (called a baseline sample). You will then be asked to drink a small amount of a pleasant lemon-flavored solution. Fifteen minutes after drinking the solution, a second breath sample will be taken. The air you breathe into this bag is tested for an increase in carbon dioxide. An endoscopy is a procedure that lets your doctor look inside your body. It uses an instrument that has a tiny camera attached to a long, thin tube. The doctor moves it through your mouth down to see inside your stomach. Any of these tests may be ordered by your doctor as part of routine care.

The usual treatment is to be prescribed antibiotics. The antibiotics that are used vary and may be ineffective. This is because so many people have an antibiotic resistance.

In this study, data will be analyzed to evaluate the antibiotic resistance patterns and design a better treatment strategies.

What is investigational about this study?
The collection of a survey, as well as certain tests on your bowel movement sample (if selected and you volunteer) are being done for the research study.

How many people will be in this study and for how long?
This study intends to enroll 500 subjects at Cooper over approximately a 19 month period.

What will happen if you take part?
Each subject enrolled in the study will be asked to complete a survey. You will be asked about your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical history, and your past/present medications.

A portion of subjects will be asked to provide a sample of their bowel movement before and after treatment with antibiotics. This is a standard test for people with *H. pylori*; however in this study they will also be testing the type of bacteria, DNA for the presence of *H. pylori* and other microorganisms in the stool sample. You will bring this sample in at your next scheduled visit.

Subjects who have not been asked to provide a sample are complete study participation after the survey is given to the physician. Subjects who have provided stool samples will have completed study participation after they provide the post treatment stool sample. The duration between the pre-treatment sample visit and the post-treatment sample

visit varies between 2 weeks and up to 6 months.

What are the possible risks of participation?
There are no physical risks due to participation. There is a slight risk to your confidentiality. Subjects who take part in this study are subject to the same risks shared by all patients who receive a similar treatment but are not in this study. Your Doctor will inform you about the risks and benefits of your medication and therapy independent from your participation in the study.

Are there benefits to taking part?
You may not receive any benefit from participating in this study. However, medical science and future patients may benefit from your participation. Please approach your doctor with any questions you may have.

What other treatment options do you have?
You do not have to participate in this study. You do not have to volunteer to participate in this data collection study in order to obtain treatment for your H. pylori. You may wish to consult your doctor for further details or other alternatives to the treatment.

Voluntary Participation
Your participation is voluntary. You do not have to be part of this study. If you decide to be in the study, you may quit at any time. Either way, the doctors at Cooper Health System will treat you the same way.

Right to Withdraw
You also have the right to withdraw yourself from the study. If you do withdraw or are withdrawn from the study, you will still need to be seen by your doctor to have your routinely scheduled visits. Contact the study Doctor, Dr. DeSipio, in writing at 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054, of your intent to withdraw yourself from the study. There will be no penalty or loss of benefits to you if you decide not to be in the study or if you decide to withdraw from the study.

The data that have been collected until the time of your withdrawal will be kept and used. If you do not agree to the further use of your data, you need to expressly inform your Doctor in writing.

Is there any cost or payment for being in this study?
For subjects completing the survey, you will receive a $25.00 gift card. For those who complete the survey and provide the bowel movement sample before and after treatment, you will receive a $50.00 gift card. The collection kit for the sample and the testing on the sample will be paid for by a research study grant.

You and your insurance company will be charged for the cost of your prescribed treatment even if you participate in this study. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including, but not limited to, the following: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. Signing this form

does not take away any of your legal rights.

If you decide to participate, you or your insurance company will be charged the same fees for the treatment under this study as those charged for the same procedure performed by your doctor on patients that are not in this study.

What happens if you are injured or hurt during the study?

This is a data collection and bowel movement sample study. Receiving the treatment is not part of this study. This study involves the collection of data from the routine visits.

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Study Doctor listed on page one of this form. You may also contact your own doctor, or seek treatment outside of Cooper University Hospital.

Your insurance or Medicare (if applicable) will be billed for the costs of medical treatment of any illness or injury you suffer.

If you are injured as a result of the treatment, medical treatment will be available. Please contact your Study Doctor if you believe you have been injured. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. This is not a waiver of your legal rights. Questions regarding these issues may be directed to Dr. DeSipio at 856-642-2133.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-~~968-785~~8342-3071).

How will information about you be kept private?

Information about you related to this study will be kept as private as possible. The information collected and analyzed by the Study Doctor will not include your name or personal data that would allow you to be identified. A study number will be used instead of your name on all of your study forms. The Study Doctor may need to let other people look at your records, but only the Study Doctor and the study staff will be able to link your study number to your name. (Please see the HIPAA Authorization for the list of people who may need to inspect your study records and the reasons they need to look at them.) The list linking subjects' names and study numbers and subjects' study files will be kept on a password protected, encrypted computer which will be stored in a locked cabinet in the Study Doctor's research office.

Your Study Doctor will keep your health information confidential in accordance with all applicable laws and regulations. The Study Doctor may disclose your health information to institutional review boards and other persons who are required to watch over the conduct of research. See HIPAA Authorization below for listing of those people. You agree to allow the Study Doctor to use study data in these ways.

If the results of this study are published, your identity will remain confidential.

Who should you contact if you have questions?
You should call the Chief Medical Officer, or his representative at (856-~~968-7858~~342-3071) if (a) you have any questions about your rights as a research subject, (b) you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

If you have any questions about the research, you may contact the investigators listed on the front of this consent form. They are responsible for the conduct of the research at Cooper Hospital. They are affiliated with the Cooper Health System. Their address is 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

Will you be told about new information that might affect your decision to take part in this research?
During the study, you will be told if any new information is learned that could affect your willingness to stay in the study.

HIPAA AUTHORIZATION: Authorization to permit the use and disclose of Health Information (Protected Health Information) for Research Purposes.

Why are you being asked to sign this form?
The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information is information about a person's physical or mental health that can be identified with or linked to that particular person. As a subject in a research study, you have the right to know what health information will be used and created about you, how this information will be used, and who will be able to see the information. You also have the right to see your own health information. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your health information for this research study. The Principal Investigator, Co-Investigators, or the Study Coordinator will be happy to answer any questions you may have regarding this form.

What information will be collected from you for use in this study?
If you decide to be in this study, the following health information will be collected from you: your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical

history, and your past/present medications. If your bowel movement samples are tested, these results are being collected due to your participation in this study.

New health information will be created about you. The new information will include the information regarding your treatment for *H. pylori*, and the results of the testing on the bowel movement samples. This information will be placed into your research study files and medical records. These files and records will be stored at the Study Doctor's research office, located at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt. Laurel, NJ 08054.

How will your health information be used and disclosed?

As described above, your de-identified information will be used to analyze antibiotic resistance. In addition to the investigators listed on the first page of this form and their research staff, other people in the Cooper Health System (CHS) will be able to see your health information (described above) related to this research study. The other people are described below.

There is an Institutional Review Board (IRB) that oversees research in the CHS. People who represent this IRB may review your health information because they need to see how the study is going.

Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the doctors) for hospital and health care (2) they need to address correct payment for tests and procedures ordered by the doctors. (3) They need to perform internal hospital operations (e.g. quality assurance).

People outside the CHS from the agencies described below will also be able to see your health information under certain circumstances. These other people outside the CHS understand how important it is to keep your health information confidential. However, the CHS cannot guarantee that your information will be kept confidential after it has been given to people outside the CHS. The federal privacy rules do not cover any disclosures of your health information by these other people and agencies described below.

A federal agency called the Office of Human Research Protection (OHRP) oversees the CHS IRB. People from OHRP may also review your health information because they need to see how the IRB is doing.

Will you have access to your health information resulting from participation in this research study?

You may already have a copy of CHS's Notice of Privacy Practices. If you do not have one, the investigator will give you one. This notice says that you are allowed to see information that is in your research records and medical records that are filed in the offices of your health care provider. For this research study, that means the office of the investigators and Cooper Hospital. However, you may not see your health information until the study is finished. You have the right to see information that was created as a

result of your participation in this study and information that was collected and used for this research study. If you want to see this information, contact the Study Doctor's office at Cooper Health System, 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054.

May you refuse to give your authorization (permission) for the use of your health information for the purpose of this research study?

You do not have to give your authorization to use and disclose your health information as described above. Your authorization is completely voluntary. However, if you do not give your written authorization for the investigators to use and disclose your health information, you may not be in the research study.

If you decide not to allow the investigators to use and disclose your health information for this research study, it will not affect your care at CHS, it's affiliated health care providers or hospitals now or in the future.

May you withdraw your authorization (permission) for the use of your health information for this research study?

You may decide at any time that you no longer want the investigators to use and disclose your health information. In that case, you will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you for this study. In addition, research staff will stop using your health information. They will also stop disclosing (releasing) your information to the parties described above, with certain exceptions. The research staff may have relied on information that has already been collected from you. For example, the research staff may need to use or disclose information that they got before you withdrew your authorization in order to keep the scientific integrity of the study. You may also decide to give consent for the investigator to continue to collect your health information after you withdraw from the study.

If you decide to withdraw your authorization, you should give a written and dated notice of your decision to the Dr. DeSipio, MD, at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054. This decision will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

How long will the investigators be allowed to use your health information?

The investigators may continue to use and disclose your health information for the purposes described above for an undetermined period of time. If you sign this form, you authorize the use and disclosure of your information for this study at any time in the future.

VOLUNTARY PARTICIPATION

I voluntarily consent to take part in this study. The study staff has discussed this research study with me. I have had adequate time to read this form and to ask questions about it. I understand by signing this form I am not giving up any of my legal rights and I am also agreeing to the use and disclosure of my Protected Health Information. I will be given a copy of this signed and dated consent form for my records.

SUBJECT

Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

WITNESS

Printed Name of Witness to Subject's Signature: _____

Signature: _____ Date: _____ Time: _____

INVESTIGATOR

I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____

Cooper University Health Care

Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information

TITLE OF STUDY: Designing Evidenced-Based Strategies for Eradicating *H. pylori* – Phase II

DEPARTMENT: Department of Medicine - Gastroenterology

INVESTIGATOR: Joshua DeSipio, MD

PHONE NUMBER: (856) 642-2133

CO-INVESTIGATORS: Imad Awan, Zoya Grigoryan, Sangita Phadtare, Lauren Treene, Lark Perez, PhD, Hyder Alikhan

STUDY COORDINATOR: Katie Grant

SPONSOR: None

SUBJECT'S NAME: _____

What does informed consent for a research study involve?

You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and his staff will discuss with you what is involved in this research study. If you decide to take part, you and the study doctor, or a member of the study team will sign this Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are suspected to have *H. pylori* infection and will be treated by the physicians at the Cooper Digestive Health Institute.

Why is this study being done?

H. pylori is a common type of bacteria that usually infects the stomach. *H. pylori* normally infect your stomach during childhood. While infections from these bacteria typically don't cause symptoms, they can lead to diseases in some people, including peptic ulcers and cancers, and an inflammatory condition inside your stomach known as gastritis.

In order to diagnose *H. pylori* infection the physician may perform a test on your bowel movement; perform a breath test, or an endoscopy. During the breath test, you will be asked to exhale into a balloon-like bag. The air you breathe into this bag is tested to provide a basis for comparison (called a baseline sample). You will then be asked to drink a small amount of a pleasant lemon-flavored solution. Fifteen minutes after drinking the solution, a second breath sample will be taken. The air you breathe into this bag is tested for an increase in carbon dioxide. An endoscopy is a procedure that lets your doctor look inside your body. It uses an instrument that has a tiny camera attached to a long, thin tube. The doctor moves it through your mouth down to see inside your stomach. Any of these tests may be ordered by your doctor as part of routine care.

The usual treatment is to be prescribed antibiotics. The antibiotics that are used vary and may be ineffective. This is because so many people have an antibiotic resistance.

In this study, data will be analyzed to evaluate the antibiotic resistance patterns and design a better treatment strategies.

What is investigational about this study?
The collection of a survey, as well as certain tests on your bowel movement sample (if selected and you volunteer) are being done for the research study.

How many people will be in this study and for how long?
This study intends to enroll 500 subjects at Cooper over approximately a 19 month period.

What will happen if you take part?
Each subject enrolled in the study will be asked to complete a survey. You will be asked about your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical history, and your past/present medications.

A portion of subjects will be asked to provide a sample of their bowel movement before and after treatment with antibiotics. This is a standard test for people with *H. pylori*; however in this study they will also be testing the type of bacteria, DNA for the presence of *H. pylori* and other microorganisms in the stool sample. You will bring this sample in at your next scheduled visit.

Subjects who have not been asked to provide a sample are complete study participation after the survey is given to the physician. Subjects who have provided stool samples will have completed study participation after they provide the post treatment stool sample.

The duration between the pre-treatment sample visit and the post-treatment sample visit varies between 2 weeks and up to 6 months.

What will be done with your stool sample?
Your stool sample will only be stored until it is tested. We are isolating the DNA produced by the bacteria in the stool sample. This is not your DNA, it is the bacteria DNA. We will not store your sample. All samples will be labeled with only a subject number. If you decide you do not want your stool sample to be tested, please contact the doctor on the first page of the consent. We will destroy your sample if it has not been tested. The testing of the sample will take place at CMSRU (Cooper Medical School of Rowan University) or Genewiz.

What are the possible risks of participation?
There are no physical risks due to participation. There is a slight risk to your confidentiality. Subjects who take part in this study are subject to the same risks shared by all patients who receive a similar treatment but are not in this study. Your Doctor will inform you about the risks and benefits of your medication and therapy independent from your participation in the study.

Are there benefits to taking part?
You may not receive any benefit from participating in this study. However, medical science and future patients may benefit from your participation. Please approach your doctor with any questions you may have.

What other treatment options do you have?
You do not have to participate in this study. You do not have to volunteer to participate in this data collection study in order to obtain treatment for your H. pylori. You may wish to consult your doctor for further details or other alternatives to the treatment.

Voluntary Participation
Your participation is voluntary. You do not have to be part of this study. If you decide to be in the study, you may quit at any time. Either way, the doctors at Cooper Health System will treat you the same way.

Right to Withdraw
You also have the right to withdraw yourself from the study. If you do withdraw or are withdrawn from the study, you will still need to be seen by your doctor to have your routinely scheduled visits. Contact the study Doctor, Dr. DeSipio, in writing at 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054, of your intent to withdraw yourself from the study. There will be no penalty or loss of benefits to you if you decide not to be in the study or if you decide to withdraw from the study.

The data that have been collected until the time of your withdrawal will be kept and used. If you do not agree to the further use of your data, you need to expressly inform your Doctor in writing.

Is there any cost or payment for being in this study?

For subjects completing the survey, you will receive a $25.00 gift card. For those who complete the survey and provide the bowel movement sample before and after treatment, you will receive a $50.00 gift card. The collection kit for the sample and the testing on the sample will be paid for by a research study grant.

You and your insurance company will be charged for the cost of your prescribed treatment even if you participate in this study. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including, but not limited to, the following: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. Signing this form does not take away any of your legal rights.

If you decide to participate, you or your insurance company will be charged the same fees for the treatment under this study as those charged for the same procedure performed by your doctor on patients that are not in this study.

What happens if you are injured or hurt during the study?

This is a data collection and bowel movement sample study. Receiving the treatment is not part of this study. This study involves the collection of data from the routine visits.

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Study Doctor listed on page one of this form. You may also contact your own doctor, or seek treatment outside of Cooper University Hospital.

Your insurance or Medicare (if applicable) will be billed for the costs of medical treatment of any illness or injury you suffer.

If you are injured as a result of the treatment, medical treatment will be available. Please contact your Study Doctor if you believe you have been injured. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. This is not a waiver of your legal rights. Questions regarding these issues may be directed to Dr. DeSipio at 856-642-2133.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-342-3071).

How will information about you be kept private?

Information about you related to this study will be kept as private as possible. The information collected and analyzed by the Study Doctor will not include your name or personal data that would allow you to be identified. A study number will be used instead of your name on all of your study forms. The Study Doctor may need to let other people look at your records, but only the Study Doctor and the study staff will be able to link your study number to your name. (Please see the HIPAA Authorization for the list of people who may need to inspect your study records and the reasons they need to look

at them.) The list linking subjects' names and study numbers and subjects' study files will be kept on a password protected, encrypted computer which will be stored in a locked cabinet in the Study Doctor's research office.

Your Study Doctor will keep your health information confidential in accordance with all applicable laws and regulations. The Study Doctor may disclose your health information to institutional review boards and other persons who are required to watch over the conduct of research. See HIPAA Authorization below for listing of those people. You agree to allow the Study Doctor to use study data in these ways.

If the results of this study are published, your identity will remain confidential.

Who should you contact if you have questions?

You should call the Chief Medical Officer, or his representative at (856-342-3071) if (a) you have any questions about your rights as a research subject, (b) you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

If you have any questions about the research, you may contact the investigators listed on the front of this consent form. They are responsible for the conduct of the research at Cooper Hospital. They are affiliated with the Cooper Health System. Their address is 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

Will you be told about new information that might affect your decision to take part in this research?

During the study, you will be told if any new information is learned that could affect your willingness to stay in the study.

HIPAA AUTHORIZATION: Authorization to permit the use and disclose of Health Information (Protected Health Information) for Research Purposes.

Why are you being asked to sign this form?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information is information about a person's physical or mental health that can be identified with or linked to that particular person. As a subject in a research study, you have the right to know what health information will be used and created about you, how this information will be used, and who will be able to see the information. You also have the right to see your own health information. If

you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your health information for this research study. The Principal Investigator, Co-Investigators, or the Study Coordinator will be happy to answer any questions you may have regarding this form.

What information will be collected from you for use in this study?

If you decide to be in this study, the following health information will be collected from you: your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical history, and your past/present medications. If your bowel movement samples are tested, these results are being collected due to your participation in this study.

New health information will be created about you. The new information will include the information regarding your treatment for *H. pylori*, and the results of the testing on the bowel movement samples. This information will be placed into your research study files and medical records. These files and records will be stored at the Study Doctor's research office, located at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt. Laurel, NJ 08054.

How will your health information be used and disclosed?

As described above, your de-identified information will be used to analyze antibiotic resistance. In addition to the investigators listed on the first page of this form and their research staff, other people in the Cooper Health System (CHS) will be able to see your health information (described above) related to this research study. The other people are described below.

There is an Institutional Review Board (IRB) that oversees research in the CHS. People who represent this IRB may review your health information because they need to see how the study is going.

Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the doctors) for hospital and health care (2) they need to address correct payment for tests and procedures ordered by the doctors. (3) They need to perform internal hospital operations (e.g. quality assurance).

People outside the CHS from the agencies described below will also be able to see your health information under certain circumstances. These other people outside the CHS understand how important it is to keep your health information confidential. However, the CHS cannot guarantee that your information will be kept confidential after it has been given to people outside the CHS. The federal privacy rules do not cover any disclosures of your health information by these other people and agencies described below.

A federal agency called the Office of Human Research Protection (OHRP) oversees the CHS IRB. People from OHRP may also review your health information because they need to see how the IRB is doing.

Will you have access to your health information resulting from participation in this research study?

You may already have a copy of CHS's Notice of Privacy Practices. If you do not have one, the investigator will give you one. This notice says that you are allowed to see information that is in your research records and medical records that are filed in the offices of your health care provider. For this research study, that means the office of the investigators and Cooper Hospital. However, you may not see your health information until the study is finished. You have the right to see information that was created as a result of your participation in this study and information that was collected and used for this research study. If you want to see this information, contact the Study Doctor's office at Cooper Health System, 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054.

May you refuse to give your authorization (permission) for the use of your health information for the purpose of this research study?

You do not have to give your authorization to use and disclose your health information as described above. Your authorization is completely voluntary. However, if you do not give your written authorization for the investigators to use and disclose your health information, you may not be in the research study.

If you decide not to allow the investigators to use and disclose your health information for this research study, it will not affect your care at CHS, it's affiliated health care providers or hospitals now or in the future.

May you withdraw your authorization (permission) for the use of your health information for this research study?

You may decide at any time that you no longer want the investigators to use and disclose your health information. In that case, you will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you for this study. In addition, research staff will stop using your health information. They will also stop disclosing (releasing) your information to the parties described above, with certain exceptions. The research staff may have relied on information that has already been collected from you. For example, the research staff may need to use or disclose information that they got before you withdrew your authorization in order to keep the scientific integrity of the study. You may also decide to give consent for the investigator to continue to collect your health information after you withdraw from the study.

If you decide to withdraw your authorization, you should give a written and dated notice of your decision to the Dr. DeSipio, MD, at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt. Laurel, NJ 08054. This decision will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

How long will the investigators be allowed to use your health information?

The investigators may continue to use and disclose your health information for the purposes described above for an undetermined period of time. If you sign this form, you authorize the use and disclosure of your information for this study at any time in the future.

VOLUNTARY PARTICIPATION

I voluntarily consent to take part in this study. The study staff has discussed this research study with me. I have had adequate time to read this form and to ask questions about it. I understand by signing this form I am not giving up any of my legal rights and I am also agreeing to the use and disclosure of my Protected Health Information. I will be given a copy of this signed and dated consent form for my records.

SUBJECT

Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

WITNESS

Printed Name of Witness to Subject's Signature: _____

Signature: _____ Date: _____ Time: _____

INVESTIGATOR

I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____

Cooper
University Health Care

Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information

TITLE OF STUDY: Designing Evidenced-Based Strategies for Eradicating *H. pylori* – Phase II

DEPARTMENT: Department of Medicine - Gastroenterology

INVESTIGATOR: Joshua DeSipio, MD

PHONE NUMBER: (856) 642-2133

CO-INVESTIGATORS: Imad Awan, Sangita Phadtare, Brian White, Lark Perez, PhD, Hyder Alikhan

STUDY COORDINATOR: Katie Grant

SPONSOR: None

SUBJECT'S NAME: _____

What does informed consent for a research study involve?

You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and his staff will discuss with you what is involved in this research study. If you decide to take part, you and the study doctor, or a member of the study team will sign this Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are suspected to have *H. pylori* infection and will be treated by the physicians at the Cooper Digestive Health Institute.

Why is this study being done?

H. pylori is a common type of bacteria that usually infects the stomach. *H. pylori* normally infect your stomach during childhood. While infections from these bacteria typically don't cause symptoms, they can lead to diseases in some people, including peptic ulcers and cancers, and an inflammatory condition inside your stomach known as gastritis.

In order to diagnose *H. pylori* infection the physician may perform a test on your bowel movement; perform a breath test, or an endoscopy. During the breath test, you will be asked to exhale into a balloon-like bag. The air you breathe into this bag is tested to provide a basis for comparison (called a baseline sample). You will then be asked to drink a small amount of a pleasant lemon-flavored solution. Fifteen minutes after drinking the solution, a second breath sample will be taken. The air you breathe into this bag is tested for an increase in carbon dioxide. An endoscopy is a procedure that lets your doctor look inside your body. It uses an instrument that has a tiny camera attached to a long, thin tube. The doctor moves it through your mouth down to see inside your stomach. Any of these tests may be ordered by your doctor as part of routine care.

The usual treatment is to be prescribed antibiotics. The antibiotics that are used vary and may be ineffective. This is because so many people have an antibiotic resistance.

In this study, data will be analyzed to evaluate the antibiotic resistance patterns and design a better treatment strategies.

What is investigational about this study?
The collection of a survey, as well as certain tests on your bowel movement sample (if selected and you volunteer) are being done for the research study.

How many people will be in this study and for how long?
This study intends to enroll 500 subjects at Cooper over approximately a 19 month period.

What will happen if you take part?
Each subject enrolled in the study will be asked to complete a survey. You will be asked about your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical history, and your past/present medications.

A portion of subjects will be asked to provide a sample of their bowel movement before and after treatment with antibiotics. This is a standard test for people with *H. pylori*; however in this study they will also be testing the type of bacteria, DNA for the presence of *H. pylori* and other microorganisms in the stool sample. You will bring this sample in at your next scheduled visit.

Subjects who have not been asked to provide a sample are complete study participation after the survey is given to the physician. Subjects who have provided stool samples will have completed study participation after they provide the post treatment stool sample.

The duration between the pre-treatment sample visit and the post-treatment sample visit varies between 2 weeks and up to 6 months.

What will be done with your stool sample?
Your stool sample will only be stored until it is tested. We are isolating the DNA produced by the bacteria in the stool sample. This is not your DNA, it is the bacteria DNA. We will not store your sample. All samples will be labeled with only a subject number. If you decide you do not want your stool sample to be tested, please contact the doctor on the first page of the consent. We will destroy your sample if it has not been tested. The testing of the sample will take place at CMSRU (Cooper Medical School of Rowan University) or Genewiz.

What are the possible risks of participation?
There are no physical risks due to participation. There is a slight risk to your confidentiality. Subjects who take part in this study are subject to the same risks shared by all patients who receive a similar treatment but are not in this study. Your Doctor will inform you about the risks and benefits of your medication and therapy independent from your participation in the study.

Are there benefits to taking part?
You may not receive any benefit from participating in this study. However, medical science and future patients may benefit from your participation. Please approach your doctor with any questions you may have.

What other treatment options do you have?
You do not have to participate in this study. You do not have to volunteer to participate in this data collection study in order to obtain treatment for your H. pylori. You may wish to consult your doctor for further details or other alternatives to the treatment.

Voluntary Participation
Your participation is voluntary. You do not have to be part of this study. If you decide to be in the study, you may quit at any time. Either way, the doctors at Cooper Health System will treat you the same way.

Right to Withdraw
You also have the right to withdraw yourself from the study. If you do withdraw or are withdrawn from the study, you will still need to be seen by your doctor to have your routinely scheduled visits. Contact the study Doctor, Dr. DeSipio, in writing at 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054, of your intent to withdraw yourself from the study. There will be no penalty or loss of benefits to you if you decide not to be in the study or if you decide to withdraw from the study.

The data that have been collected until the time of your withdrawal will be kept and used. If you do not agree to the further use of your data, you need to expressly inform your Doctor in writing.

Is there any cost or payment for being in this study?

For subjects completing the survey, you will receive a $25.00 gift card. For those who complete the survey and provide the bowel movement sample before and after treatment, you will receive a $50.00 gift card. The collection kit for the sample and the testing on the sample will be paid for by a research study grant.

You and your insurance company will be charged for the cost of your prescribed treatment even if you participate in this study. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including, but not limited to, the following: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. Signing this form does not take away any of your legal rights.

If you decide to participate, you or your insurance company will be charged the same fees for the treatment under this study as those charged for the same procedure performed by your doctor on patients that are not in this study.

What happens if you are injured or hurt during the study?

This is a data collection and bowel movement sample study. Receiving the treatment is not part of this study. This study involves the collection of data from the routine visits.

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Study Doctor listed on page one of this form. You may also contact your own doctor, or seek treatment outside of Cooper University Hospital.

Your insurance or Medicare (if applicable) will be billed for the costs of medical treatment of any illness or injury you suffer.

If you are injured as a result of the treatment, medical treatment will be available. Please contact your Study Doctor if you believe you have been injured. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures. This is not a waiver of your legal rights. Questions regarding these issues may be directed to Dr. DeSipio at 856-642-2133.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-342-3071).

How will information about you be kept private?

Information about you related to this study will be kept as private as possible. The information collected and analyzed by the Study Doctor will not include your name or personal data that would allow you to be identified. A study number will be used instead of your name on all of your study forms. The Study Doctor may need to let other people look at your records, but only the Study Doctor and the study staff will be able to link your study number to your name. (Please see the HIPAA Authorization for the list of people who may need to inspect your study records and the reasons they need to look

at them.) The list linking subjects' names and study numbers and subjects' study files will be kept on a password protected, encrypted computer which will be stored in a locked cabinet in the Study Doctor's research office.

Your Study Doctor will keep your health information confidential in accordance with all applicable laws and regulations. The Study Doctor may disclose your health information to institutional review boards and other persons who are required to watch over the conduct of research. See HIPAA Authorization below for listing of those people. You agree to allow the Study Doctor to use study data in these ways.

If the results of this study are published, your identity will remain confidential.

Who should you contact if you have questions?
You should call the Chief Medical Officer, or his representative at (856-342-3071) if (a) you have any questions about your rights as a research subject, (b) you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

If you have any questions about the research, you may contact the investigators listed on the front of this consent form. They are responsible for the conduct of the research at Cooper Hospital. They are affiliated with the Cooper Health System. Their address is 501 Fellowship Road, Suite 101, Mt Laurel, NJ 08054.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

Will you be told about new information that might affect your decision to take part in this research?
During the study, you will be told if any new information is learned that could affect your willingness to stay in the study.

HIPAA AUTHORIZATION: Authorization to permit the use and disclose of Health Information (Protected Health Information) for Research Purposes.

Why are you being asked to sign this form?
The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information is information about a person's physical or mental health that can be identified with or linked to that particular person. As a subject in a research study, you have the right to know what health information will be used and created about you, how this information will be used, and who will be able to see the information. You also have the right to see your own health information. If

you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your health information for this research study. The Principal Investigator, Co-Investigators, or the Study Coordinator will be happy to answer any questions you may have regarding this form.

What information will be collected from you for use in this study? If you decide to be in this study, the following health information will be collected from you: your age, gender, educational level, ethnic, area of residence, zip code, annual household income, number of people in your household, social, medical and surgical history, and your past/present medications. If your bowel movement samples are tested, these results are being collected due to your participation in this study.

New health information will be created about you. The new information will include the information regarding your treatment for *H. pylori*, and the results of the testing on the bowel movement samples. This information will be placed into your research study files and medical records. These files and records will be stored at the Study Doctor's research office, located at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt. Laurel, NJ 08054.

How will your health information be used and disclosed?
As described above, your de-identified information will be used to analyze antibiotic resistance. In addition to the investigators listed on the first page of this form and their research staff, other people in the Cooper Health System (CHS) will be able to see your health information (described above) related to this research study. The other people are described below.

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Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the doctors) for hospital and health care (2) they need to address correct payment for tests and procedures ordered by the doctors. (3) They need to perform internal hospital operations (e.g. quality assurance).

People outside the CHS from the agencies described below will also be able to see your health information under certain circumstances. These other people outside the CHS understand how important it is to keep your health information confidential. However, the CHS cannot guarantee that your information will be kept confidential after it has been given to people outside the CHS. The federal privacy rules do not cover any disclosures of your health information by these other people and agencies described below.

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Will you have access to your health information resulting from participation in this research study?

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May you refuse to give your authorization (permission) for the use of your health information for the purpose of this research study?

You do not have to give your authorization to use and disclose your health information as described above. Your authorization is completely voluntary. However, if you do not give your written authorization for the investigators to use and disclose your health information, you may not be in the research study.

If you decide not to allow the investigators to use and disclose your health information for this research study, it will not affect your care at CHS, it's affiliated health care providers or hospitals now or in the future**.**

May you withdraw your authorization (permission) for the use of your health information for this research study?

You may decide at any time that you no longer want the investigators to use and disclose your health information. In that case, you will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you for this study. In addition, research staff will stop using your health information. They will also stop disclosing (releasing) your information to the parties described above, with certain exceptions. The research staff may have relied on information that has already been collected from you. For example, the research staff may need to use or disclose information that they got before you withdrew your authorization in order to keep the scientific integrity of the study. You may also decide to give consent for the investigator to continue to collect your health information after you withdraw from the study.

If you decide to withdraw your authorization, you should give a written and dated notice of your decision to the Dr. DeSipio, MD, at The Cooper Health System, 501 Fellowship Road, Suite 101, Mt. Laurel, NJ 08054. This decision will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

How long will the investigators be allowed to use your health information?

The investigators may continue to use and disclose your health information for the purposes described above for an undetermined period of time. If you sign this form, you authorize the use and disclosure of your information for this study at any time in the future.

VOLUNTARY PARTICIPATION

I voluntarily consent to take part in this study. The study staff has discussed this research study with me. I have had adequate time to read this form and to ask questions about it. I understand by signing this form I am not giving up any of my legal rights and I am also agreeing to the use and disclosure of my Protected Health Information. I will be given a copy of this signed and dated consent form for my records.

SUBJECT

Printed Name of Subject: _____

Signature: _____ Date: _____ Time:

WITNESS

Printed Name of Witness to Subject's Signature:

Signature: _____ Date: _____ Time:

INVESTIGATOR

I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: