

Research Oversight Committee – ANNUAL RENEWAL Submission Checklist

Instructions: Use the ANNUAL RENEWAL TO CONDUCT RESEARCH form for all ROC annual renewals, notification of significant adverse event (unscheduled submission), significant protocol amendment (unscheduled submission) and closure.

Documents for ROC ANNUAL RENEWAL study submission:

- ROC annual renewal to conduct research form (UW Medicine VMC ROC specific form)
- IRB approved renewal (status report) (from your IRB)

If your study has patient consent and/or HIPAA authorization forms*:

- Send a copy of all signed VMC patient consents to the ROC Coordinator (since the last ROC submission)
- Send a copy of all signed VMC patient HIPAA authorization forms to the ROC Coordinator (since the last ROC submission)

If updated since last ROC submission:

- Protocol (study specific – from study sponsor or investigator)
- Informed consent form (s), if applicable (approved document from your IRB)
- HIPAA authorization form(s), if applicable (approved document from your IRB)
- New or updated study materials (Such as case report forms, telephone scripts, advertisement/flyers, educational tools, surveys, questionnaires, etc.) (study specific – from study sponsor or investigator)
- IRB Authorization Agreement (UW Medicine VMC ROC specific form)

Submit new study submission electronically to the ROC Coordinator at: Research@Valleymed.org
Full ROC study submission is due 2 weeks prior to the ROC meeting. Study review and ROC determination will be withheld until the ROC Coordinator verifies the submission is complete.

Day of ROC meeting:

Study staff representative are not required to be present at the ROC meeting. Please contact the ROC Coordinator if you wish to attend the meeting.

Documentation of ROC determination:

The ROC coordinator will email study staff the preliminary results. Formal letter will be sent to study staff via email within 1 week.

If you have any questions regarding ROC or the review process, contact the ROC coordinator at Research@valleymed.org

* Submission of signed consent forms and HIPAA authorization forms are required on a quarterly basis. As per ROC policy, the ROC Coordinator reviews signed consent forms and HIPAA authorization forms. The ROC Coordinator submits the signed forms to HIM for submission into the patients electronic medical record