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**Submission of a New Protocol for PRMC Review**

**Part A: Basic Information**

Before completing this form, please review the Submission Instructions on the PRMC website: [http://www.augusta.edu/cancer/research/toolbox/prmc/submit.php](http://www.augusta.edu/cancer/research/toolbox/prmc/submit.php%20) . If you have any questions on how to fill out this form or questions related to this process, please call (706) 721-0730 or email prmc@augusta.edu.

## Protocol Information

***All submitted protocols must be in final format. No draft protocols or pre-finalized versions will be accepted.***

**Study Title:**

**PI:**

**Study Type:** [ ] Therapeutic [ ]  Non-therapeutic

**Type of Sponsor:** [ ] Investigator-Initiated [ ] Pharmaceutical

[ ] Cooperative Group/NCI [ ] Outside Institution

**Sponsor Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Will this trial be conducted at GCC/AU Health Center?   [ ]  Yes [ ]  No

Will this trial be conducted at multiple sites within AU Health Center? [ ] Yes [ ] No

Please specify sites:

Will this trial be conducted at multiple sites nationally or internationally? [ ] Yes [ ] No

Please specify number of sites:

Does the Study require a local IND application? [ ] Yes\* [ ] No

\*If yes, please specify who will be the IND holder?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Disease Group Leader(s) Sign-Off**

All cancer-related protocols must be reviewed by the applicable Georgia Cancer Center Disease-Oriented Working Group (DOWG) Leader(s) and competing studies and priority issues adequately discussed. ***Please Note****: For PRMC submission packet, you will be required to attach a Support Letter from a DOWG Leader.*

Check each DOWG that applies:

[ ]  Gynecologic Oncology (Gyn Onc) *~ Sharad Ghamande, MD*

[ ]  Hematology-Oncology & Bone Marrow Transplantation (Heme/BMT) ~ *Anand Jillella, MD*

[ ]  Pediatric Oncology (Ped Onc) *~ Colleen McDonough, MD*

[ ]  Radiation Oncology (Rad Onc) ~ *John Barrett, MD, PhD*

[ ]  Solid Tumor ~ *Jigarkumar Parikh, MD*

**Biostatistician Sign-Off**

All Augusta University investigator-initiated studies must be reviewed by a biostatistician. A Biostatistician Support Letter must be signed off on and submitted with the PRMC submission packet

**Does this study compete with any current/future Cancer Center studies in this specific disease area?**   [ ] Yes [ ] No

Please list all competing trials and prioritize below (more can be listed on a separate sheet):

Protocol #: [ ]  Highest (1st) [ ]  High (2nd) [ ]  Priority Other:

Protocol #: [ ]  Highest (1st) [ ]  High (2nd) [ ]  Priority Other:

**Part B: Requirement Checklist**

***Please Note:*** *The protocol will not be put on the PRMC meeting agenda until the PRMC receives a completed submission packet, which will include the following:*

[ ]  This Completed Submission form

[ ]  Completed Routing Sheet

 *Note: there are two types of Routing Sheet depending on the type of sponsor.*

* *“Routing Sheet for Full Review” is for Pharmaceutical or investigator-initiated studies.*
* *“Routing Sheet for Expedited Review” is for Cooperative Group studies.*

[ ]  DOWG Support Letter(s)

[ ]  Biostatistician Support Letter (for Augusta University investigator-initiated studies only)

[ ]  Protocol, Appendices, and Investigator Brochure, if applicable