Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.
SRC/IACUC/IBC approval required before experimentation.

Student's Name(s) Enyo Okeoma

Title of Project Semen extracellular vesicles (SEVs) contain proteins that inhibit HIV-1 reverse transcriptase RNA-dependent DNA polymerization in vitro

To be completed by the QUALIFIED SCIENTIST/DESIGNATED SUPERVISOR in collaboration with the student researcher(s). All questions are applicable and must be answered; additional page(s) may be attached.

SECTION 1: PROJECT ASSESSMENT

1. Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism.

   HIV RT, blood EVs, seminal EVs. HIV RT is a recombinant enzyme from HIV. Blood and seminal plasma EVs will be isolated from blood and semen of anonymous donors. The concentration of HIV RT used ranged from 0.04 to 2 units/µl. Blood and seminal EV concentrations are between 1 to 5 µg/ml for blood and 1 to 10 µg/ml for seminal EVs. These materials are used under BSL2+.

2. Describe the site of experimentation including the level of biological containment.

   Experiments will be conducted in the Okeoma lab at Stony Brook University. The laboratory is located on the 7th floor of the health sciences building. The experiments will be conducted under BSL2+.

3. Describe the procedures that will be used to minimize risk (personal protective equipment, hood type, etc.).

   All investigators must take safety training: ELS 002, ELS 003, ELS 009, ENV 001, ENV 005, and EOS 004, and associated quizzes prior to experimentation. Safety protocol goes as shown in these trainings. Experiments must be conducted with personal protective equipment, such as latex gloves and 100% cotton lab coats. All biohazardous materials will be disposed of in the appropriate biohazard container and subsequently autoclaved by designated lab members prior to disposal.

4. What final biosafety level do you recommend for this project given the risk assessment you conducted?

   BSL2+

5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

   All biohazardous materials will be disposed of in the appropriate biohazard container and subsequently autoclaved by designated lab members prior to disposal.

SECTION 2: TRAINING

1. What training will the student receive for this project?
   Prior to experimentation, all investigators must take required safety training and associated quizzes.
2. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable).
   13 years experience of safe research using hazardous biological materials

SECTION 3: For ALL CELL LINES, MICROORGANISMS AND TISSUES – To be completed by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR - Check the appropriate box(es) below:

☐ Experimentation on the microorganisms/cell lines/tissues to be used in this study will NOT be conducted at a Regulated Research Institution, but will be conducted at a (check one) ☐BSL-1 or ☐BSL-2 laboratory. This study has been reviewed by the local SRC and the procedures have been approved prior to experimentation.

☑ Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution and was approved by the appropriate institutional board prior to experimentation; institutional approval forms are attached.
Origin of cell lines:_____ Date of IACUC/IBC approval ~~09/11/19~~ 09/11/19

☐ Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution, which does not require pre-approval for this type of study. The SRC has reviewed that the student received appropriate training and the project complies with ISEF rules.

CERTIFICATION – To be SIGNED by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR

The QS/DS has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above. This study has been approved as a (check one) ☐ BSL-1/ ☑ BSL-2 study, and will be conducted in an appropriate laboratory.

Hussein Kaddour — QS/DS Printed Name

Signature

11/02/19
Date of review (mm/dd/yy)

SECTION 4: CERTIFICATION – To be completed by the LOCAL or AFFILIATED FAIR SRC

The SRC has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above.

SRC Printed Name

Signature

Date of review (mm/dd/yy)