The Protocol Review and Monitoring Committee (PRMC) has undergone many changes within the last six months. Some of those changes were announced in an email memo distributed on June 25, 2015. Click here to log into the Commons to view the June announcement, or click here to see it on the UVMCC website. Below are some additional changes to the PRMC and related processes.

Summary:

1. PRMC no longer reviews retrospective chart review studies.
2. Initial protocol submissions must be done by electronic submission on the UVM Commons starting in January 2016.
3. PRMC only requires one copy of a protocol amendment. Some may not be reviewed by the committee.
4. All studies will need to submit accrual data quarterly to the PRMC.
5. PRMC will assign a “Level of Risk” to investigator-initiated studies.
6. PRMC will start reviewing accrual data for all studies.
7. Reminders: submit all closure to accrual and permanent closure notices to the PRMC; any amendments involving recruitment changes do not need to be submitted to the PRMC; the only key personnel changes needing PRMC submission are for PI or primary/key contact.

1. PRMC Review of Studies

The Change: The PRMC only reviews studies that involve participants OR are lab-based and utilize human specimens.

How this changes your role: If a PI has a non-human specimen laboratory study or a retrospective chart review, it does not need to be submitted to the PRMC.

2. How to Submit a Protocol: Initial Submission

The Change: As of January 1st, 2016, new protocols must be submitted electronically through the UVM Commons (https://commons.med.uvm.edu/cp/uvmcc/prmc/default.aspx) and only one hard-copy of protocol documents, instead of 5 to 9 copies depending on study type.

How this changes your role: Instead of submitting multiple paper copies, you can simply upload the documents to the Commons. Training on the Commons will be offered by Emily Harwood on December 2nd at 3pm in Med Ed 204 and December 7th at 3pm in Courtyard S359. If you cannot attend those trainings, please arrange a time to meet with Emily individually.

3. What to Submit for a Protocol: Amendments

The Change: All amendments must continue to be submitted to the PRMC Coordinator, however, they will either be reviewed by the Full Committee or simply acknowledged depending on the nature of the proposed changes.

How this changes your role: Instead of submitting many copies of Amendment documents, please submit one copy of the Amendment documents to the PRMC Coordinator by email and you will be notified if more information is needed or not.
4. What to Submit for a Protocol: Quarterly Reports

The Change: All cancer studies approved by the PRMC, regardless of type (investigator-initiated, cooperative group, industry) must submit the new Quarterly Report Form to the PRMC Coordinator on a routine basis. Additional information regarding screened and screen-failed patients is required on the form. Lab studies will submit a Study Progress Report semi-annually.

How this changes your role: You will need to complete the Quarterly Report Form for each of your studies and submit them to the PRMC Coordinator quarterly. This may mean that you need to change your own tracking methods for patients screened, screen-failed, enrolled, and withdrawn in order to fill out the Quarterly Report Form.

5. For Your Information: PRMC Will Assign Level of Risk

The Change: A level of risk will be assigned to interventional investigator-initiated studies.

How this changes your role: The Approval Memo that you receive from the PRMC will include a risk level assignment. You will need to refer to this risk level when you fill out the Quarterly Report (see the section about Quarterly Reports). The assigned risk level will also determine the level of oversight provided by the soon-to-be-formed Data Safety and Monitoring Committee (DSMC).

6. For Your Information: PRMC Will Be Tracking Accrual

The Change: All cancer studies approved by the PRMC, regardless of type, will be monitored by the PRMC for progress (accrual of patients and/or analysis of specimens).

How this changes your role: You and the PI may be notified by the PRMC regarding accrual status and accrual rates.

7. Reminders:

Additional changes were announced on June 25, 2015 via email. Please click here to log into the Commons and view the memo from 6/25/15. You can also find the June 2015 memo by clicking here.

Please see the PRMC website for additional details regarding the documents required for submissions to the committee.

The PRMC website home page is:
http://www.uvm.edu/medicine/vtcancercenter/?Page=protocol.html&SM=protocolsubmenu.html

The PRMC website regarding submission guidelines is:
http://www.uvm.edu/medicine/vtcancercenter/?Page=submission.html&SM=protocolsubmenu.html

If you have any questions, feel free to contact the PRMC Coordinator, Emily Harwood at 656-2967 or by email, Emily.Harwood@med.uvm.edu.