Study: Neuroendocrine Tumors - Patient Reported Outcomes (NET-PRO)

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INFORMED CONSENT DOCUMENT

Project Title: **Neuroendocrine Tumors – Patient Reported Outcomes (NET-PRO)**

Principal Investigator: **[SITE PI NAME]**

Research Team Contact: [SITE COORDINATOR NAME]
[SITE EMAIL]
[SITE PHONE NUMBER]

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study based on your neuroendocrine tumor (NET) diagnosis.

This study is being conducted for several reasons:

1. To describe the symptoms and quality of life with different NET treatments.
2. To learn what patient and tumor factors influence the order that treatments are given.
3. To learn whether treatment order affects quality of life, symptoms and survival.
4. To help others conduct research on NETs and other rare diseases.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately [SITE ENROLLMENT NUMBER] people will take part in this study conducted by investigators at [SITE NAME]. About 3100 persons will take part in this study nation-wide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 36 months, though your direct involvement will be over after 18 months. This study involves taking four surveys spaced six months apart. The first survey will take about 40 minutes to complete; the other three surveys will take about 20 minutes each to complete.

We will also collect information from your medical record for about 36 months from the time you enroll in the study.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in this study, you will be asked to take four surveys over the next 18 months. This can be done using the study website (www.netprostudy.org) or by completing the "NET-PRO Study Enrollment Packet" provided to you by a study coordinator.

Please note that there is no travel required for this study.

Study Website

The study website (www.netprostudy.org) has been specifically developed for the NET-PRO study for participants to complete surveys, view their responses, and access other tools for NET patients. It is a secure website with strict security protocols, hosted and maintained by the University of Iowa, the lead institution and coordinating center for this study.

When you first go to the website, there will be a question to answer to make sure you are eligible to join the study. Then after you learn about the study details and join the study (by signing this form), you'll be asked to create a study account and enter basic information about yourself (like your name and address) so that you can access your study website account in the future.

If you were provided a paper version of the survey instead, your survey responses will be entered into the study website by a member of the research team at the University of Iowa: you do not need to use the study website.

The website will record the date and time you use it, and which pages you use. This will help us identify any problems that may arise with the website and improve it for this and other studies. We are also interested in knowing which features are used, and how long certain features take to use. We may add other features to the website over time and we may contact you to let you know about these features.

Surveys

Each of the four study surveys ask questions about your health and health care, and many questions are related to your neuroendocrine tumor. The surveys also ask about current and past health conditions and treatments, symptoms, health behaviors, feelings, concerns, and general preferences about health and health care, physical and mental health, and basic information about you (like marital status, and height and weight). There are also a few questions to assess your comfort with and understanding of health information. Almost all survey questions ask you to check a response, but a few ask you to enter numbers (for example, for your weight) or text. You are always free to skip any survey questions you prefer not to answer.

Below is a list of when you will be invited to complete each survey and your compensation:

Activity	**When**	**Compensation for completing the survey**
Survey #1	Right after you join the study	$40.00 check
Survey #2	6 months after you complete Survey #1	$20.00 check
Survey #3	12 months after you complete Survey #1	$20.00 check
Survey #4	18 months after you complete Survey #1	$20.00 check

As a reminder, a member of the research team may contact you if you haven't completed Survey #1 within approximately 7 days after joining the study.

Between each survey, there is nothing that you need to do for this study. However, if you join the study through the study website, you are welcome to use your study account to explore NET resources that the research team has compiled.

Study website (online) participants: When it is time to take Survey #2, #3 or #4 (about 6 months after you completed the previous survey), the research team at the University of Iowa will send you a reminder by email and/or mail and/or phone.

Study packet (paper) participants: When it is time to take Survey #2, #3 or #4 (about 6 months after you completed the previous survey), the research team at the University of Iowa will send you a reminder by mail and/or phone.

The research team will contact you by email, mail, and/or phone if you do not complete a survey within approximately one week of being invited to do so. The research team will attempt to contact you up to 6 times. If the research team cannot reach you, the research team will contact your health care provider to see if they have updated contact information for you, and that information will be used to try and reach you.

The research team at the University of Iowa may also notify you periodically about new information or features available in the study website.

Medical Record Data

We will collect data from your medical record and the data will be shared with the study coordinating center at the University of Iowa. The data will cover the period two years prior to your NET diagnosis through approximately 36 months after the date you joined the study. Examples include additional information about your demographics (like sex and race); cancer treatments and treatment outcomes; vital status; laboratory tests and results in the period of your cancer treatments; existing health conditions; tumor characteristics; and disease status.

If you happen to also get care from another hospital that is part of this study, we will know that because we will send a confidential code to the study's coordinating center. This will allow those hospitals to provide the same kinds of data from your medical record to the University of Iowa for this study. In some cases, we might need you to sign a form saying it is okay for us to get the information we need for the study.

The three data sources – medical record, survey, and study website - will be linked for this study.

Data Storage for Future Use

As part of this study, we are obtaining survey, study website, and medical record data from you. We would like to study these data from you in the future, after this study is over without further consent. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it will be stripped of identifiers (such as name, date of birth, address, etc.). Other qualified researchers who obtain proper permission may gain access to your anonymized data for use in ethically approved research studies that may or may not be related to the purpose of this study.

The methods in which we want to study your data in the future may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding neuroendocrine tumors, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products, tests, or discoveries that could be

patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored *with a code which may be linked to* your name, date of birth, contact information, and dates of health care visits, tests, results, and diagnoses. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact [SITE PI NAME], [SITE PI PHONE NUMBER]. However, if some research with your data has already been completed, the information from that research may still be used.

We will keep your contact information so that we can invite you to participate in future research studies. That information includes your name, address, email, phone, date of birth, sex, gender, race, ethnicity, and healthcare site. Agreeing to be in the current study does not obligate you to participate in any subsequent study - a separate Consent Document that describes the new study details would be signed for any future study participation.

WILL I BE NOTIFIED IF MY DATA RESULT(S) IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- As with any study involving identifiable information, there is a risk of unauthorized disclosure of your information. If that were to occur, it may cause feelings of distress.
- It is possible that you will experience some emotional discomfort from responding to questions about your health or health care.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study. Data from this study will highlight the patient perspective on managing NETs and may provide clinicians helpful information to guide recommendations on which treatments (and combinations) to use given individual patient symptom and tumor factors and how the ordering of treatments may affect future treatment options. All of these issues have been deemed important by NET patients, but the scientific evidence is currently lacking.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There are no costs to you for being in this research study.

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 202104599
APPROVAL DATE: 05/06/22

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your address for a check to be mailed to you.

You will be paid $40.00 for completing Survey #1 and $20.00 for completing Survey #2-4, for a total of $100.00. You will be paid by check using the information that you provide when you agree to join the study.

WHO IS FUNDING THIS STUDY?

The Patient-Centered Outcomes Research Institute (PCORI) is funding this research study. This means that [SITE NAME] is receiving payments from PCORI to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from PCORI for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. We will not share or sell your personally identifiable data. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- the funder, PCORI, may also inspect any part of your medical record for the purposes of auditing the conduct of the study,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, the study website will include a security certificate, and your study account will be protected by a unique username and password that you create. Electronic data collected from the study website will be stored in a password-protected database managed by the University of Iowa. Medical record data collected from study sites will be transferred to the University of Iowa using secure methods and will be stored on a password-protected research drive at the University of Iowa. Hard copy (paper) records will be stored in locked file cabinets in locked offices, and only research team members will have access to these records. When transported or transferred, paper materials will be obscured, for example, by placing them in a bag or briefcase, so that others will not be able to view your personal information. Access to study data will be restricted to members of the research team who need such access. Analyses using study data will be stripped of all directly identifying data elements that are not needed (for example, name, address, phone, and email) and stored on a password-protected research drive at the University of Iowa. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

[SITES MAY CHOOSE TO EITHER USE IOWA'S HIPAA LANGUAGE OR REPLACE WITH THEIR OWN, AS LONG AS THE KEY ELEMENTS OF THE SECTION ARE COVERED]

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information

that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, and the University of Iowa Institutional Review Boards and support staff. The funder, PCORI, may also inspect any part of your medical record for the purposes of auditing the conduct of the study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **[SITE PI NAME], [STREET ADDRESS], [CITY], [STATE] [ZIP CODE].** However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study funder, or we have removed your identifying information, it may not be possible to prevent its future use. Your signature on this Consent Document authorizes your health care provider to give us permission to create health information about you. A copy of this signed consent will be made available to you for your records.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. Please see the table below to decide who to contact about questions you may have.

If you have questions or concerns about:	**Please contact:**
The NET-PRO study	Your local study team: [SITE COORDINATOR NAME]: [SITE PHONE NUMBER], or [COORDINATOR EMAIL]
If you experience a research-related injury, please contact:	

Research Team Contact: [SITE COORDINATOR NAME]
[SITE EMAIL]
[SITE PHONE NUMBER]

If you have questions or concerns about:	**Please contact:**
Your rights as a research participant	The lead Institutional Review Board (IRB): University of Iowa IRB: irb@uiowa.edu 319-335-6564 Human Subjects Office/ IRB Hardin Library, Office 105 600 Newton Rd Iowa City, IA 52242-1098
	Your local Institutional Review Board (IRB): [SITE NAME] IRB [EMAIL ADDRESS] [PHONE NUMBER] [ADDRESS LINE 1] [ADDRESS LINE 2] [CITY], [STATE] [ZIP CODE]
The NET-PRO study website	The Coordinating Center at the University of Iowa: cph-netpro@uiowa.edu 800-383-3755 (toll-free)
Your study compensation	
Continuing in the NET-PRO study	
Withdrawing your permission for us to use your health information for the current or future research studies, please send a written notice to:	[SITE PI]: [ADDRESS LINE 1] [ADDRESS LINE 2] [CITY, STATE ZIP CODE] [PI PHONE NUMBER]

General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions (if any) have been answered, and that you agree to take part in this study. You will receive a copy of this form for your own records.

Subject's Name (printed): _____

_____	_____
(Signature of Subject)	(Date)