

RESEARCH OVERSIGHT COMMITTEE APPLICATION TO CONDUCT RESEARCH

Instructions: Use this form for all ROC new study applications. Email all submissions to the ROC Coordinator at Research@valleymed.org. All questions may be directed to the ROC Coordinator at Research@valleymed.org.

NAME OF STUDY	
STUDY PERIOD	
CORPORATE SPONSOR (IF APPLICABLE)	
IRB NAME (IF APPLICABLE)	
IRB NUMBER (IF APPLICABLE)	
PRINCIPAL SITE OF STUDY	
LEAD INVESTIGATOR NAME	
LEAD INVESTIGATOR CONTACT INFORMATION (ADDRESS & PHONE NUMBER)	
UW MEDICINE VMC LOCAL CHAMPION (INVESTIGATOR) NAME	
UW MEDICINE VMC LOCAL CHAMPION (INVESTIGATOR) CONTACT INFORMATION (ADDRESS, PHONE NUMBER, & E-MAIL ADDRESS)	
ClinicalTrial.gov #	

Please attach the following documents for consideration.

- Copy of IRB approval letter
- Copy of IRB approved Informed Consent form and/or HIPAA authorization form
- Executed IRB Authorization Agreement form (original copy must be submitted)
- Provide a synopsis and detailed protocol regarding study
- Provide additional materials supporting study i.e., educational brochures, surveys, questionnaires, patient incentives, and communication scripts

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. Please provide a brief synopsis of the study:

3. Has your study been reviewed by an IRB?

- Yes, attach the IRB approval and provide the current IRB approval dates below
IRB approval dates: _____ to _____
 - Pending, application has been submitted to the IRB and approval is pending review*
 - Study has been determined to be IRB exempt, letter from the IRB determining exemption must be submitted to the ROC
 - No, explain below
-
-

*Once available, forward a copy of the IRB approval to the ROC coordinator at Research@valleymed.org

4. Does your study have any billable services (whether to a patient, insurance, study account or study sponsor)?

- No
- Yes, check the appropriate box below:

Study is running through UW. Has your study been reviewed by CRBB at UW Medicine (Clinical Research Billing and Budget office)?

- No
- Yes*
- Not applicable

*If yes, then the ROC Coordinator will contact CRBB directly to obtain billing information

Study is not running through UW. Please identify the services billed to:

Study account/sponsor: _____

Patient/Insurance: _____

5. Does the investigator or study staff have a financial relationship with the sponsor?

- NA
 No
 Yes*

*If yes, please describe: _____

6. Does your study have a potential of significant harm?

- No
 Yes, list risks below or in a supplemental document.

*Potential risks: _____

Any significant adverse events* that occurs during the study will need to be submitted immediately to the ROC.

*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)

7. Does your study have a consent form(s)?

- NA – exempt
 No
 Yes, attach a copy of the consent form(s)*

Title of form(s): _____

*Submit all signed VMC study consents to the ROC coordinator at Research@valleymed.org on a quarterly basis to ensure the consent is placed in the medical record as per VMC policy

8. Does your study have a research HIPAA authorization form(s)

- NA – exempt
- No
- Yes, attach a copy of the research HIPAA authorization form(s)*

Title of form(s): _____

*Submit all signed VMC research HIPAA authorization forms to the ROC coordinator at Research@valleymed.org on a quarterly basis to ensure the consent is placed in the medical record as per VMC policy

9. Does your study have any additional IRB reviewed study materials (such as case report forms, telephone scripts, advertisement/flyers, educational tools, surveys, questionnaires, etc.)?

- No
- Yes, attach a copy of the study material(s)*

Title of form(s): _____

10. Will this study require staff resource at UW Medicine Valley Medical Center?

- No
- Yes, which department(s) will this study impact?

11. Has the study been discussed with and supported by the affected UW Medicine Valley Medical Center department?

- NA
- No*
- Yes*

*Please provide details to either "Yes" or "No" answer.

ATTACHMENT CHECKLIST

Please indicate the applicable attachments (completion of this section is mandatory).

Submit 1 copy electronically to Research@valleymed.org.

Approved IRB application	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
IRB exemption letter	<input type="checkbox"/> Yes <input type="checkbox"/> NA
Protocol	<input type="checkbox"/> Yes
Informed consent form(s)	<input type="checkbox"/> Yes <input type="checkbox"/> N/A , study is exempt. Documentation of waiver is attached.
HIPAA authorization form(s)	<input type="checkbox"/> Yes <input type="checkbox"/> N/A , study is exempt. Documentation of waiver is attached.
Study materials Such as case report forms, telephone scripts, advertisement/flyers, educational tools, surveys, questionnaires, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Executed IRB Authorization Agreement	<input type="checkbox"/> Yes

Please be advised that submission of this 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.

UW Medicine

VALLEY
MEDICAL CENTER

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

Type of review*: <input type="checkbox"/> Full ROC review <input type="checkbox"/> Expedited review
Study Status**: <input type="checkbox"/> Approved <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deferral <input type="checkbox"/> Disapproval <input type="checkbox"/> Suspension <input type="checkbox"/> Closed
UW Medicine VMC ROC Co-Chairperson:
Signature _____ Date: _____
ROC Approval Valid Through: _____
*Assessed by ROC Coordinator **Determined by the ROC Co-Chairperson
If expedited review:
Study Status**: <input type="checkbox"/> Approved <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deferral <input type="checkbox"/> Disapproval <input type="checkbox"/> Suspension <input type="checkbox"/> Closed
UW Medicine VMC ROC Co-Chairperson:
Signature _____ Date: _____
**Determined by the ROC Co-Chairperson
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.