PI Preaward Questionnaire

To proceed with the Sponsor requested preaward activities, the PI and/or department must respond to questions regarding the following topics:

•	Revised Budget	•	CITI
•	Export Control	•	Biosafety & Hazardous Materials
•	IACUC	•	Controlled Substances
•	IRB	•	Clinical Trial

Revised Budget

1. Has the sponsor requested a revised line item budget? (If yes, please submit a copy of the revised budget with The completed questionnaire).

Export Control Review

Yes

No

2. Are you aware of any of the following restrictions or Prior approval for dissemination/publication Limitation that will be applied to eventual awards? **Export control restrictions** (Select all that apply). Restrictions on access or participation of foreign nationals

Need for a U.S. government security clearance

3. Are you proposing to provide any deliverables other Yes than reports, publications, and presentations which will No be available to the general public (e.g., proprietary or Not sure restricted dissemination reports, prototypes, models,

4. Do you anticipate receiving technical information that Yes Is not publicly available (e.g., proprietary information No Or U.S. Government limited access from sponsor Collaborators, subcontractors, or vendors)?

Not sure

5. Will military or weapons of mass destruction (items specifically designed or developed for a military or intelligence application), space or encryption (other than ancillary encryption capabilities associated with a commercial item) equipment, software, materials, or components be accessed, used, or developed as part of the proposed activities?

software, and algorithms)?

Yes No Not sure

Intellectual Property Details

6. Do you have background VCU intellectual property that Yes will be used in the performance of this project? No 7. Will you require third party intellectual property for the Yes Performance of this project? Nο 8. Are you a subject matter expert providing services as Yes Part of this sponsored project that are unlikely to No Generate new intellectual property? 9. Will you be creating new knowledge, otherwise known Yes As Intellectual Property (IP), in the course of this No

sponsored project?

If yes, who will be involved in created IP? (Select all that apply).

PI Team members Students

 What form would the IP likely take? (Examples include invention, copyright, trademark, trade secrets). Please also identify types of new knowledge. (Examples include curriculum, software, report, etc.)

11. Does the project rely on existing intellectual property?

Yes No

If yes, describe the existing intellectual property. (Select all that apply).

Intellectual property developed solely at VCU In the public domain Intellectual property owned in whole or in part by another party

If IP owned in whole or in part by another party, who owns it?

If owned in whole or in part by another party, who is authorized to utilize the IP? (Select all that apply).

VCU has authorization from the owner to utilize the IP

VCU's license could/would extend to the Sponsor

Sponsor has/will need authorization from the owner to utilize the IP

12. If necessary, provide any additional details to clarify your answers related to intellectual property.

Preaward Compliance Review

13. For each item listed below, indicate if it is involved in this project:

HIPAA covered data:	Yes	No
Human Subjects:	Yes	No
Laboratory Animals:	Yes	No
Recombinant DNA:	Yes	No
Hazardous Materials:	Yes	No
Radioactive Materials or Radiation Producing Devices:	Yes	No
Select Agents:	Yes	No
Controlled Substances:	Yes	No
Embryonic Stem Cells:	Yes	No

Laboratory Animal Research Details

(Complete if applicable)

- 14. Have you submitted the research related to this project to the IACUC for review?
- 15. Direct funding from PHS requires congruence review of protocol and final science. If applicable, have you submitted for congruency review? You must also list the protocol submitted for congruence review in the associated IACUC studies.
- 16. List all associated IACUC studies:
- 17. If approved by the IACUC, enter the date of approval: (Please provide a copy of the approval letter with the completed questionnaire).
- 18. If approval is pending, enter the date the protocol was Submitted to the IACUC:

Human Subject Research Details

(Complete if applicable)

- 19. Have you submitted the research related to this project to the IRB for review?
- 20. Direct funding from PHS requires congruence review of protocol and final science. If applicable, have you submitted for congruency review? You must also list the protocol submitted for congruence review in the associated IRB studies.
- 21. List all associated IRB studies:
- 22. If approved by the IRB, enter the date of approval: (Please provide a copy of the approval letter with the completed questionnaire).
- 23. If approval is pending, enter the date the protocol was Submitted to the IRB:
- 24. Identify individuals who will have contact with human subjects. (Please provide a copy of the CITI training certificate for all individuals listed with the completed questionnaire).

Yes No

Yes Not yet, but will submit No congruence review required

Yes No

Yes Not yet, but will submit No congruence review required

Recombinant DNA Research Details

32. Have you submitted your protocol to Chemical/

Biological Safety (OEHS)?

(Complete if applicable)

25. Have you submitted a Memorandum of Understanding Yes and Agreement (MUA) to Chemical/Biological Safety No (OEHS)? 26. Is the research related to this project approved by the Approved Institutional Biosafety Committee (IBC) or pending review? Pending Not yet submitted 27. If IBC approval is pending, enter the date the protocol was submitted to the IBC. Provide IBC protocol # if available: 28. If approved by the IBC, enter the date of approval. Provide IBC protocol #: **Hazardous Material Usage Details** (Complete if applicable) 29. Have you submitted your protocol to Chemical/ Yes Biological Safety (OEHS)? No 30. Is the use of hazardous material related to this project Approved Approved by the Safety Committee or pending review? Pending If approved, enter date of approval: Provide registration #: Radioactive Materials or Radiation Producing Devices Details (Complete if applicable) 31. Have you submitted your application and protocol Yes To Radiation Safety (OEHS)? No **Select Agent Details** (Complete if applicable)

Yes

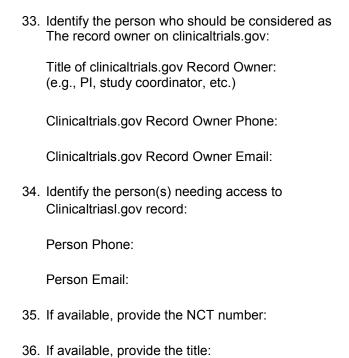
No

Clinical Trial Details

(Complete if applicable)

All clinical trials must be registered on clinicaltrails.gov. Registration is the PI's responsibility if the CT is investigator-initiated. Registration is the sponsor's responsibility if the CT is sponsor-initiated.

Investigator Initia	ted Trial Details
(Complete if application	able)



Sponsor Initiated Trial Details

(Complete if applicable)

- 37. Provide the NCT number:
- 38. Provide the title: