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Informed Consent

**Protocol Title: REPOSITORY OF DATA AND SPECIMENS FOR MERKEL CELL
CARCINOMA RESEARCH (IRB #6585)**

Principal Investigator: PAUL NGHIEM, MD, PhD

**Sites: FRED HUTCHINSON CANCER RESEARCH CENTER (FHCRC)
UNIVERSITY OF WASHINGTON
SEATTLE CANCER CARE ALLIANCE**

Study-Related Phone Number: PAUL NGHIEM, MD, PhD / (206) 221-4594

We are doing a research study to examine clinical data, leftover tissue samples, and blood from patients with known Merkel cell carcinoma (MCC). We hope to identify genes involved in causing MCC. We also hope to identify factors that help predict survival in MCC.

Since you have MCC, we would like you to join this study. Although the study will not benefit participants directly, we hope this research will lead to new therapeutic approaches.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

Taking part in this study will not lead to added costs to you or your insurance company. You will receive no payment for taking part in this study.

If you agree to participate we will ask you to consent to some or all of the following:

- **Fresh Tissue:** If you are going to have medically necessary surgery to remove MCC, your doctor will remove the same amount of tissue, but will send a small sample of the removed tissue to us for research.
- **Archival Tissue:** If you have already had surgery to remove MCC, it is likely that your doctor has sent that tissue to a pathologist to establish the diagnosis. The pathologist may release some leftover tissue to us for research.
- **Blood:** We would like to collect blood from you for research. In most cases, we will collect about 4 teaspoons (20 milliliters), and we would collect this blood no more than twice. The amount of blood is very small, and the blood loss poses no increased risk to you. In some cases, with your specific permission, we would collect about 3 ounces (100 milliliters) of blood. This is a slightly larger volume of blood, but it is less than ¼ the volume collected for a typical blood donation. Risks of drawing blood with a syringe include fainting or feeling light-headed, discomfort and minor bleeding at the collection site (on the arm, for example). There is also a very small risk of infection, although the standard sterile instruments will be used to minimize this risk.
- **Collaborative Studies:** If you submit samples to the Nghiem Lab, we will keep these samples in storage for current and future MCC research. Additionally, we may send a small amount of tissue to researchers at other institutions interested in MCC. We would send no

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personal identifying information with the tissue. We will verify the proposed studies are approved by the appropriate ethics committees at the collaborating institution.

- **Medical Records and Follow-Up:** As an MCC patient, your doctor (or doctors) may keep medical records about your disease and treatment plan that could be valuable for our research on MCC. With your consent, your physician(s) may release these records to the Nghiem Lab. This may include personal identifying information that will allow us to contact you in the future to determine if your disease has progressed. You may be contacted by a study team member by telephone or email for more follow-up information about your treatment and disease status. The need for us to contact you will be affected by whether you or your doctors keep us informed about your health status. We would like at least one update a year for the first three years after diagnosis. We will also include some of your medical history in a database about MCC. This database will NOT include any personal identifying information. We may choose to share this generalized data with researchers at other institutions. Your identifying information will be kept under lock and key at the Nghiem Lab and never shared with outside collaborators.
- **Notification Upon Identification of Relevant Findings:** If you give your consent we will attempt to inform you in the unlikely case that new information arises that could importantly affect the management of your MCC.

You may quit this study at any time for any reason, through verbal or written communication. Otherwise you will be enrolled as long as we are doing MCC research.

CONFIDENTIALITY

We will keep your medical records confidential, but we cannot guarantee total confidentiality. Your personal information may be given out if required by law. Some organizations may need to look at your records for research, quality assurance, or data analysis. These include the institutions involved in this study, their institutional review boards (groups who review the study to protect your rights), and the US National Institutes of Health, National Cancer Institute, Office of Human Research Protections, and other agencies as required.

The greatest risk in this study is the release of information from your health records. This risk is very small. If a breach of confidentiality is discovered during the study, the Principal Investigator will report it immediately to the Institution as required.

FOR MORE INFORMATION

If you have questions about this study, please call Dr. Paul Nghiem at 206-221-4594 (study related questions only, please). If you have questions about your rights as a research participant, call Karen Hansen in the Hutchinson Center's Institutional Review Office at 206-667-4867.

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SIGNATURE

If you have read this form (or had it read to you), asked any questions, and agree to participate, please check yes or no for each box and then sign below:

YES <input type="checkbox"/>	Use of <u>leftover tissue</u> samples for MCC research, including previously removed tissue and leftover tissue that may be removed as part of future, medically necessary treatment.
NO <input type="checkbox"/>	
YES <input type="checkbox"/>	Having <u>blood</u> drawn. This will be stored and used only for MCC research purposes.
NO <input type="checkbox"/>	
YES <input type="checkbox"/>	Release of my <u>case history</u> to the Nghiem lab for MCC research, including storage of my de-identified medical information in a database. I also consent to being contacted in the future as needed to follow my progress over time.
NO <input type="checkbox"/>	
YES <input type="checkbox"/>	<u>Being contacted</u> if the MCC study team learns of a discovery that could importantly affect the management of my MCC.
NO <input type="checkbox"/>	

Participant or Legal Guardian	Date	MCC Study Personnel	Date
			<input type="checkbox"/> In person
			<input type="checkbox"/> Phone contact
			(Check one)

Name (Print clearly): _____

Email: _____

Phone (home): _____

(cell): _____

Address: _____

If not signing in person, please mail or fax **this signed page only** to:

Paul Nghiem, MD, PhD
815 Mercer St.
Seattle, WA 98109
Fax: 206-221-4364

FHCRB IRB Approval	
Consent Released Date	<u>9/22/08</u>
Consent Expiration Date	<u>8/26/09</u>