



CTRU Protocol Support Application

This application is required for scientific review and support of protocols coordinated through the Clinical Trials Research Unit

General Protocol Information

Date received in CTRU: Full Protocol Title (list at end of application if necessary): Short Title/Protocol #: Principal Investigator:	Name/Department: PO Box: Phone & Fax: Email:						
CTRU Study Coordinator:							
Sub-Investigator(s): *Additional Sub-I(s)? List names below:	<table border="1"> <thead> <tr> <th style="background-color: #e0ffff;">Name</th> <th style="background-color: #e0ffff;">Department/Secion</th> <th style="background-color: #e0ffff;">PO Box/Email</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Name	Department/Secion	PO Box/Email			
Name	Department/Secion	PO Box/Email					
Sponsor/Granting Agency:	Sponsor Name: Primary Study Contact CRO Sponsor Other Name/Title: Phone: Fax: Email:						

Study Type:

- Therapeutic (Cancer Treatment)
- Non-Therapeutic (Treatment of Chemo or Therapy-Related Adverse Effects)
- Prevention
- Treatment
- Non-Treatment (e.g., QOL Survey)
- Device

Other (Describe)

Study Duration:

Projected Open Date:

Close Date:

****Is the study unusually long in duration? Yes No**

****Is the study unusually complex (i.e. dosing schedule, clinic visits, multiple inpatient procedures)? Yes No**

Please provide additional information that will assist CTRU in preparing the application and consent form, IRB submission, and budgeting—attach to this form or email Leah Darr, Regulatory Specialist ldarr@hsc.wvu.edu

Questions? Please call the CTRU at (304) 293-7374.



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Vulnerable Populations:

Minors	Student/Employee of PI
Hospitalized or institutionalized	Women of childbearing potential
VA Patients	Adults w/impaired decision-making capacity
gametes, embryos, fetuses or tissue from embryos	Prisoners
Target or exclude a particular ethnic or racial group	Exclude fertile women

Accrual:

Accrual goal for all sites

WVU accrual goal

Number of eligible patients seen in past year

**Does the Principal Investigator have access to the study population? Yes No

1. Are the inclusion/exclusion criteria overly restrictive? Yes No
2. Consider the likely screen failure ratio. Will the sponsor pay for screening and/or failures? Yes No N/A
3. Will you need to recruit subjects from external sources? Yes No
If yes, will the sponsor provide funding (explain):

Competing Protocols:

Are there any active protocols that compete with this proposed protocol? Yes No

If yes, please describe actions that will be taken on competing studies:

If concurrent, which study will have priority?

Financial Information

Does the sponsor's preliminary budget appear adequate? Yes No N/A

If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities such as IRB submissions, meetings, or chart reviews? Yes No N/A

Will the sponsor pay for start-up and close-out costs? Yes No N/A

****Study Coordinator please note: Please provide a copy of the proposed protocol and this application to the CTRU accountant and schedule a time to review the budget and other specific financial aspects of the protocol.**

Reimbursement:

Per subject

IRB

Other

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Supplemental Information

Central Laboratory: No central laboratory

Name

Address

Other

WVUH Clinical Labs? Not using Central lab processing *only* Required for lab results

Other outside services: Yes No

Describe:

Special Procedures: (Check box if “yes”)

- Storing blood or tissue samples beyond publication of study results
- Using an existing depository or collection of blood or tissue samples
- Testing for genetic markers on blood or tissue samples
- Administering to subjects recombinant DNA materials

Standard of Care vs. Research? (describe)

Alternatives: (describe)

Questionnaires/Diaries: Yes No (if yes, estimate time for completion and attach copies)

Clinic Visits: Yes No

Clinic Name

Number of visits

Length of visits

CTRU Evaluation Recommendation:

- Do not proceed
- IRB and accounting
- Full support

CTRU Director Signature

Date

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Protocol Review Monitoring Committee (PRMC) Evaluation

Suggested PRMC Reviewers (optional)

**The following individual(s) do not have a conflict with this study and would provide the necessary expertise to evaluate the expertise.*

- 1.
- 2.

Conflict of Interest: (Principal Investigator)

I have no financial interest in the sponsor(s) of this study.

I have significant financial interest in one or more of the sponsor(s) of this study.

*Please describe:

Principal Investigator's Signature

Date

PRMC Action (for PRMC use only)

This protocol was presented and discussed at the RCB HSC PRMC meeting on _____.

PRMC Decision:

Approved with no changes

Approved with recommendations (communicated to PI via letter or email, see attached)

May Proceed to WVU IRB.

Approved with stipulations (communicated to PI via letter or email, see attached)

The Principal Investigator has met the stipulations set forth by the PRMC and this protocol may proceed to the WVU IRB.

Tabled—Returned to Principal Investigator for revision (communicated to PI via letter or email, see attached)

Rejected—Returned to Principal Investigator (contacted by PRMC Chair)

This protocol may not proceed to the WVU IRB at this time.

PRMC Chair Signature

Date

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IRB Submission

*Upon PRMC approval please provide the following documents to CTRU Regulatory Specialist.

Completed and signed CTRU Protocol Support Application

Protocol [Version: _____]

Investigator’s Brochure(s) [Version(s): _____]

IND Safety Reports (must be submitted to IRB with initial application)

Recruitment materials (i.e. advertisements, brochures)

Regulatory documents (please include electronic copies if available)

Tentative Date of IRB Submission:

Regulatory Specialist	Date
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Study Coordinator	Date
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Notes/Comments:

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