SOP 602H: Stephenson Cancer Center Scientific Review Committee

1. POLICY

The Scientific Review Committee (SRC) of the Stephenson Cancer Center (SCC) shall review cancer-related research for scientific merit and SCC priority prior to IRB review. The SRC shall provide review and feedback to investigators, who will forward SRC-approved submissions to the IRB for review of research participant protection issues.

Specific Policies

1.1 SRC & IRB Interaction

The IRB shall review cancer-related research projects following review by the SRC. The SRC approval letter shall be included as part of the IRB submission. SRC deliberations shall not be shared with the IRB unless specific participant protection issues are raised by the SRC. The SRC letter shall either indicate approval or state issues of concern raised by the SRC.

2. SCOPE

This SOP applies to all cancer-related human participant research.

3. RESPONSIBILITY

3.1 The investigator is responsible for submitting all new cancer-related research projects to the SRC prior to submission to the IRB.

3.2 The SRC will forward the SRC approval letter to the investigator and to the IRB once the SRC review is complete.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

21 CFR 56.111

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 301: Research Submission Requirements

SOP 302: Administrative Review & Distribution of Materials

SOP 401: Research Exempt from IRB Review

SOP 402: Expedited Review


6. ATTACHMENTS

305-C Reviewer Checklist

602H-A Cancer Center Scientific Review Committee Approval Letter

7. Process Overview

7.1 The investigator submits all cancer-related research projects to the SRC for review. If this procedure has not taken place prior to submission to the IRB, the
IRB Administrator returns the submission to the investigator for completion of SRC review.

7.2 Following SRC review, the SRC forwards a letter to the investigator indicating SRC approval or areas of concern, with copy to the HRPP Office.

7.3 The investigator submits the approved cancer-related project to the IRB in accordance with SOP 403. The HRPP Office processes submitted documents per SOP 301, Research Submission Requirements; and SOP 302, Administrative Review and Distribution of Materials.

7.4 The project is reviewed per SOP 401: Research Exempt from IRB Review; SOP 402: Expedited Research; or SOP 403: Initial Review Criteria for IRB Approval, as applicable.

APPROVED BY: _____________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016