High-Dose Dual Therapy vs Standard Triple Therapy for Treatment-Naïve H. Pylori: A Prospective Randomized Control Trial in a Diverse Urban New York City Population
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Initial Application
IRB-19-01590
Ilan Weisberg

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1. Summary - Title

Protocol Title

High Dose Dual Therapy vs. Clarithromycin Triple Therapy for Treatment Naive H. pylori Infection in an Urban Population: A Prospective, Randomized Clinical Trial

Principal Investigator Ilan Weisberg

When the application is complete, it will be sent to the PI for submission

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Primary Department Medicine - Gastroenterology

When the application is complete, it will be sent to the PI for submission

Application Initiated By Kelsey Collins

Lay Summary

H. pylori is the most prevalent chronic bacterial infection affecting humans in the world. H.pylori eradication rates using clarithromycin triple therapy are decreasing in the USA due to clarithromycin resistance. High dose dual therapy, consistent only of a proton pump inhibitor (PPI) and amoxicillin, is proving to be an effective alternative with higher eradication rates.

The purpose of our study is to determine if high dose dual therapy is as efficacious as the current standard treatment regimen of clarithromycin triple therapy for patients with Helicobacter pylori infection. The study will be a randomized, prospective clinical trial which will measure H. pylori eradication rates in patients with treatment naïve infection with either clarithromycin triple therapy or high dose dual therapy. This randomized clinical trial is relevant given the rising incidence of clarithromycin resistance that is seen in urban populations.

This is a phase 4 study looking at relative effectiveness of two regimens endorsed by the American College of Gastroenterology that use FDA-approved medications to treat H. pylori bacterial infection of the stomach. It will be a randomized study with subjects enrolled in one of the two treatment arms. There is no placebo group. The study aims to enroll a total of 166 subjects. Participating subjects will complete two weeks of therapy followed by a breath test to check for H. pylori eradication 4 weeks later, with a total participation time of 6 weeks. All tests and procedures are considered standard practice and there is no experimental intervention. The study is simply assessing the relative efficacy of two endorsed treatment regimens in our unique patient population.

IF Number IF2411170

2. Summary - Setup

Funding Has Been Requested / Obtained	No
Application Type	Request to Rely on Mount Sinai IRB
Research Involves	Prospective Study ONLY
Consenting Participants	Yes
Requesting Waiver or Alteration of Informed Consent for Any Procedures	No
Humanitarian Use Device (HUD) Used Exclusively in the Course of Medical Practice	No
Use of an Investigational Device to Evaluate Its Safety or Effectiveness	No
Banking Specimens for Future Research	No
Cancer Related Research that Requires Approval from the Protocol Review and Monitoring Committee (PRMC).	No

Is this Cancer Related Research? Cancer Related Research is defined as research that has cancer endpoints or has a cancer population as part of or all of its targeted population. This includes protocols studying patients with cancer or those at risk for cancer.

Clinical Trial	Yes

**** A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).***
**** Used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.***

Drugs / Biologics	No

**** Drugs / Biologics That Are Not a Part of Standard Practice***
**** Controlled Substances***
**** Drugs / Biologics Supplied by the Research Sponsor or Purchased with Study Funds***

Ionizing Radiation for imaging or therapy, including X-Ray, Fluoroscopy, CT, Nuclear Medicine, PET andor Radiation Therapy:

*** Purely for standard of care:**	No
*** In frequency or intensity that exceeds what is necessary for standard of care:**	No

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Hazardous Materials	No

**** Recombinant DNA***

**** Viral Vectors***
**** Plasmids***
**** Bacterial Artificial Chromosomes***
**** Toxic Chemicals, Potentially Toxic Medications, Carcinogens***
**** Autologous Cell Lines***

Request Use of Clinical Research Unit Resources No

3. Summary - Background

Objectives

Is utilizing high dose dual therapy in treatment naïve adults diagnosed with H. pylori as effective as clarithromycin triple therapy in H. pylori eradication? Based on this information, should high dose dual therapy become a more widely utilized initial treatment regimen? We aim to determine if high dose dual therapy has comparable eradication rates for H. pylori infection when compared to clarithromycin triple therapy, specifically among our diverse New York City population. We will also assess the demographics among the population enrolled and being treated. We will then compare our data to that of recently published data describing the efficacy of high dose dual therapy as first line therapy in the management of H. pylori infection. Our main objective is to determine if using high dose dual therapy is non-inferior to standard triple therapy.

Background

Helicobacter pylori (HP) infection, the most prevalent chronic bacterial infection in the world, is the leading cause of peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosal associated lymphoid tissue (MALT) lymphoma. Its prevalence has been reported to be > 50% globally and roughly 35% within the United States. HP is also notably more prevalent amongst African American, Hispanic Americans, Asian Americans, and patients of low socioeconomic status. Per American College of Gastroenterology (ACG) guidelines, testing for HP should be done in patients with uninvestigated dyspepsia under the age of 60 without alarm features, patients with active PUD or history of PUD, patients on chronic treatment with NSAID's, and prior gastric malignancies. Although invasive testing using endoscopy with biopsy may be warranted in some patients, less invasive methods are available. Both the urea breath test (UBT) and the stool antigen assay are widely used, and both have sensitivities and specificities averaged at 95%.

Traditionally, HP infections have been empirically treated with standard triple therapy which includes a proton pump inhibitor (PPI), amoxicillin, and clarithromycin (metronidazole in those with penicillin allergy). Although initially found to be efficacious with an eradication rate of 77.5% in 2007, this number has been declining due to rising rates of antimicrobial resistance, particularly to clarithromycin. A recent retrospective study published in 2016 by Park, et al. evaluated clarithromycin resistance in the USA via DNA sequencing and found the resistance rate to be 32.3%. Current ACG guidelines advise to avoid clarithromycin triple therapy among populations where clarithromycin resistance rates exceed 15% and in patients with prior macrolide exposure.

High dose dual therapy (HDDT), a specific regimen of interest, has become an effective alternative to standard triple therapy, especially in areas with clarithromycin-resistance. This two-drug regimen, consistent of only a PPI and amoxicillin, is supported as an alternative regimen by the ACG and has limited data supporting its use as first line therapy. Its favorable qualities include a much lower bacterial resistance rate to amoxicillin, increased function of amoxicillin at an increased intragastric pH, less overall antibiotic exposure, and decreased propagation of clarithromycin resistance. Current data pertaining to its efficacy is limited to small population sizes and amongst specific populations in Asia and Europe. A recent study by Yang, et al. in 2015 evaluated the efficacy of HDDT vs. clarithromycin triple therapy in Taiwan, and found the eradication rate to be 95.3% vs. 80.7%, respectively.

We propose to conduct a prospective study aimed to determine if high dose dual therapy is as effective at HP eradication when compared to clarithromycin triple therapy amongst our diverse urban population in New York City.

Primary and Secondary Study Endpoints

Primary Endpoint: Eradication rate of HP infection treated with HDDT vs. clarithromycin triple therapy

Secondary Endpoints: Patient compliance with treatment regimen, patient satisfaction with treatment regimen, symptom control (assess improvement in epigastric pain, nausea, vomiting) adverse effects, age, sex, ethnicity, and country of origin

Protocol Was Already Approved by the Icahn School of Medicine at Mount Sinai (ISMMS) Institutional Review Board (IRB) Under a Different Principal Investigator	No

Protocol Was Previously Submitted to an External(non-ISMMS) IRB	No

4. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Ilan Weisberg / Medicine - Gastroenterology	PI /	Yes	SIGNAUTH		212-844-1755	
Kelsey Collins / Medicine	Co-Investigator /	Yes	SIGNAUTH			
Daniel Pang / Office of Clinical Research	Study Coordinator / Staff (non MD)	Yes	SIGNAUTH		212-420-4528	
Ray Dong / Medicine - Gastroenterology	Co-Investigator /	Yes	SIGNAUTH			

5. Sites

Site Name	Mount Sinai Beth Israel
Other External Site Name	
Contact Details	
Approved	1
Approval Document	
Funded By Mount Sinai	1
Reviewed By	Mount Sinai IRB
Other IRB	

6. Subjects - Enrollment

Site Name	Mount Sinai Beth Israel
Subjects To Be Enrolled	
Total Number of Subjects to be Enrolled Across All Listed Sites Above (Auto Populated)	0

7. Subjects - Setting and Resources

Setting of Human Research Faculty Practice Associates

Total Number of Subjects Needed To Complete Study 166

Feasibility of Meeting Recruitment Goals

We do not foresee any barriers to recruitment with a relatively high incidence of H. pylori seen in our large, ethnically diverse population.

Facilities To Be Used for Conducting Research

Mount Sinai Downtown Union Square, 10 Union Square East, New York, NY 10003- Gastroenterology and Hepatology Clinic

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Multi-Center Study Yes

Mount Sinai Principal Investigator is Responsible for All Centers Yes

Management of Multi-Center Study

Co-Investigators are routinely present at the study site and are able to coordinate subject recruitment and screening for the study.

Community-Based Participant Research Study No

PI must attest to the following.

**** Process is adequately described to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.***

8. Subjects - Populations

Inclusion Criteria

1. Male or female subject aged 18 years and older
2. Clinical diagnosis of H. pylori based on urea breath test
3. Treatment naïve adults
4. Subject willing to participate in the study and willing to give informed consent
5. Subject willing to take treatment regimen
6. Subject willing to return to clinic one month after finishing treatment to complete a survey and repeat urea breath testing

Exclusion Criteria

1. Previous H. pylori treatment failure
2. Antibiotic exposure within the past 4 weeks of H. pylori diagnosis
3. Documented or reported penicillin allergy
4. Pregnancy or breastfeeding
5. History of active gastric or non-gastric malignancy
6. Severe illness requiring hospitalization during treatment period
7. Starting additional antibiotic while on treatment

Enrollment Restrictions Based Upon Gender, Pregnancy, Childbearing Potential, or Race	Yes

Justify Restriction(s)

Amoxicillin is generally not recommended for pregnant women due to possible association with cleft lip and cleft palate.

Age Range(s)	18 to 64 Years, 65 Years and Over
Targeted Population(s)	Adults - Patients

Other Aspects that Could Increase Subjects Vulnerability

There is a risk of loss of private health information, but there are procedures in place to minimize this risk.

Safeguards to protect Subjects rights and welfare

Data will be stored in REDCap, a web application for building and managing online surveys and databases. Institutional safeguards (such as disclosure of financial interests, HIPAA/ GCP training) are in place to guarantee protection of subjects' rights and welfare.

9. Subjects - Participation

Duration of an Individual Subjects Participation in the Study

Participation in this research study is expected to last up to 6 weeks for completion of both 2 week treatment and eradication testing 4 weeks later.

Duration Anticipated to Enroll All Study Subjects

1 year

Estimated Date for the Investigators to Complete This Study Within two years

Procedures for Subjects to Request Withdrawal

Subjects may withdraw by contacting the PI or research staff. Subjects may withdraw permission for the use and disclosure of any of the subject's protected information for research, but must do so in writing to the Principal Investigator at the address on the first page. Even if subject withdraws permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study.

Procedures for Investigator to Withdraw Subjects

The study doctor or the institution may stop subject's involvement in this research study at any time without their consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in the subject's best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

Participants Will Be Recruited Yes

Recruitment Method(s) Clinical Practice, Records (e.g. Medical, Employment, School), Physician Referral

How Participants Will Be Identified

Researchers will identify patients with treatment-naïve H. pylori with use of the urea breath test, which is routinely offered at the clinic. Potential subjects will be consented on the day of testing. If the test is positive, the laboratory will notify the physician and then randomization for treatment will occur, with subjects randomized to receive either clarithromycin triple therapy or high dose dual therapy. In addition, the study officials may look at the subject's clinic record to confirm the test results.

Who Will Initially Approach Potential Participants Member of Primary Care Team, Treating Physician

How Research Will Be Introduced to Participants

All patients with suspected H. pylori will be introduced to this study by their clinician, and if agreeable, they will be consented for the study prior to urea breath testing. Potential subjects will consist of those on the research teams' clinic panel. Only if the urea breath test is positive, and the patient is consented, will the subject be randomized to receive treatment according to this study.

How Participants Will Be Screened

Participants will be screened based on the inclusion and exclusion criteria. Medical records will be viewed by the study personnel.

10. Subjects - Risk and Benefits

Risks to Subjects

The risk of loss of private information. Physical risks including medication side effects including headaches, GI upset, vulvovaginal infection, all of which are temporary and can be reversed. There is risk for a false negative result during urea breath testing, especially if the participant is taking a proton-pump inhibitor, bismuth, or antibiotics. This risk is also increased if the subject has an active peptic ulcer bleed.

Description of Procedures Taken to Lessen the Probability or Magnitude of Risks

Data will be stored in REDCap, a mature, secure web application for building and managing online surveys and databases. Study staff are also trained to use their utmost discretion when handling subject's protected health information.

Provisions for Research Related Harm / Injury

If the subject believes that they have suffered an injury related to this research as a participant in this study, they will contact the Principal Investigator for medical treatment.

Expected Direct Benefit to Subjects

There is no direct benefit to subjectss participating in the study.

Benefit to Society

Information from this study may benefit other people diagnosed with treatment naïve H. pylori in this urban population in the future.

Provisions to Protect the Privacy Interests of Subjects

Consent will be obtained in the PI's/ Co-I's offices at the time of the subject's visit prior to any study assessments/ procedures. The investigator will approach eligible potential subjects and explain the study in a private room, including the reasons why subjects are eligible, risks and benefits and the regimens to be evaluated. Subjects privacy interests are always considered from the time subjects are identified for recruitment until they have completed the study. Only research personnel involved in the conduct of this research will have access to identifiable information and will be communicating with subjects throughout the trial. When trying to get in contact with subjects through mail or telephone messages etc., the utmost discretion will be utilized.

Economic Impact on Subjects

We do not foresee any additional expenses that the subject might incur from participation in this study. They will be billed according to their insurance plans. The subjects' clinical care will remain the same, with all subjects receiving 1 of 2 established antibiotic regimens for treatment therapy.

11. Procedures - Narrative

Description of the Study Design

Subjects with a diagnosis of treatment naïve H. pylori (B96.81) will be randomized to receive either high dose dual therapy (HDDT) or clarithromycin triple therapy.

Subjects will then receive an electronic prescription for their respective assigned regimen along with a medication log to self-report drug compliance.

After completing their assigned regimen, subjects will be scheduled for a post-treatment visit after 4 weeks. At this visit, subjects will undergo repeat urea breath testing. They will also bring in their medication log, pill bottles so that compliance can be recorded by research staff, and also complete a patient satisfaction survey.

Description of Procedures Being Performed

Patient survey- post treatment survey to determine patient satisfaction and patient compliance.

Description of the Source Records that Will Be Used to Collect Data About Subjects

Data collected will be entered into the REDCap database.

Description of Data that Will Be Collected Including Long-Term Follow-Up

Demographic data such as age, gender, and ethnicity. Subject health information such as presence or absence of concomitant medications, method of initial H. pylori diagnosis, and results from the eradication testing after treatment. Will also obtain patient satisfaction survey and patient compliance survey.

Research Requires HIV Testing No

12. Procedures - Genetic Testing

Genetic Testing Will Be Performed No

Guidance and Policies > Future Use Data Sharing and Genetic Research

13. Procedures - Details

Surveys or Interviews Yes

Type of Instruments Being Used Created By Research Team

Description of Instruments Created By Research Team

A survey will be conducted for each subject at the end of their respective treatment regimen to assess patient satisfaction, patient compliance, and any adverse effects. In addition, subjects will be given a medication log to fill out after each dose of medication is taken. The subject will be instructed to return the log to clinic on their follow-up visit 4 weeks after completing treatment.

Audio / Photo / Video Recording No

Deception No

Results of the Study Will Be Shared with Subjects or Others Yes

How the Results Will Be Shared

Results of the eradication testing will be shared with the subject and explained by a qualified clinician.

When the Results Will Be Shared

Results will be shared in person or via telephone encounter once results are available from the lab.

14. Procedures - Instruments

Instruments Created By Research Team

Type	Medication Log
Name	HDDT Medication Log
Upload	Patient Medication Log-Dual Therapy.docx
Type	Medication Log
Name	Triple Therapy Medication Log
Upload	Patient Medication Log- triple therapy.docx
Type	Patient Survey
Name	Patient Survey
Upload	Day14_Patient Survey.pdf

15. Procedures - Compensation

Compensation for Participation No

16. Consent - Obtaining Consent

Consent Process Adult Consent

Where and When Consent Will Be Obtained

Consent will be obtained during the operating hours of the Gastroenterology and Hepatology Clinic at Mount Sinai Downtown Union Square.

Waiting Period for Obtaining Consent

No waiting period is required for this study as both medications are approved for use by ACG for H. pylori. All patients with newly diagnosed, treatment naïve H. pylori and who meet the inclusion and exclusion criteria are being approached to participate in this study. Subjects will be given as much time as they need to consider if they want to participate in the study.

SOP HRP-090 Informed Consent Process for Research Is Being Used Yes

PPHS Worksheets, Checklists and SOPs

Process to Document Consent in Writing Will Use Standard Template

Non-English Speaking Participants Will Be Enrolled Yes

What Languages Other Than English Will Be Used

Spanish, Simplified Chinese

What Process Will Be Used Long Form

The consent document must be translated into the language of the potential subject, and approved by the IRB, before you can go through the consent process with the non-English speaking person. If, after the project is approved, a short form consent process is needed, please see the PPHS policy and submit a modification.

17. Consent - Documents

Consent Documents

Type	Informed Consent
Name	H. pylori Informed Consent
Upload	HP_Informed Consent_20190530_v1.0_clean.updated.docx
Type	Research Study Figure
Name	Figure of H. pylori Research Study
Upload	Figure of H. pylori Research Study.docx

Consent Templates

18. Data - Collection

Health Related Information Will Be Viewed, Recorded, or Generated Yes

Description of Health Information That Will Be Viewed, Recorded, or Generated

Under the HIPAA waiver, medical records will be reviewed to ensure the date of initial positive urea breath test, list of current medications, any history of allergies, history of recent antibiotic use within 4 weeks, history of H. pylori infection, pregnancy status, and known comorbidities. In addition, the medical record will be reviewed to evaluate repeat urea breath testing after treatment is completed.

Non-Health Related Information Will Be Viewed or Recorded Yes

Description of Non-Health Information That Will Be Viewed or Recorded

Name, MRN, ethnic background, address, phone number, email address, and dates directly related to individuals

HIV / AIDS Related Information Will Be Viewed or Recorded No

Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information Yes

Will Be Viewed Name, Medical Record Number, Address by street location, Telephone number, All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date), Email Address

Will Be Recorded Name, Medical Record Number, Address by street location, Telephone number, All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date), Email Address

Data Collection Sheet

A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here.

Data Collection Source(s) Participant, Medical Chart (Paper or Electronic)

19. Data - HIPAA

Obtaining HIPAA Authorization No

Requesting Waiver or Alteration Waiver

Research Could Be Practicably Conducted Without Access to and Use of Protected Health Information (PHI) No

Explanation Why Research Could Not Be Practicably Conducted Without Access to and Use of PHI

Each patient's PHI must be accessed in order to review each patient's medical history in a retrospective manner, prior to inclusion in the study. Information including urea breath test results, history of H. pylori infection, recent antibiotic usage, allergies to medications, pregnancy status, and current medication regimen must be confirmed via PHI. In addition, by participating in the study, there will be new health information that must be added to the patient's PHI.

Explanation Why Research Could Not Be Practicably Conducted Without a Waiver or Alteration of Authorization

Data must be collected from medical charts and the shared electronic medical database at the clinic contains information to help identify potential candidates for the study,

How PHI Will Be Protected from Improper Use or Disclosure

PHI will be stored according to the guidelines set by the PPHS data security standards. No patient identifiers will be used.

PHI Will Be Destroyed at the Earliest Opportunity Consistent with the Research Yes

When and How PHI Will Be Destroyed

PHI will be archived in REDCap after data analysis has been completed.

PHI Will Be Shared No

PI must attest to the following.

**** I assure that the protected health information (PHI) will not be disclosed to any other person or entity not listed on this form except where required by law or for the authorized oversight of this research project. If at any time I want to reuse this PHI for other purposes or disclose it to other individuals or entities I will seek approval from the IRB.***

20. Data - Storage

Location Where Data Will Be Stored

Data will be entered into a REDCap database.

How will the data be stored? Other

Specify How Data Will Be Stored

Data will be entered into a REDCap database by authorized research staff that are listed in the research personnel tab.

Research Personnel Responsible for:	Ilan Weisberg
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Kelsey Collins
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Daniel Pang
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Ray Dong
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No

Duration Data Will Be Stored

Data will be stored for 7 years after the completion of this study.

Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission

Data will only be stored on the REDCap database and can only be accessed by research staff that can access the Mount Sinai network. On top of that, research staff will have to be given permission by database administrator to gain access to this database.

Power Analysis/Data Analysis Plan (Including Any Statistical Procedures)

Data will be analyzed without any identifying information. We plan to utilize t-tests (for continuous, normally distributed variables), the non-parametric Mann-Whitney test (for non normally distributed variables) and the chisquare test (for categorical variables).

21. Data - Safety Monitoring

More Than the Minimum Data Safety Monitoring Will Be Done No

The following minimum requirements apply to all projects, including retrospective reviews of medical records, use of tissue samples, and many minimal risk studies, such as observational and survey research. Because these minimum requirements apply to all studies, a specific written DSMP will not usually be required for projects that do not pose greater than minimal risk to subjects. The MSSM PPHS may alter the required level of monitoring if appropriate.

For all projects, the principal investigator must have a plan to assure that data integrity will be maintained during its collection, storage and analysis. All research projects must adhere to MSSM recommendations on the storage of research data. Loss of data containing identifiable information is reportable to the IRB within 5 business days.

Any problems concerning the consent process and any subject complaints should be monitored by the investigator. Reports of such problems must be made at least annually. The discretion of the protocol director will guide the need to report these problems immediately or more frequently.

The principal investigator is, typically, the monitoring entity for the minimum DSMP. When a principal investigator is not a faculty member, the supervising faculty member must be responsible for the data and safety monitoring aspect of the protocol.

Will the Research Include Data Coordinating Center Activities? No

22. Financial Administration

This information will help the Financial Administration of Clinical Trials Services (FACTS) office determine whether a Medicare Coverage Analysis (MCA) is needed for the research study. If you have any questions while completing this form, please contact the FACTS office at (212) 731-7067 or FACTS@mssm.edu.

Clinical Research Study Category Investigator Initiated

Payment Options:
**** Option 1: No protocol-required services will be billed to patients or third-party payers. Does Not Need MCA***
**** Option 2: Protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Must Have MCA***
**** Option 3: Study is initiated and federally funded by a Government Sponsored Cooperative Group who will only pay for services that are solely conducted for research purposes and other protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Billing Grid Only Required, NO MCA***
**** Option 4: Study involves only data collection and has no protocol-required clinical services. Does Not Need MCA***
**** Option 5: Study is not described in any of the above options. Please describe the study and specify whether External Sponsor (i.e., industry, government, or philanthropic source) and/or patient/third party payer will pay for protocol required services. MCA MAY Be Required***

Payment Option Option 1

No MCA is needed per option selected above.

Payment Option 1:
**** Option 1A: Department/collaborating departments will act as internal sponsor paying for all protocol-required services and no protocol-required services will be billed to patients or third party payers.***
**** Option 1B: Study involves protocol-required clinical services and an External Sponsor (i.e., industry, government, or philanthropic source) will pay for all protocol-required services.***

Payment Option 1 Option 1A

23. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Instruments	Patient Medication Log-Dual Therapy.docx	1	New	Patient Medication Log-Dual Therapy.docx	01/25/2019
Instruments	Patient Medication Log- triple therapy.docx	1	New	Patient Medication Log- triple therapy.docx	01/25/2019
Consent Documents	HP_Informed Consent_20190121_v1.0.docx	1	New	HP_Informed Consent_20190530_v1.0_clean.updated.docx	05/30/2019
Instruments	Patient Survey.pdf	1	New	Day14_Patient Survey.pdf	02/08/2019