PI Name:

FP Number:

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).
   - ○ Yes
   - ○ No

Export Control Review

2. Are you aware of any of the following restrictions or Limitation that will be applied to eventual awards? (Select all that apply).
   - ☐ Prior approval for dissemination/publication
   - ☐ Export control restrictions
   - ☐ 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 than reports, publications, and presentations which will be available to the general public (e.g., proprietary or restricted dissemination reports, prototypes, models, software, and algorithms)?
   - ○ Yes
   - ○ No
   - ○ Not sure

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

Intellectual Property Details

6. Do you have background VCU intellectual property that will be used in the performance of this project?
   - ○ Yes
   - ○ No

7. Will you require third party intellectual property for the Performance of this project?
   - ○ Yes
   - ○ No

8. Are you a subject matter expert providing services as Part of this sponsored project that are unlikely to Generate new intellectual property?
   - ○ Yes
   - ○ No

9. Will you be creating new knowledge, otherwise known As Intellectual Property (IP), in the course of this
   - ○ Yes
   - ○ No

sponsored project?

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

- ☐ PI
- ☐ Team members
- ☐ Students

10. 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?
    - ○ Yes
    - ○ No

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.
    - ○ Yes
    - ○ Not yet, but will submit
    - ○ No congruence review required

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?
    - ○ Yes
    - ○ No

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.
    - ○ Yes
    - ○ Not yet, but will submit
    - ○ No congruence review required

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).

Recombinant DNA Research Details
(Complete if applicable)

25. Have you submitted a Memorandum of Understanding and Agreement (MUA) to Chemical/Biological Safety (OEHS)?
    - ○ Yes
    - ○ No

26. Is the research related to this project approved by the Institutional Biosafety Committee (IBC) or pending review?
    - ○ Approved
    - ○ 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/ Biological Safety (OEHS)?
    - ○ Yes
    - ○ No

30. Is the use of hazardous material related to this project Approved by the Safety Committee or pending review?
    - ○ Approved
    - ○ 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 To Radiation Safety (OEHS)?
    - ○ Yes
    - ○ No

Select Agent Details
(Complete if applicable)

32. Have you submitted your protocol to Chemical/ Biological Safety (OEHS)?
    - ○ 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 Initiated Trial Details
(Complete if applicable)

33. Identify the person who should be considered as The record owner on clinicaltrials.gov:

    Title of clinicaltrials.gov Record Owner: (e.g., PI, study coordinator, etc.)

    Clinicaltrials.gov Record Owner Phone:

    Clinicaltrials.gov Record Owner Email:

34. Identify the person(s) needing access to Clinicaltriasl.gov record:

    Person Phone:

    Person Email:

35. If available, provide the NCT number:

36. If available, provide the title:

Sponsor Initiated Trial Details
(Complete if applicable)

37. Provide the NCT number:

38. Provide the title: