Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798

DATE:	December 20, 2019
TO:	Lisa B Shields
FROM:	The University of Louisville Institutional Review Board
IRB#:	19.1288
STUDY TITLE:	Testicular Cancer and Risk of Venous Thromboembolism
REFERENCE #:	698670
IRB STAFF CONTACT:	Sherry Block 852-2163 slbloc04@louisville.edu

This study was reviewed on 12/18/2019 and determined by the Chair/Vice-Chair of the Institutional Review Board that the study is exempt with changes according to 45 CFR 46.101(b) under Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: i. The identifiable private information or identifiable biospecimens are publicly available; ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

The changes were reviewed and approved by HSPPO staff on 12/20/2019

This study was also approved through 45 CFR 46.116 (D), which means that it has been granted a waiver of informed consent.

Documents/Attachments reviewed and approved:

Submission Components			
Title	Version #	Version Date	Outcome
Testicular Cancer and Venous Thromboembolism IRB Protocol	Version 1.0	12/09/2019	Approved
Testicular Cancer and Venous Thromboembolism Data Collection Tool Shields	Version 1.0	12/09/2019	Approved
Request for Waiver of HIPAA Research Authorization	Version 1.0	12/09/2019	Approved

Requirements for an exempt study:

- Any study documents submitted with this protocol must be used in the form in which they were approved.
- Human Subjects & HIPAA Research training are required for all study personnel. It is the responsibility of the investigator to ensure that all study personnel maintain current Human Subjects & HIPAA Research training while the study is ongoing.
- Personnel amendments must be submitted to the IRB to add/remove research personnel from your study team.
- If your research focus or activities change, please submit an Amendment to the IRB for review to ensure that the indicated exempt category still applies.

Additional reporting, such as submission of continuation reviews, is not required.

For guidance on using iRIS, including finding your approved documents, please follow the instructions at https://louisville.edu/research/humansubjects/iRISSubmissionManual.pdf

Site Approval

Permission from the insitution or organization where this research will be conducted **must** be obtained before the research can begin. For example, site approval is required for research conducted in UofL Hospital/UofL Health, Norton Healthcare, and Jefferson County Public Schools, etc...

Privacy & Encryption Statement

The University of Louisville's Privacy and Encryption Policy requires identifiable medical and health records; credit card, bank account and other personal financial information; social security numbers; proprietary research data; and dates of birth (when combined with name, address and/or phone numbers) to be encrypted. For additional information: http://louisville.edu/security/policies.

Implementation of Changes to Previously Approved Research

Prior to the implementation of any changes in the approved research, the investigator must submit modifications to the IRB and await approval before implementing the changes, unless the change is being made to ensure the safety and welfare of the subjects enrolled in the research. If such occurs, a Protocol Deviation/Violation should be submitted within five days of the occurrence indicating what safety measures were taken, along with an amendment to revise the protocol.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)

A UPIRTSO is any incident, experience, or outcome, which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research

places subjects or others at a greater risk of harm than was previously known or suspected. The investigator is responsible for reporting UPIRTSOs to the IRB within 5 working days. Use the UPIRTSO form located within the iRIS system. Event reporting requirements can be found at: http://louisville.edu/research/humansubjects/lifecycle/event-reporting.

Payments to Subjects

In compliance with University policies and Internal Revenue Service code, payments to research subjects from University of Louisville funds, must be reported to the University Controller's Office. For additional information, please call 852-8237 or email controll@louisville.edu. For additional information: http://louisville.edu/research/humansubjects/policies/PayingHumanSubjectsPolicy201412.pdf

We value your feedback; let us know how we are doing: https://www.surveymonkey.com/r/CCLHXRP

Julie L. Goldman, MD, Vice Chair
Biomedical Institutional Review Board
JG/slb