SOP 602H: STEPHENSON CANCER CENTER
PROTOCOL REVIEW AND MONITORING COMMITTEE

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

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

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 PRMC prior to submission to the IRB.
3.2 The PRMC will forward the PRMC approval letter to the investigator and to the IRB once the PRMC 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 PRMC Approval Letter
7. PROCESS OVERVIEW

7.1 The investigator submits all cancer-related research projects to the PRMC 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 PRMC review.

7.2 Following PRMC review, the PRMC forwards a letter to the investigator indicating PRMC 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: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020