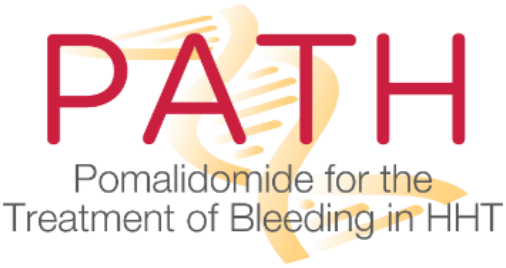

POMALIDOMIDE FOR THE TREATMENT OF BLEEDING IN HEREDITARY HEMORRHAGIC TELANGIECTASIA

NCT03910244

Protocol 133646-2

Part 2 Local Site Information Consent Template

Version 2.3, March 9, 2020

PART 2: LOCAL SITE INFORMATION *(customized per site-add delete as appropriate delete all highlighted instruction)*

Site Name:
Site Principal Investigator:

CONTACT INFORMATION

Who do you contact with questions about the study?

If you have any questions, you can ask the Site Investigator, *(insert name and phone number)* and/or research staff at *(insert name(s) and phone number)*.

Who do you contact after hours or in case of an emergency?

If you need to contact study staff outside normal business hours, you may contact *(insert phone number and process for 24 hour assistance)*.

Where can you get more information?

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about concerns regarding the study, research participant's rights, research-related injury, or other human subjects research issues, you may contact the Cleveland Clinic Institutional Review Board at (216) 444-2924. *(Add local IRB if applicable)*

LOCAL REQUIREMENTS *(delete section if not applicable)*

CONFLICT OF INTEREST *(delete section if not applicable)*

COMPENSATION AND REIMBURSEMENT

Are there any payments to you if you participate in this study? *(edit per local context)*

(Add any IRS tracking information if applicable)

RESEARCH RELATED INJURY *(add local context if applicable)*

What will happen if you are injured as a result of taking part in the research?

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury.

PRIVACY and CONFIDENTIALITY *(use this or replace with local HIPAA authorization)*

HIPAA AUTHORIZATION

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, you are permitting your site, the Principal Investigator, and the research staff to create, collect, use, store, and share protected health information (PHI) that identifies you for the purposes of this research.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Institutional Review Board. Your PHI may also be used by and/or disclosed (released) to:

- With each other and with other researchers involved with the study;
- With law enforcement or other agencies, when required by law;
- With the sponsor/funding agency of the research, National Heart, Lung and Blood Institute, as required to conduct the research and/or confirm the results of the research;
- With non-CCF collaborators of the research study:
  - Research Triangle Institute, (Raleigh, North Carolina); they will serve as the data coordinating center
  - Celgene Pomalyst REMS Program (Summit, New Jersey); they will provide study drug and administer the REMS program

- Ambry Genetics (Aliso Viejo, California); they will perform genetic testing for HHT genes
- With representatives of government agencies (e.g., Food and Drug Administration, The Department of Health and Human Services, etc.), review boards including the Cleveland Clinic Institutional Review Board and its representatives, and other persons who watch over the conduct of research (e.g., data safety and monitoring boards); and

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Dr. Name
Dr. Address
Dr. Phone number

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside your site cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

Your site will not use your information collected in this study for another research purpose without your written permission; unless an Institutional Review Board assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

SIGNATURES

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

I understand and agree to receive counseling and to comply with the pregnancy precaution requirements of the POMALYST REMS™ program.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent