

The PRC is changing!

As of June 10, 2015, the PRC was renamed and revitalized to more closely align with the NCI expectations for scientific review committees.

What does that mean?

- The PRC is officially renamed to the Protocol Review and Monitoring Committee (PRMC)
- PRMC review will focus on scientific merit, prioritization of Cancer Center resources, and progress of approved clinical trials (i.e. accrual)

So what does that mean for you?

Initial Review submission requirements have changed!

- The PRC cover form is no longer required (including the Lab-based cover form)
- A **NEW** Protocol Checklist is now required with ALL submissions
- All interventional protocols that involve multiple departments must be approved by the appropriate Transdisciplinary Team (TDT) **PRIOR** to submission to the PRMC for review.* TDT review/approval is documented on the **NEW** Protocol Checklist. Studies that enroll multiple disease sites and/or do not fall within an established TDT can be submitted by the PI to the PRMC, but still require a completed Protocol Checklist
**Please note that TDT review process has not been finalized. Until that happens, PIs will be temporarily responsible for completing the sections of the new Protocol Checklist that would normally be completed by the TDT. The TDT leaders will be formally notified of their role in reviewing protocols by July 9th. Please contact Emily Harwood, 656-2967, eharwood@uvm.edu, with any questions.*
- All other forms/submission requirements for initial review remain the same

Initial Review timelines have changed!

- NCTN studies and lab-based, chart review or other minimal risk studies can be submitted and will be reviewed on a rolling basis through a new process called “Basic Review”
- All other studies will be reviewed at the Full Committee meeting. The submission deadline for items requiring Full Committee review remains 2 weeks prior to the meeting date. Meeting dates and deadlines are found online: <http://www.uvm.edu/medicine/vtcancercenter/?Page=meeting.html>

Amendment submission requirements have changed!

- Key personnel updates are no longer required UNLESS you are updating the PI or key-contact
- Ads and/or recruitment materials are no longer required and will not be reviewed

Safety submission requirements have changed!

- The PRMC will no longer review external safety reports, Investigator Brochures and/or IB updates, or other non-local safety information
- Local Serious Adverse Event Reports and/or protocol deviations that potentially impact safety are still required to be submitted

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@uvm.edu