

Thalidomide in GAVE Bleeding

PI: Chien-Huan Chen  
IRB ID #: 201607061

Mod Checklist

XIV.1 Does this modification require additional description/justification for the IRB to understand the changes being proposed?  
No

Other Mod and/or Comments

XIII.1 Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.

Modifications

II.5 Team Members  
Old Value (with Track Changes)  
WUSTL Team Members

Role	Name	E-mail	Title	School	Department	Contact	Consent Process Involvement
PI	Chien-Huan Chen, MD	<a href="mailto:cchen@dom.wustl.edu">cchen@dom.wustl.edu</a>	Assoc Prof of Medicine	School Of Medicine	Int Med - Gastroenterology	Yes	
	<del>Alexis Bayudan, BA, MD</del>	<del><a href="mailto:ambayudan@email.wustl.edu">ambayudan@email.wustl.edu</a></del>	<del>Resident</del>	<del>School Of Medicine</del>	<del>Int Med - Medical Education</del>	<del>No</del>	
	Pierre Blais, MD	<a href="mailto:pblais@dom.wustl.edu">pblais@dom.wustl.edu</a>	Clinical Fellow	School Of Medicine	Int Med - Gastroenterology	Yes	

Name	Financial Interests
Chien-Huan Chen, MD	none
<del>Alexis Bayudan, BA, MD</del>	<del>none</del>
Pierre Blais, MD	none

Non-WUSTL Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	Consent Process Involvement
Nothing found to display							

Name	Financial Interests
Nothing found to display	

II.5 Team Members  
New Value  
WUSTL Team Members

Role	Name	E-mail	Title	School	Department	Contact	Consent Process Involvement
PI	Chien-Huan Chen, MD	<a href="mailto:cchen@dom.wustl.edu">cchen@dom.wustl.edu</a>	Assoc Prof of Medicine	School Of Medicine	Int Med - Gastroenterology	Yes	
	Alexis Bayudan, BA, MD	<a href="mailto:ambayudan@email.wustl.edu">ambayudan@email.wustl.edu</a>	Resident	School Of Medicine	Int Med - Medical Education	No	
	Pierre Blais, MD	<a href="mailto:pblais@dom.wustl.edu">pblais@dom.wustl.edu</a>	Clinical Fellow	School Of Medicine	Int Med - Gastroenterology	Yes	

Name	Financial Interests
Chien-Huan Chen, MD	none
Alexis Bayudan, BA, MD	none
Pierre Blais, MD	none

Non-WUSTL Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	Consent Process Involvement
Nothing found to display							

Name	Financial Interests
Nothing found to display	

## Enrollment as Reported on Previous Forms

Type	Approval Date	Total Subjects Approved by IRB	Total Subjects Reported	Enrollment Stopped
Mod	02/13/18	0		
Mod/CR	05/31/17	0	16	Yes
New	07/20/16	0		

## Form Content

### I. Demographics

- I.1** Project Title:  
Thalidomide for Gastrointestinal Bleeding Due to Refractory Gastric Antral Vascular Ectasia
- I.2** Short Title (required):  
Thalidomide in GAVE Bleeding
- I.3** Project is primarily:  
Biomedical
- I.4** Do you want the IRB to give this project  
Regular (expedited or full board) review
- I.7** Enter the estimated date you will be ready to begin recruiting participants or collecting data for this project.  
07/2016
- I.8** Provide a short summary of the purpose and procedures of the study proposed in this IRB application.
- DO NOT include information on studies not proposed in this application. (If your source of support proposal describes multiple aims, refer to the information button for an example on how to complete this question.)
  - Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
  - DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.
- For patients with recurrent refractory bleeding secondary to gastric antral vascular ectasia (GAVE), current standard of care therapies are limited. Recently medical management has been attempted with anti-angiogenic drugs like thalidomide, with isolated case reports demonstrating efficacy, but data remain extremely limited. Our study will assess the total clinical experience of patients with recurrent refractory GAVE including those who have been treated with thalidomide to see if a comparison study can be performed between those who did and did not receive the medication. At the very least, our center's experience with thalidomide in bleeding due to GAVE would produce the most extensive data to date published in the literature.
- I.9** Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")  
In this study, we aim to collect outcomes data from patients treated with thalidomide in the attempt to achieve hemostasis in patients with refractory GAVE bleeding. At the same time, we would propose to collect a total cohort of all patients with refractory GAVE bleeding in order to determine outcomes from patients not treated with thalidomide. If possible, we would aspire to be the first to look at such bleeding cases with a comparison group, yielding the first ever cohort study for medical management of refractory GAVE bleeding. Regardless, this study would represent the first evidence beyond the form of a case report for treatment of recurrent refractory bleeding from GAVE with thalidomide.
- I.10** Background and significance and/or Preliminary studies related to this project.  
(do not indicate "see protocol")  
Gastric antral vascular ectasia (GAVE) represents a rare cause of upper gastrointestinal bleeding (UGIB). Standard of care for patients with bleeding from GAVE is to attempt endoscopic thermal therapy via serial argon plasma coagulation (APC).<sup>1</sup> Nonetheless, in a significant proportion of patients the rebleeding rate can remain as high as 70-80%, and second line therapies remain limited (Ref 2-3).

Portal hypertensive gastropathy (PHG) is a lesion in the stomach for which GAVE is commonly mistaken (Ref 4). Still, unlike medical management for hemostasis in PHG, attempts at treating GAVE-related bleeds with medications have been less successful. Outdated treatments with estrogen and progesterone were found ineffective and associated with increased mortality compared with conservative therapy. In addition, beta blockade and octreotide administration to decrease portal pressures and mesenteric perfusion, respectively, have not proven effective for

GAVE (Ref 5).

Recent efforts, then, have turned to medications with anti-angiogenic effects as a possible second line therapy. For angiodysplasias, a separate kind of lesion known to cause refractory gastrointestinal bleeding, a few studies have demonstrated possible efficacy of thalidomide therapy in producing hemostasis (Ref 6-9). These data, however, remain limited to uncontrolled observational case series, and no comparable case series data exists in the case of refractory GAVE bleeding. Still, individual case reports of success with thalidomide do exist for bleeding from refractory GAVE (Ref 10-12), and this evidence combined with durable responses in the more common cases of angiodysplasia-related bleeding has guided clinical decision making in the management of such patients within the Barnes-Jewish healthcare system.

**I.11** Literature cited / references (if attaching a grant or protocol enter N/A).

1. Ripoll C, Garcia-Tsao G. The management of portal hypertensive gastropathy and gastric antral vascular ectasia. *Dig Liver Dis.* 2011 May;43(5):345-51.
2. Chiu YC, Lu LS, Wu KL, Tam W, Hu ML, Tai WC, Chiu KW, Chuah SK. Comparison of argon plasma coagulation in management of upper gastrointestinal angiodysplasia and gastric antral vascular ectasia hemorrhage. *BMC Gastroenterol.* 2012 Jun 9;12:67.
3. Boltin D, Gingold-Belfer R, Lichtenstein L, Levi Z, Niv Y. Long-term treatment outcome of patients with gastric vascular ectasia treated with argon plasma coagulation. *Eur J Gastroenterol Hepatol.* 2014 Jun;26(6):588-93.
4. Payen JL, Cales P, Voigt JJ, Barbe S, Pilette C, Dubuisson L, Desmorat H, Vinel JP, Kervran A, Chayvialle JA. Severe portal hypertensive gastropathy and antral vascular ectasia are distinct entities in patients with cirrhosis. *Gastroenterology.* 1995;108(1):138.
5. Swanson E, Mahgoub A, MacDonald R, Shaikat A. Medical and endoscopic therapies for angiodysplasia and gastric antral vascular ectasia: a systematic review. *Clin Gastroenterol Hepatol.* 2014 Apr;12(4):571-82.
6. Bauditz J. Effective treatment of gastrointestinal bleeding with thalidomide – Chances and limitations. *World J Gastroenterol.* 2016 Mar 21;22(11):3158-64.
7. Bond A, Ahmed W. Thalidomide for the treatment of angiodysplasia in a patient with acute upper gastrointestinal haemorrhage. *BMJ Case Rep.* 2016 Jan 20;2016.
8. Engelen ET, van Galen KP, Schutgens RE. Thalidomide for treatment of gastrointestinal bleedings due to angiodysplasia: a case report in acquired von Willebrand syndrome and review of the literature. *Haemophilia.* 2015 Jul;21(4):419-29.
9. Draper K, Kale P, Martin B, Cordero K, Ha R, Banerjee D. Thalidomide for treatment of gastrointestinal angiodysplasia in patients with left ventricular assist devices: case series and treatment protocol. *J Heart Lung Transplant.* 2015 Jan;34(1):132-4.
10. Moser S, Tischer A, Karpi A, Schleicher M, Stavjanik S, Gschwantler M. Evidence that thalidomide is effective in recurrent bleeding from watermelon stomach associated with liver cirrhosis. *Endoscopy.* 2014;46 Suppl 1 UCTN:E384.
11. Dunne KA, Hill J, Dillon JF. Treatment of chronic transfusion-dependent gastric antral vascular ectasia with thalidomide. *Eur J Gastroenterol Hepatol.* 2006 Apr;18(4):455-6.
12. Garrido Serrano A, Leon R, Sayago M, Marquez JL. Thalidomide treatment in cirrhotic patients with severe anemia secondary to vascular malformations. *Dig Dis Sci.* 2012 Apr;57(4):1112-3.

**I.12** Select up to three key words below that best describe this research study:

- Internal Medicine
- Gastroenterology

## II. Research Team

**II.0** Principal Investigator

Name	E-mail	Title	School
Chien-Huan Chen	cchen@dom.wustl.edu	Assoc Prof of Medicine	School Of Medicine

**II.1** The Principal Investigator of this study is:  
Faculty

**II.3** Do you want to add a team member who is a WUSTL faculty, student or staff member?  
Yes

**II.4** Do you want to add a team member who is **not** a WUSTL faculty, student or staff member?  
No

**II.5** Team Members

**WUSTL Team Members**

Role	Name	E-mail	Title	School	Department	Contact	Consent Process Involvement
PI	Chien-Huan Chen, MD	<a href="mailto:cchen@dom.wustl.edu">cchen@dom.wustl.edu</a>	Assoc Prof of Medicine	School Of Medicine	Int Med - Gastroenterology	Yes	
	Alexis Bayudan, BA, MD	<a href="mailto:ambayudan@email.wustl.edu">ambayudan@email.wustl.edu</a>	Resident	School Of Medicine	Int Med - Medical Education	No	

Pierre Blais, MD	<a href="mailto:pblais@dom.wustl.edu">pblais@dom.wustl.edu</a>	Clinical Fellow	School Of Medicine	Int Med - Gastroenterology	Yes
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Name	Financial Interests
Chien-Huan Chen, MD	none
Alexis Bayudan, BA, MD	none
Pierre Blais, MD	none

#### Non-WUSTL Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	Consent Process Involvement
Nothing found to display							

Name	Financial Interests
Nothing found to display	

### III. Source(s) of Support

#### III.1 Source(s) of Support

Type	Source	Grant Title	Name of PI on Grant	Status	Status Description
No Support					

\* new source name

### IV. Waiver of Consent

**IV.1** Are you requesting a waiver of informed consent (participants will not be given any oral or written information about the study prior to their participation)?  
Yes, for all subjects

**IV.3** Will you provide any information about the study after their participation?  
No

**IV.5** Indicate type of study (check all that apply)  

- Retrospective review of medical record data with ALL data existing as of application date

Estimated maximum number of charts/records: 20

**IV.6** For the set of data you wish to review, list the earliest (beginning) date the data you wish to review were created:  
01/01/2005

**IV.7** List the latest (ending) date the data you wish to review were created:  
07/01/2016

**IV.8** Indicate sources of your data or specimens (check all that apply)  

- WUSM/BJH/SLCH records/specimens - Hospital and clinic records for patients with recurrent refractory bleeding due to GAVE

**IV.9** List ALL  

- data points
- identifiers or links to identifiers

you plan to obtain/use for purposes of this study. (The information accessed should be the minimum data necessary for performing the desired analysis.)

Patient information to be collected

- Last and first names
- Date of birth
- Means of GAVE diagnosis (endoscopy, pathology)
- Index date for determination of recurrent refractory status of GAVE-related bleeding (bleeding following second endoscopic treatment for GAVE)
- Index age
- Gender
- Race/ethnicity
- BMI
- Presence of cirrhosis
- Presence of gastroenterology follow-up
- Date of initial outpatient visit with gastroenterology
- Initiation date for thalidomide

- m. Hospital admissions for acute blood loss anemia in the 1yr period prior to thalidomide initiation
- n. Hospital admissions for acute blood loss anemia in the 1yr period following thalidomide initiation
- o. Number of blood transfusions in the three month period prior to thalidomide initiation
- p. Number of blood transfusions in each month following thalidomide initiation, up to 6mo afterwards
- q. Number of endoscopies performed in the three month period prior to thalidomide initiation
- r. Number of endoscopies performed in each month following thalidomide initiation, up to 6mo afterwards
- s. Number of days in the hospital in the three month period prior to thalidomide initiation
- t. Number of days in the hospital in each month following thalidomide initiation, up to 6mo afterwards
- u. Total duration of therapy on thalidomide
- v. Adverse symptoms or side effects on thalidomide therapy
- w. If stopped, reason for stopping medication
- x. Outcomes following determination of recurrent refractoriness of bleed: mortality, significant morbidity data
- y. Receipt of any other treatments for recurrent refractory bleeding (antrectomy, endoscopic band ligation, octreotide, hormonal therapies, etc).

**IV.10** A minimal risk study is a study in which the **probability and magnitude** of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Explain why this study involves no more than minimal risk to participants or to their privacy.  
Standard of care will not be altered prospectively in any instance. Patients will not be identifiable based on the study outcomes to be analyzed in the retrospective review. Breach of confidentiality remains a possible risk, but all measures will be taken to prevent this from happening including isolation of raw data to intra-institutional servers, password protected and inaccessible outside the hospital or to those not included in this IRB protocol.

**IV.11** Explain why this consent waiver will not adversely affect the participant's rights and welfare.  
Potential results from the study will not affect outcomes of patients who have already been treated for their bleeding. The deidentified data will be sufficiently protected, and no violation of privacy will take place.

**IV.12** Explain why it is impracticable (not possible) to conduct this research without a waiver of consent.  
Many patients included in the study may already have passed away.

**IV.13** Will you be accessing any medical records or medical information, or do any of the data you plan to access meet the federal regulatory definition of **protected health information (PHI)**?  
Yes

**IV.14** Explain why it is impracticable (not possible) to conduct this research without access to and use of protected health information.  
The protected health information will form the crux of data from which our results will be created.

**IV.15** Describe your plan to protect any participant and/or specimen identifiers from improper use and disclosure. (Identifiers include but are not limited to names, addresses, dates directly related to the participant (such as birth date, date of admission/discharge, date of clinic visit/procedure/diagnosis), social security number, medical record number, pathology accession number, or other account numbers, etc.)  
Potential risks specific to participation in this study are minimal. Data collected for research purposes will be kept confidential and will not be used for purposes other than this study. Patient information will be collected on a computer database, and all patient specific data will be housed on the institutional research network shared drive. Only IRB protocol members will have access to the drive, and no access will be granted outside the hospital.

**IV.16** Describe EITHER

- your plan to destroy participant identifiers at the earliest opportunity consistent with the conduct of the research, OR
- explain the health or research justification for retaining participant identifiers.

Only approved study personnel will have access to this database. All data will be deidentified after collection but before results analysis (association studies, logistic regression, comparison with negative controls). No paper collection sheets will be used. No other academic centers will have access to this data. When data is presented, individuals and individual data will not be identified. Research data will be kept confidential between the subject and the research team.

## V. Other Institutional Reviews/Requirements

**V.1** Do you or a family member have within the past twelve months or anticipate having within the next twelve months any financial interests in the company/organization providing support for this research or from a company/organization that owns or licenses the drug, device, or intellectual property being utilized in this research?

Name	Financial Interests
Chien-Huan Chen, MD	none
Alexis Bayudan, BA, MD	none
Pierre Blais, MD	none

**V.4** Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?  
No

- V.5** Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?  
No
- V.7** Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or radiopharmaceutical therapy)?  
No
- V.10** Does your study involve the administration of radiopharmaceuticals (radioactive drugs) for research purposes?  
No
- V.12** Will any participant be asked to undergo any of the following:
- a standard radiology procedure involving ionizing radiation (includes X-rays, fluoroscopy, DEXA, CT)  
OR
  - a standard nuclear medicine examination with FDA-approved radioactive drugs (including bone scans, radionuclide ventriculogram (RVG or MUGA), myocardial perfusion imaging, FDG-PET)
  - DO NOT include MRI or ultrasound
- No
- V.17** Will the study involve any of the following activity at WUSM or any BJC hospitals, *even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?*
- Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or
  - Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)
- No
- V.18** Does this project involve administration of recombinant DNA (gene therapy) or microorganisms?  
No
- V.19** Does this study involve the use of human embryonic stem cells or human induced pluripotent stem cells?  
No
- V.20** Does this study involve research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero?  
No
- V.21** Will you be utilizing participants, data or tissue from the Memory & Aging Project (MAP) or Alzheimer's Disease Research Center (ADRC)?  
No
- V.22** Is the PI of this study a BJH Registered nurse or a staff member of Patient Care Services (Pharmacy, PT/OT/, Respiratory, Rehabilitation, and Social work)?  
No
- V.23** Will any portion of this project be conducted in any Center for Applied Research Sciences Units, Clinical Research Unit (CRU), Clinical Trials Unit (CTU) and/or the Pediatric Research Unit (PCRU)?  
No
- V.24** Will this research be performed in the Neonatal Intensive Care Unit (NICU)?  
No
- V.25** Is this research being conducted in the Emergency Department?  
No
- V.26** Are you recruiting or screening patients in the Emergency Department?  
No

## VI. Participants

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- VI.27.a** Does this project involve the use of fetal tissue from any source?  
No
- VI.41** Does this project involve prisoners as participants?  
No

## VII.C. Genetic Research

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**VII.C.1** Does this project involve any research on genes or genetic testing/research?

No

## VIII. Risks

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**VIII.1** What are the risks to participants including

- emotional or psychological
- financial
- legal or social
- physical?

Potential risks specific to participation in this study are minimal. So long as personalized health information is deidentified and no breach of privacy occurs, there should be no potential for emotional, psychological, financial, legal, social, or physical harm.

**VIII.2** What have you done to minimize the risks?

- If applicable to this study ALSO include:
  - How you (members of your research team at WUSTL) will monitor the safety of individual participants.
  - Include a description of the availability of medical or psychological resources that participants might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)
  - Provide a description of the procedures being performed already for diagnostic or treatment purposes.

Only approved study personnel will have access to this database. All data will be deidentified as soon as possible. No paper collection sheets will be used. No other academic centers will have access to this data. When data is presented, individuals and individual data will not be identified. Research data will be kept confidential between the subject and the research team.

## IX. Benefits

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**IX.1** What are the direct benefits to the participant (do not include compensation)?

Participants in the study most likely will not see benefit, given the retrospective nature of the study. Shifts in standard of care would likely require prospective studies to validate the findings from this study first.

**IX.2** What are the potential benefits to society in terms of knowledge to be gained as a result of this project?

Standard of care regarding management of recurrent refractory bleeding due to GAVE may shift across healthcare settings around the world, in part due to studies such as this one.

## X. Privacy & Confidentiality

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**X.1** Describe your plans to protect the privacy interests of the participants during the conduct of the study including:

- How will you provide a private setting during the recruitment process
- How will you provide a private setting for the consent process including an opportunity for the participant to ask questions privately
- Describe how interventions occur in a private setting and/or how information will be collected using methods that protect the participant's privacy.
- Discuss why the information collected during the study is necessary to the conduct of the study and does not unnecessarily invade the rights of participants to privacy of their personal information.

No patient recruitment is needed given the study design. No informed consent process need occur. Only the information which is needed for purposes of the study will be extracted, and patient data will be deidentified as soon as possible, while any existing PHI will be kept on a secure network drive within the hospital.

**X.2** Are you collecting or using the Social Security Number of any participants for any purpose?

No

**X.4** How will information/data be collected and stored for this study (check all that apply):

- Electronic records (computer files, electronic databases, etc.) - Patient information will be collected on a computer database, and all patient specific data including date of birth, date of hospitalizations or clinic visits, and all health outcomes will be housed on the institutional research network shared drive which is accessible only by approved study personnel. Such information will not be available outside the institutional network, and password protections will be in place to ensure that no unauthorized access is granted. Patient identifiable data will be restricted to this location, and no laptops, jump drives, or other media will be allowed to carry research data until all potential identifiers have been removed. The entirety of the identifiable data will consist of patient names, dates of birth, dates of admission/clinic visits. No social security numbers or linked code identifiers will be necessary to record.

- X.5** Do the confidentiality protections indicated above allow only members of the research team to access identified data/specimens?  
Yes

## XI. Data Analysis

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- XI.1** Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.  
As a retrospective cohort study at best and a case series at worst, this study will focus on highlighting the details regarding patient characteristics and associated outcomes for patients who did and did not receive thalidomide as treatment for bleeding secondary to GAVE. For the purposes of a case series, hospital admissions and transfusion requirements in the period leading up to and immediately following thalidomide administration will be measured, as well as secondary outcomes of morbidity, mortality, and adverse drug effects. As much as the data permits, some correlation will be made to prior case reports of successful hemostasis of GAVE-related bleeding after administration of thalidomide. It is possible that a comparison can be made even to non-GAVE-related bleeding treated by thalidomide.
- For the purposes of cohort analysis, we will analyze patients with GAVE-related bleeding and assess patient characteristics of each arm to search for significant differences between the two. In this case it may be particularly difficult to parse out causation, as therapeutic decisions such as bleeding severity or overall clinical status will direct patients towards or away from the pathway towards receipt of thalidomide. Nonetheless, for binary dependent variables—such as the primary outcome of number of hospitalizations and transfusions after determination of refractoriness—the Chi-squared test will be employed to assess for significant differences between patients that have received thalidomide versus those who have not. For continuous variables (patient characteristics like BMI or age), the Student's t-test will be used instead. The expectation will be that patients receiving thalidomide are more likely to be healthier on average, with fewer comorbidities, making it more likely that they will tolerate the medication going in. Our hypothesis is also that cirrhotics will have lower rates of thalidomide receipt, for this same reason.
- XI.2** Provide the rationale or power analysis to support the number of participants proposed to complete this study.  
No prior published data exists regarding rates of bleeding in GAVE for patients who do or do not receive thalidomide, so sample size estimation cannot take place. Overall it is expected that sample size numbers for patients receiving thalidomide will not be large, so the ability to power the study adequately will be less of a concern.

## XII. Future Research

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- XII.1** Do you wish to keep any information about participants involved with this research project so that other researchers outside the current study team may contact them for future research?  
No
- XII.3** Does this project involve storing any data for future research?  
Yes - contribution for future use is mandatory for participation in the study
- XII.4** Does this project involve storing any tissues or specimens for future research?  
No

## XIII. Other Mod and/or Comments

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- XIII.1** Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.

## XIV. Mod Checklist

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- XIV.1** Does this modification require additional description/justification for the IRB to understand the changes being proposed?  
No

## Project Modification Attachments

Attachment Name	Category	Ver	Size		Attached
<a href="#">07-14-16 GAVE Thalidomide Blais Chen.pdf</a>	Assurance Document	1	321 k	E	07/14/16