PENN MEDICINE RESEARCH SUBJECT COMBINED INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:	PARPVAX: A Phase 1B/2, open label study of Niraparib plus either Ipilimumab or Nivolumab in patients with advanced Pancreatic Cancer whose disease has not progressed on platinum- based therapy
Funding Supporters:	Bristol-Myers Squibb and TESARO, Inc. a GlaxoSmithKline (GSK) Company
Regulatory Sponsor	University of Pennsylvania
Principal Investigator:	Kim Reiss Binder, MD Abramson Cancer Center of the University of Pennsylvania Philadelphia, PA 19104 215-360-0735
Sub-investigators:	[redacted]
Emergency Contact:	24 Hour Emergency – Call 215-662-4000 Ask for Oncologist On-Call

Summary

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.
You are being invited to participate in a research study because you have pancreatic cancer. This research study is designed to learn more about the safety and effectiveness of drugs niraparib with either ipilimumab or nivolumab given to individuals who have been diagnosed with pancreatic cancer. You may or may not receive direct medical benefit from participating in this study. The hope is that this study treatment may provide a new treatment option for patients with pancreatic cancer, however, such a benefit cannot be guaranteed.

If you agree to join the study, you will be asked to complete the following research procedures: research blood tests and tumor biopsy. Additional procedures that are consistent with your standard of care treatment will also be performed.

Your participation will last up to until your disease progresses or you experience side effects that require treatment be stopped. Even after you discontinue study treatment, you will be contacted 30 days, 90 or 100 days and then annually by a study team representative who will ask questions about your health.
The following are some of the most commonly observed side effects: with Niraparib decreased blood cells such as white blood cells, red blood cells, and platelets; with Nivolumab fatigue, rash, diarrhea, and with Ipilimumab increased liver enzymes. . There is always the possibility that unknown risks and side effects may occur. These may be mild or very serious, and in some cases, may be very serious, long-lasting, or may never go away. There may also be a risk of death.

Other treatment options may be available to you. These could include treatment of your symptoms, without any effect on your disease, and/or treatment with currently approved drugs for pancreatic cancer .