University of Pennsylvania
Research Subject Authorization – Confidentiality & Privacy Rights

PROTOCOL TITLE: CLINICALLY USEFUL PROGNOSTIC MODELS IN PRIMARY MELANOMA

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As a patient of the University of Pennsylvania Pigmented Lesion Group you have given consent for the use of your medical record and residual surgical material for medical education and research. In the study referred to above, the co-Principal Investigators, as well as physicians and research scientists of the Pigmented Lesion Group will use information from your medical record and information about the characteristics of your residual surgical material. Our goal is to make use of this information to better understand the causes and consequences of skin cancer, evaluate new diagnostic tests and treatments for skin cancer, as well as to disseminate these results to the medical and scientific community. This authorization form gives additional information about how your health information will be protected and includes:

- **What personal health information about you will be collected in this study.**
- **Who will use your information within the institution any why.**
- **Who may disclose your information and to whom.**
- **Your rights to access research information about you.**
- **Your right to withdraw your authorization (approval) for any future use of your personal health information.**

By signing this document you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study.

- **What personal health information is collected and used in this study, and might also be shared (disclosed)?**

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study.

  - Name, address, and telephone number
  - Information from physical examinations, tissue samples, biopsies, laboratory tests, x-rays, scans, medications, and photographs of your skin and such things as moles and skin cancers.
  - Past history of sun exposure and the response of your skin to it, as well as your history of past skin and other cancers.
  - Family medical history.

- **Why is your personal health information being used?**

Your personal contact information is important for the University of Pennsylvania Health System and School of Medicine research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The medical doctors of the Pigmented Lesion Group also use the results of the tests and procedures to treat you.

- **Which of our personnel may use or disclose your personal health information?**

The following individuals and organizations may use or disclose your personal health information for this research project:

  - The co-Principal Investigators, the physicians and research scientists of the Pigmented Lesion Group, and their study team (other University staff associated with the study).
  - The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs.
  - The University of Pennsylvania Office of Human Research (the office which monitors research studies).
  - Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

- **Who outside of the University of Pennsylvania Health System and School of Medicine might receive your personal health information?**

As part of the study the co-Principal Investigators, physicians and research scientists of the Pigmented Lesion Group, their study team and others listed above may disclose your personal health information, including the results of the research study tests and procedures to the following:

  - Collaborating academic research centers and hospitals: Wistar Institute, University of California at San Francisco, Harvard University, Abbington Hospital and other institutions including those that are part of the Specialized Program of Research Excellence in Skin Cancer sponsored by the National Cancer Institute where investigators are working in collaboration with PENN investigators to study causes and consequences of skin cancer, and new diagnostic tests and therapies related to skin cancer and to educate the public and health care professionals.
  - Government agency and/or their representative: the National Cancer Institute that has provided funding for this research study.

Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations.

  - However, in all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless law requires disclosure.
  - Additionally, in records and information disclosed outside of the University of Pennsylvania Health System and School of Medicine, you will be assigned a unique code number. The co-Principal Investigators will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

- **How long will the University of Pennsylvania Health System and School of Medicine be able to use or disclose your personal health information?**

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research database. However, the University of Pennsylvania Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for a purpose other than the research described in this document unless you have given written permission to the co-Principal Investigators to do so. Nevertheless, the University of Pennsylvania Institutional Review Board may grant permission to the co-Principal Investigators or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care *will not* be included in your medical record.

- **Will you be able to access your records?**

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigators are not required to release to you research information that is not part of your medical record.

- **Can you change your mind?**

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to one of the co-Principal Investigators at the address on the first page. Even if you withdraw your permission, the co-Principal Investigators for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that mean you will also be withdrawn from the research study.

If you withdraw your permission to use any tissue, the co-Principal Investigators will ensure that all information that could identify you is removed from the research database.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document you are permitting the University of Pennsylvania Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

_____	_____	_____
Name (print)	Signature	Date