

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

## RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

**Protocol Title:** A Nerve Sheath Tumor Bank from Patients with NF1

**Application No. :** IRB00096544

**Sponsor:** Neurofibromatosis Therapeutic Acceleration Program

**Principal Investigators:**

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### 1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- If children and adults can join this study, the word “you” in this consent form will refer to both you and your child.

## 2. Why is this research being done?

This research is being done to collect, process and store biospecimens (e.g. blood, urine and tissue samples) in a repository (bank) in order to improve access to samples for current and future research, and to support discovery of new therapeutics for patients with neurofibromatosis type 1 (NF1).

In addition, through a collaboration with other cancer centers, this research study will create a comprehensive database of clinical information from people with malignant peripheral nerve sheath tumors (MPNST), including information generated during genetic testing on specimens collected under banking studies. This database may be accessed for future research projects designed to learn more about MPNST. Because this is a registry study, you will not be having any tests or procedures done solely because you enroll in this study; we are simply collecting information about tests or procedures that you have had or will have regardless of your participation.

Currently, surgery is the only treatment option for NF patients with symptomatic plexiform neurofibromas (PN). Progress developing nonsurgical therapies has been limited due to a lack of available primary PN tissue from NF1 patients. These samples may be used by Johns Hopkins researchers, banked with other scientific collaborators and institutions, and provided for ongoing research within the NF1 research community.

Your tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Your tissue may also be implanted into special laboratory mice that lack an immune system in an attempt to grow tumor cells in a living animal for future research.

### **What you should know about the cell lines that will be derived in the course of this study?**

- The cell lines created will be similar or identical to you genetically.
- The cell lines may be kept indefinitely.
- There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
- The cell lines may be shared with researchers both inside and outside of Johns Hopkins, including our commercial partners.
- The cell lines may be used to develop treatments for a variety of diseases and conditions.

Patients with neurofibromatosis type 1 (NF1) who present to Johns Hopkins for the purpose of resection or biopsy of a cutaneous neurofibroma, plexiform neurofibroma, malignant peripheral nerve sheath tumors (MPNST), breast cancer, GIST (gastrointestinal stromal tumor), glioma, or other neurofibromatosis-associated malignancy, will be offered participation in this research study.

### **How many people will be in this study?**

About 150 people are expected to take part.

## 3. What will happen if you join this study?

This is not a treatment study.

If you agree to be in this study, we will ask you to do the following things:

- Allow us to collect extra blood for research purposes during the time of clinical blood collections.
- As a part of the study, unused tissue from a diagnostic procedure or surgery will be kept for current and future research studies. Some of the extra tissue will also be provided to the NF1 research community.
  - 1) **Peripheral Blood Samples:** When blood is drawn for routine tests, you will be asked to give an extra 4 teaspoons of blood for this tumor research study. A clinical blood collection typically takes about 5-10 minutes.
  - 2) **Leftover Tumor Biopsy Samples:** If you have been diagnosed with, or are suspected to have neurofibromatosis then a tumor biopsy will be done as a part of your routine clinical care. We plan to obtain any tissue left over after analysis is completed by the Department of Pathology for the purpose of this research. Harvesting of leftover tumor will not add any additional time or discomfort to your procedure.
- **Short Questionnaire:** If you have MPNST, we will ask you to complete a short questionnaire which will include questions about your demographic information, contact information, diagnosis and family history, and willingness to participate in different types of future research. Once you have done that, your physician will be prompted to enter information from your medical record into the database, such as additional information regarding your diagnosis, information about treatments you have received, information about how your MPNST has responded to treatment, imaging information, and the results of any analyses performed on specimens collected under tissue banks, including the results of genetic research.

The collected cells and/or fluid are taken to a research laboratory for processing. The technician will code the sample with a unique identifier and remove all participant identifying information. These samples can be used for NF1 research to reveal new information about your cancer and aid in the discovery of new treatment options.

Sometimes samples provided for research are used for genetic research. If your tissue or blood is used for this kind of research, you will not be given the results of the tests, and the results will not be put in your health records.

The study team may contact you at future time points either by phone or at your routine clinic visit (possibly 2-3 times per year depending on your scheduled doctor visits and resources available). The purpose of this contact is to collect information about your health status and quality of life. If we cannot reach you, this information may be obtained by reviewing your medical records or by accessing public records. The National Death Index (NDI) may be utilized to confirm your vital status if necessary. The NDI is a centralized database of death record information on file in state vital statistics office maintained by the Centers for Disease Control and Prevention. Social security number is used to search the NDI. Although we are collecting your social security number as part of your participation in this study in order to meet NCI requirements, you may opt out of allowing us to use your social security number to search the NDI.

The research may involve research tools such as gene sequencing or the creation of cell lines.

- Gene sequencing of your DNA provides researchers with the code to your genetic material.

- Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your complete DNA.

Your tissue will be de-identified when given to researchers for their work. A label with a unique identifier will be used which can only be linked to your name, address, and phone number through a secure database maintained and utilized by Hopkins Clinical staff, and staff members of Dr. Christine Pratilas' laboratory.

Information regarding your diagnosis will be obtained from your medical records. The information will be linked to the sample by the unique identifier assigned to it. Demographic information such as your age, race, and sex, as well as medical history and basic treatment information will be collected.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

### **Will you collect my social security number?**

You will be asked to provide your social security number at the time of enrollment to this registry. The reason for collecting your social security number is to confirm your vital status in the NDI. Collecting your social security number for this purpose is strictly optional and is not required for participation in the study.

I allow you to collect and use my social security number for the purposes outlined above.

I DO NOT allow you to collect or use my social security number for the purposes outlined above.  
(Initial your choice above)

### **Request to collect and store biospecimens for future research**

As part of this research study, we would like to ask you to let us provide your biospecimens and health information for future research to other scientific collaborators and institutions. The Children's Tumor Foundation (CTF), the Neurofibromatosis Therapeutic Acceleration Program (NTAP), and others are working collaboratively to find effective treatments for people worldwide living with neurofibromatosis. We would like permission to send your samples to other organizations, researchers, and institutions outside of Johns Hopkins. The research done with these samples could include other diseases.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

**Will you save my samples or research data to use in future research studies?**

As part of this study, we are obtaining data from you. We would like to use these data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding MPNSTs, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, St. Louis, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories, only qualified researchers who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if data have been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Will you allow another collaborative NF1 biospecimen repository outside Johns Hopkins to store the biospecimens we collect for this study for use in future research?

YES  \_\_\_\_\_  
Signature of Participant

NO  \_\_\_\_\_  
Signature of Participant

**How long will you be in the study?**

After the initial blood collection at the time of a clinical visit, you will not have any additional procedures performed as part of this study.

Your consent to participate in this study will allow us to store leftover tumor and blood; indefinitely or until consent is withdrawn.

**4. What are the risks or discomforts of the study?**

**Confidentiality**

The greatest risk to you is the collection of information from your health records.

Efforts will be made to keep your personal information confidential. The number of people who have access to your identifying information will be limited. Still, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Research personnel collecting and processing the specimen prior to banking will ensure your name and medical record information are removed from the sample. This information will be stored in a database where it can only be accessed by personnel on the Principal Investigator's research team.

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

### **Blood sample collection**

The risks associated with having a blood sample taken are minimal. As blood collection for this study will be done at the time blood is being collected for clinical tests, no additional discomfort beyond the initial needle stick and potential bruising and tenderness from the blood collection is likely.

### **Tumor sample collection**

This study uses only leftover tumor sample from tumors which will be removed as part of your medical care. No extra tumor will be collected for this research trial, and thus there will be no additional biopsy procedures or discomfort beyond what is necessary for your clinical care.

## **5. Are there benefits to being in the study?**

There is no direct benefit to you from being in this study.

If you take part in this study, your participation may result in future therapies for others with similar diagnoses.

## **6. What are your options if you do not want to be in the study?**

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

If you decide not to sign this form, it will not affect:

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

## **7. Will it cost you anything to be in this study?**

No.

## **8. Will you be paid if you join this study?**

No.

## **9. Can you leave the study early?**

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.

- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 10. Why might we take you out of the study early?

You may be taken out of the study if:

- The study is cancelled.
- If the samples provided do not have enough material to bank for the study.

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. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure by storing it on a secure server in a password-protected file. You may request that your personal information be removed from this file at any time by contacting the research team member identified at the top of this document.

To help protect your confidentiality, we will make sure that your study information is kept secure. Hard copy records (such as a copy of this consent form) will be stored in a locked office. The majority of the information collected during this study will be stored in a secure database that requires a username and password. Subjects are given a unique subject ID. The link between the patient and the unique ID is maintained by the study team. 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.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

Your de-identified data will be used in connection with this study and may also be shared with outside institutions for further research study. However, all access to the de-identified data will be controlled in accordance with applicable laws and regulations. This may include written agreements that require that the data be kept confidential and secure and be used only for the purposes permitted by this consent form or applicable laws and regulations.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

## **12. Will the study require any of your other health care providers to share your health information with the researchers of this study?**

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

You will be asked to give us a list of other health care providers that you use.

### **13. What other things should you know about this research study?**

#### **a. What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

#### **b. What do you do if you have questions about the study?**

Call the principal investigator, Dr. Christine Pratilas at 410-502-4997. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

#### **c. What happens to Data and Biospecimens that are collected in the study?**

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

### **14. Assent Statement**

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

**15. What does your signature on this consent form mean?**

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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Signature of Participant	(Print Name)	Date/Time
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Signature of Person Obtaining Consent	(Print Name)	Date/Time
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Signature of Parent	(Print Name)	Date/Time
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Signature of Legally Authorized Representative (LAR) <b>For CHILD PARTICIPANT</b>	(Print Name)	Date/Time
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Description of LAR's authority under state or applicable local law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)		Date/Time
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Signature of Child Participant (optional unless IRB required)	(Print Name)	Date/Time
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Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time
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**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**