SUPPLEMENTAL MATERIAL

Supplemental Methods: Text-based informed consent template (individualized for each site)

Supplemental Methods: Script for video-based informed consent

Supplemental Methods: Text-based informed consent template (individualized for each site)

Consent to Participate in a Research Study

Title of Study: **Patient and Provider Assessment of Lipid Management Registry**

Investigator *[name of site PI, contact information for PI and study team:]*

WHAT ARE SOME GENERAL THINGS TO KNOW ABOUT RESEARCH STUDIES?
You are being asked to take part in this registry because you have had heart disease or have risk factors for developing heart disease. Research studies include only those people who choose to take part. Your participation is voluntary. Please read this consent form carefully. We encourage you to talk with your family, friends, and doctor before you decide to take part in this research study. Please tell the study doctor or a study staff member if you are taking part in another research study.

WHO WILL PROVIDE FUNDING?
Regeneron Pharmaceuticals, Inc. and its collaboration partner Sanofi A.S. are paying *[Site]*, *[PI]* and the PI's research staff to do this registry.

WHY IS THIS STUDY BEING DONE?
Cholesterol, also called a lipid, is naturally occurring in the human body and helps to make vitamins, important hormones, and supports your body to function well. However, "bad cholesterol", called LDL, can be found in certain fatty foods, leading to clogged arteries and heart disease. Statins are medications used to help lower LDL levels and decrease the effects and risk of heart disease.

The purpose of this registry is to learn more about doctor prescribed cholesterol lowering medications using the current and previous health guidelines. We also want to learn about barriers to disease prevention and knowledge of treatment goals among patients using cholesterol lowering medications and those that do not. We hope the information gained will help us to understand doctors' treatment patterns, introduce new treatments and make current treatment guidelines clearer for cholesterol lowering therapies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 7,500 people at 175 outpatient clinics in the United States will take part in this registry.

WHAT IS INVOLVED IN THE STUDY?
If you agree to take part in this research registry, here is what will happen:

- **You will be asked to complete a Survey via a mobile tablet device**
  The survey questions will ask you about your understanding of:
  - Heart disease and disease prevention.

- Cholesterol lowering medication costs and medication taking behaviors

After completion of the survey, you will return the tablet to the study coordinator.

- **You will have your blood Drawn**
  - Approximately two teaspoons of your blood will be drawn from your arm to check your cholesterol levels. The results from these tests will not be made available to you nor will they be used to treat or diagnose you. The blood samples may be stored for the purposes of this registry only.
- **Clinical information will be collected about you and stored in a database**

  The study coordinator will record information from your medical record including:
  - Demographics (i.e., age, gender, race, insurance status, etc.)
  - Past medical history
  - Family medical history
  - Vital Signs
  - Medications
  - Laboratory data

  Your information will be stored in a database along with information from other participants in this registry. The database will be maintained by our partners at Duke University.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this registry will end once you have completed the questionnaire and had your blood drawn while in the clinic. The data collected about you will be stored indefinitely.

WHAT ARE THE RISKS OF THE STUDY?

Risks associated with study procedures

Risks associated with drawing blood from you include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is also possible, although unlikely.

Some of the questions we will ask you on the survey as part of this registry may make you to feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the registry visit. If you mention having feelings about wanting to harm yourself, we will make sure to refer you to a doctor who will talk to you about these feelings.

Privacy Risks

There is a potential risk of loss of confidentiality. We will, however, make every effort to protect your confidential information to minimize this risk.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There may not be direct medical benefit to you, however we hope that the information learned from this registry will benefit other people with your condition in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

You do not have to participate in this study. You can get treatment or care for your illness even if you are not in a research study.

WHAT PERSONAL HEALTH INFORMATION ARE YOU ASKING PERMISSION TO GET FROM MY MEDICAL RECORD?

If you sign this consent form, certain information about you will be shared, used and/or disclosed for the purposes of this study. You are giving your permission for the following people or groups to give the researchers certain information about you:

- Any health care providers, professionals or agencies who have provided you health services or treatment
- Any agencies that provide payment for health care, such as insurers, or government agencies

If you sign this form the health information about you that the people or groups listed above may give to the researchers to use in this research study include**:**

- Demographics (i.e., age, gender, race, insurance status, etc.)
- Past medical history
- Vital Signs
- Family medical history
- Medications
- Laboratory data

This information may be shared with used by, or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and government agencies (like the FDA or the National Institutes of Health) if needed to oversee the research study. Your information, without direct identifiers, may be shared with, used by, or seen by the funder of this registry, Regeneron Pharmaceuticals, Inc., who may also share it with their affiliated corporate entities (including the Sanofi group of companies.) Anybody who receives your information from us could share it with others without your permission and would not be protected by the HIPAA Privacy Rules (the Health Insurance Portability and Accountability Act, which includes federal privacy regulations that provide safeguards for privacy, security, and authorized access of patient information and provides patient rights over their health information) . We can use or share your information if we do so in a way such that nobody can tell it is your information.

If you want to participate in this study, you have to sign this authorization to allow access to your medical records. If you choose to not sign it, your regular care and benefits to which you are entitled will not be affected. If you do sign it, you can change your mind later by writing a letter that states you are taking back your permission. Mail the letter to *[Address]* or you can send an email at *[List email address]*. Stopping your authorization will prevent sharing of information in the future, but will not affect any information that has already been shared.

The permission you give us to access your medical record will last until the end of the study. You will be given a copy of this authorization.

If the results of this study are made public, information that identifies you will not be used.

HOW WILL MY PRIVACY AND CONFIDENTIALITY BE PROTECTED?
Registry records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access of patient information and provides patient rights over their health information). Your records may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, representatives of the <<Clinic/health care provider's>> Institutional Review Board, the registry staff; including the Duke Clinical Research Institute (Duke University) and its representatives, the sponsor and its contractors and agents.

All information transferred from the mobile tablet device to Duke Clinical Research Institute (DCRI) will be encrypted over a secure connection and only accessible by authorized registry personnel. The data that DCRI receives from study sites will be coded with a unique code number. Enrolled patient information will be entered, stored and maintained on a secure password-protected electronic data capture (EDC) website for this registry. All sites are required to have a secure email server for participation. If you elect to receive a copy of the signed consent via email to your personal email box, we cannot guarantee the security of that transmission.

Registry results will be kept in your research record for at least 6 years after the registry is completed. After that time, the research information that's not in your medical record will be destroyed, and information identifying you will be removed from the registry research results.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov . This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. If the results of this registry are made public, information that identifies you will not be used.

WHAT ARE THE COSTS TO ME IF I PARTICIPATE IN THIS STUDY?
There are no costs to you for participating in this research project.

WHAT ABOUT COMPENSATION?
You will not be paid for participation in this registry.

WHAT IF I AM INJURED?
Immediate necessary medical care is available at *[Insert institution/clinic]* in the event that you are injured as a result of your participation in this research registry. However, there is no commitment by Regeneron Pharmaceuticals, Inc. nor Duke Clinical Research Institute or your registry doctor to pay for or provide free medical care to you in the event of a registry-related injury.

WHAT IF I WANT TO STOP BEFORE MY PART IN THE STUDY IS COMPLETE?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. If you withdraw, no new information will be collected but we will use data that has already been collected.

NEW FINDINGS
If important new findings come up that might change your decision to be in this registry, you will be given information about those findings as soon as possible. If you choose to stay in the registry, you may be asked to sign a new version of the consent form.

FUTURE STUDIES
The research team at *[Insert site]* may contact you in the future about participating in other research studies. If you participate in this registry, we may contact you in the future to ask if you would be interested in participating in other research studies. Signing this consent form does not mean that you agree to participate in any additional future studies, or that you have to participate in future studies. However, if you are contacted in the future about a new research study and agree to participate, you will be given a separate consent form to sign.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the registry or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. *[PI]* at *[PI's Number with Area Code]* during regular business hours and at *[PI's 24-hour Number with Area Code]* after hours or on a weekend or holiday.

For questions about your rights as a research participant, contact *[the IRB name and contact number]*

STATEMENT OF CONSENT

The purpose of this study, the procedures to be followed, the study's risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form (or it has been read to me) and I agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a copy of this consent form and that a copy of this form will become part of my medical record.

I authorize the use and disclosure of health information from my medical record to the people or groups identified in this consent form for the purposes described in this document.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Research Team Member Who Obtained Consent Date

_____

Printed Name of Research Team Member Who Obtained Consent

Supplemental Methods: Script for video-based informed consent

WHAT ARE SOME GENERAL THINGS TO KNOW ABOUT RESEARCH STUDIES?
Hi, my name is Tracy Wang and I'm a cardiologist here at Duke University. Along with several other Duke physicians, I'm leading the PALM Registry. Duke is being paid by Regeneron Pharmaceuticals, Inc. and their collaborating partner, Sanofi NA, to manage the study. Your healthcare provider is one of about 175 sites who is working with Duke to conduct this registry, and he or she is also being reimbursed by Regeneron Pharmaceuticals for participating.

We'd like you to consider participating with us in the PALM registry. Your participation is voluntary, which means that we'll include only those people who choose to take part. Please listen to these videos carefully. After you've reviewed everything, you'll have a chance to ask questions, and talk with your family, friends, and your healthcare provider, before you make a decision. Regardless of what you decide, you'll still receive the same care from your healthcare provider, and you won't lose any rights or benefits. Thank you for considering participation in PALM.

WHY IS THIS STUDY BEING DONE?
"Bad cholesterol", called LDL, can be found in certain fatty foods, leading to clogged arteries and heart disease. Statins are medications used to help lower LDL levels and decrease the effects and risk of heart disease.

The purpose of this registry is to learn more about how doctors prescribe cholesterol lowering medications using the current and previous health guidelines. We also want to learn about barriers to disease prevention and knowledge of treatment goals among patients who use cholesterol lowering medications and among those who don't.

WHAT IS INVOLVED IN THE STUDY?
Approximately 7,500 people at *175* outpatient clinics in the United States will take part in this registry. In order to participate in the study you will have to complete the following activities during today's office visit.

- You'll be asked to watch the consent videos on this tablet. You'll be able to ask questions, and talk with friends and family before you make a decision. If you decide to participate, the study coordinator will assist you with providing your electronic signature on the tablet.
- After signing the consent, you'll complete a Survey using this tablet. The survey questions will ask about your understanding of heart disease and disease prevention, your experience with cholesterol-lowering medications, your thoughts about your healthcare costs, and your medication taking behaviors. After taking the survey, you'll return the tablet to the study coordinator.
- Approximately two teaspoons of blood will be drawn from your arm and sent to a centralized lab to check your cholesterol levels. This blood will be tested and stored only for this registry, and the results will be shared with Duke University for the purposes of this registry only.
- The study coordinator will collect clinical information about you from your medical record and share it with Duke University using only your coded study ID number. It will be stored at Duke in a secure database along with information from other participants in this registry.

The information will include your medical history, vital signs like heart rate and blood pressure, lab results, medications, and demographics like your age and gender.

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HOW LONG WILL I BE IN THIS STUDY?

Your participation in this registry will end once you have completed the questionnaire and had your blood drawn while in the clinic. The data collected about you will be stored indefinitely, but only using your coded study ID number.

ARE THERE ANY RISKS TO ME?

The risks for participating in this study are minimal.

When your blood is drawn, you may experience momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Some of the questions on the survey may make you to feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the registry visit.

Your personal information will be protected throughout this study, including when it is in the secure database at Duke. There is a slight risk of loss of your confidentiality, but every effort will be made to minimize that risk.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records identifying you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you won't be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of your study location. For records that are disclosed outside of your study location, you will be assigned a unique code number. The key to the code will be stored and maintained in a secure location at your study doctor's office or clinic.

As part of the study, your study doctor and his or her study team will use your unique code number to report information from your medical records to the Duke Clinical Research Institute, who in turn will share the information with the sponsor, Regeneron Pharmaceuticals, and their collaborating partner, Sanofi NA. Results of your study-related centralized lab tests will also be reported to Duke and shared with the sponsor using your unique code number. This information may be further shared by the sponsor of this study, in which case the information is no longer covered by the federal privacy regulations.

Your records may also be reviewed to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives of the sponsor and their collaborators, or the Duke University Health System Institutional Review Board. If any of these groups review your research record, they may also need to review your entire medical record. If this information is shared with outside reviewers for audit purposes, it may be further shared by them and may not be covered by the federal privacy regulations. If the results of this study are made public you won't be identified in any way.

Registry results will be kept in your research record for at least 6 years after the registry is completed. After that time, the research information that's not part of your medical record will

be destroyed, and any information identifying you will be removed from the registry research results.

A description of this research study will be available on the website clinicaltrials.gov.
You'll be given a copy of this signed consent form, and you may be able to choose between a paper or email copy. If you choose email, the study staff will use a secure email account to send it. However, the security of the email account at which you receive the consent may not be guaranteed, so it's possible that your copy of the consent document will no longer be confidential.

NEW FINDINGS
If important new findings come up that might change your decision to be in this study, you'll be given that information as soon as possible. If you choose to stay in the study, you may be asked to sign a new version of the consent form.

FUTURE STUDIES
This consent form is only for the PALM study. If you decide to participate, you may also be considered for participation in future studies related to this one. If that happens, you would be contacted in advance and given the same opportunity to decide to participate in the next study. You also would be given a separate consent form to sign. Agreeing to participate in this study does not mean you have to participate in future studies.

ARE THERE BENEFITS?
There may not be direct medical benefit to you if you decide to participate, but we hope that the information learned from this registry will benefit other people with your condition in the future.

ARE THERE ALTERNATIVES?
You do not have to participate in this study. You'll receive the treatment or care to which you are entitled even if you are not in this research study.

WHAT ARE THE COSTS TO ME IF I PARTICIPATE IN THIS STUDY?
There are no costs to you for participating in this research project. Any care you would normally receive will be billed to your insurance company

WHAT ABOUT COMPENSATION?
You will not be paid for participation in this registry.

WHAT IF I WANT TO STOP BEFORE MY PART IN THE STUDY IS COMPLETE?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. In either case, we will use data that has already been collected, but we won't collect any new information. If you do decide to withdraw, please contact your study doctor in writing and let him or her know that you are *withdrawing* from the study. Your study doctor's mailing address is given below.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions about the study or if you have problems, concerns or suggestions about the research, you can contact your local study doctor, whose name and contact information is listed below. If you have questions about your rights as a research participant, you can contact the Institutional Review Board that oversees this research study. Their contact information is shown below. All of this contact information will also be printed in your signed copy of the consent document.

STATEMENT OF CONSENT (non-narrated)
The purpose of this study, the procedures to be followed, the study's risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form (or it has been read to me) and I agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a copy of this consent form and that a copy of this form will become part of my medical record.

I authorize the use and disclosure of health information from my medical record to the people or groups identified in this consent form for the purposes described in this document.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Research Team Member Who Obtained Consent Date

_____
Printed Name of Research Team Member Who Obtained Consent