UW Medicine
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MEDICAL CENTER

RESEARCH OVERSIGHT COMMITTEE
ANNUAL RENEWAL TO CONDUCT RESEARCH

Instructions: Use this form for all ROC annual renewals, notification of significant adverse event (unscheduled submission), significant protocol amendment (unscheduled submission) and closure. Email all submissions to **Research@valleymed.org**. All questions may be directed to the ROC Coordinator at **Research@valleymed.org**.

NAME OF STUDY	
STUDY PERIOD	
IRB NAME (IF APPLICABLE)	
IRB NUMBER (IF APPLICABLE)	
PRINCIPAL SITE OF STUDY	
LEAD INVESTIGATOR NAME	
UW MEDICINE VMC LOCAL CHAMPION (INVESTIGATOR) NAME	
ClinicalTrial.gov #	

Current study status:

i. Continued ROC approval required because:
☐ Enrollment still in progress
☐ Enrollment closed, but participants still active in the research
☐ Enrollment closed, study is active for long term follow-up only
☐ Participant involvement complete; remaining activities limited to analysis or publication
☐ Enrollment not started

ii. ROC approval no longer required because:
☐ Study completed and no further use/analysis of data at this time
☐ Study never started

iii. ROC approval has lapsed and requesting study be re-opened:
☐ Indicate above the study status once re-opened and **explain** the following: (1) why the lapse occurred; (2) whether any research activities occurred with VMC participants after the lapse; and (3) what corrective actions will be taken to prevent future lapses:

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Please attach the following documents for consideration.

- Copy of the current approved IRB renewal letter
- If applicable and updated, a copy of IRB approved Informed Consent form or HIPAA waiver
- Submit all signed VMC patient research informed consent forms and research HIPAA authorization forms to the ROC Coordinator (quarterly submission is required)
- Provide any new/updated additional materials supporting study i.e., DSMB reports, educational brochures, surveys, questionnaires, patient incentives, communication scripts, etc.

Please answer the following questions:

1. Type of study

☐ Medical Record Review
☐ Human Subjects Recruitment for Off-Campus Research (VMC patients recruited, however study will be performed off-campus). Specify type of patient contact:
☐ Direct patient contact ☐ Indirect patient contact
☐ External IRB approval for On-Campus Research (VMC patients recruited, study will be performed on-campus). Specify the type of research:
☐ IND (Investigational New Drug) – IND#_____
☐ IDE (Investigational Device Exemption) – IDE# _____
☐ Other, specify _____
☐ Tissue Collection
☐ Other, specify _____

2. Provide a brief synopsis of the study:

_____

_____

_____

_____

_____

_____

_____

3. Report the current IRB approval period*: _____ to _____
*Submission of current IRB approved renewal (if applicable) is required
☐ Not applicable, study is IRB exempt

4. Please provide an update on your enrollment

Patient enrollment	Number of patients enrolled since the last ROC approval	Number of patients enrolled overall
Study wide – all sites (if applicable)		
All patients enrolled through your center		
VMC patients*		

*If your study has a research consent and/or HIPAA, submit copies of all signed research consents and/or HIPAA forms from VMC patients on a quarterly basis. The ROC Coordinator will verify enrollment numbers based on consents submitted on an annual basis (at the annual renewal time point). The ROC Coordinator will ensure the consent is in the VMC electronic medical record.

5. Please provide a brief progress report of your study

6. Is the overall enrollment proceeding as expected?
☐ No, please explain below
☐ Yes

7. Have you seen any significant adverse events* on the patients enrolled/treated?
   - ☐ No
   - ☐ Yes, please explain below

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*Significant adverse event is defined as any of the following:
1. Death of a patient treated by the investigator/study staff,
2. A serious adverse event of a patient treated by the investigator/study staff per sponsor definition
3. Halt of study per Data Safety Monitoring Board (or equivalent) due to adverse event(s)

8. Have you received any complaints from VMC study participants or others during the current approval period?
   - ☐ No
   - ☐ Yes, please detail below and attach the new/updated study materials

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9. Have there been any issues/problems with any billable services (whether to a patient, insurance, study account or study sponsor)?
   - ☐ No
   - ☐ Yes, please detail below

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10. Has there been a change to either the investigator or study staff's financial relationship with the study sponsor?

- ☐ NA
- ☐ No
- ☐ Yes*

*If yes, please describe: _____

11. Are there any new/updated study materials within the past reporting period*?

- ☐ No
- ☐ Yes, please detail below and attach the new/updated study materials

*Including DSMB reports, educational brochures, surveys, questionnaires, patient incentives, communication scripts, etc.

12. Has any IRB modifications or amendments been approved within since the last review that affects VMC?

- ☐ No
- ☐ Yes, please detail below and attach the approved IRB modification(s)

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ATTACHMENT CHECKLIST

Please indicate the applicable attachments (completion of this section is mandatory).
Submit 1 copy electronically to Research@valleymed.org.

Current approved IRB renewal (status report)	☐ **Yes** ☐ **No** ☐ **NA**
IRB approved informed consent form, if applicable and updated	☐ **Yes** ☐ **NA**
IRB approved HIPAA authorization form, if applicable and updated	☐ **Yes** ☐ **NA**
VMC patient signed Informed consent form(s)* *Since the last ROC approval. Consents need to be submitted quarterly to the ROC Coordinator.	☐ **Yes** ☐ **No** ☐ **N/A, study is exempt**
VMC patient signed HIPAA authorization form(s)* *Since the last ROC approval. HIPAA authorization forms need to be submitted quarterly to the ROC Coordinator.	☐ **Yes** ☐ **No** ☐ **N/A, study is exempt**
New/updated study materials Such as case report forms, telephone scripts, advertisement/flyers, educational tools, surveys, questionnaires, etc.	☐ **Yes** ☐ **No** ☐ **NA**
IRB modification(s) that affect VMC* *Since the last ROC approval	☐ **Yes** ☐ **No** ☐ **NA**

Please be advised that submission of this renewal application to the Research Oversight Committee at UW Medicine Valley Medical Center does not subject approval of your study/research at UW Medicine Valley Medical Center. UW Medicine Valley Medical Center does not accept any liability or responsibility for any study/research unless you receive a signed and dated approved letter from the UW Medicine Valley Medical Center Research Oversight Committee.

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UW Medicine Valley Medical Center Research Oversight Determination (ROC use only)

Type of review*: ☐ Full ROC review ☐ Expedited review

Study Status: ☐ Approved ☐ Conditional approval ☐ Deferral ☐ Disapproval ☐ Suspension ☐ Closed

UW Medicine VMC ROC Co-Chairperson:

Signature _____ Date: _____

ROC Approval Valid Through: _____

*Assessed by ROC Coordinator

If expedited review:

Study Status: ☐ Approved ☐ Conditional approval ☐ Deferral ☐ Disapproval ☐ Suspension ☐ Closed

UW Medicine VMC ROC Co-Chairperson:

Signature _____ Date: _____

IRB APPROVAL must be kept current in order to conduct research at UW Valley Medical Center

Study Status Definitions as per the ROC Policy:

APPROVAL: The submission is approved by the ROC. The activity may be conducted within the constraints (if any) established by the ROC. No changes or additional information are required and all of the applicable criteria for ROC approval are met.

CONDITIONAL APPROVAL: The ROC has determined that the applicable criteria for ROC approval have been met, based on the assumption that specific conditions will be met by the investigator and subsequently verified.

DEFERRAL: The ROC is unable to approve the research because it cannot make the determinations required for approval (i.e. the applicable criteria for IRB approval have not been met). The ROC defers the item for further review at a future date after the additional information has been provided by the investigator.

DISAPPROVAL: If the investigator and the ROC Coordinator are unable to agree on whether the investigator's response satisfies the conditions, they consult with the ROC Co-Chairs. If no agreement can be reached, the response to the conditional approval letter must come back to the ROC for review. This is considered "re-review." Approval criteria and waivers must be reconsidered, approval dates change, and the application submission is re-signed.

SUSPENSION: ROC approval for some or all parts of an approved research study is temporarily withdrawn. Suspension is not available through an expedited review process.

CLOSURE: The ROC approval for some or all parts of an approved research study is permanently withdrawn.