# 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) Victoria Levy, Vimala Alagappan

Title of Project The Effect of Fibrin on the Differentiation of Dental Pulp Stem Cells

**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.

   Dental Pulp Stem Cells (BSL 2) from Stony Brook School of Dental Medicine
2. Describe the site of experimentation including the level of biological containment.

   Stony Brook University - BSL 2
3. Describe the procedures that will be used to minimize risk (personal protective equipment, hood type, etc.).

   Safety googles, lab coats, gloves, etc. All cell work will be conducted in the biosafety cabinet.
4. What final biosafety level do you recommend for this project given the risk assessment you conducted?

   Biosafety Level 2
5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

   Cultured materials will be disposed of in labeled biohazard waste and removed by EH&S

**SECTION 2: TRAINING**

1. What training will the student receive for this project?

   Biosafety training; formaldehyde training; blood borne pathogen training
2. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable).

   PhD and Laboratory Director

**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: Primary Tissue Culture Date of IACUC/IBC approval IRB# 2015-3236-R3

☑ 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.

Miriam Rafailovich — QS/DS Printed Name

MRafailo — Signature

06/24/19 — 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)

Stony Brook Research

**Stony Brook University Institutional Review Board (IRB)**

| | |
|---|---|
| DATE: | July 17, 2018 |
| TO: | marcia simon, PhD |
| FROM: | Stony Brook University IRB (CORIHS A) |
| SUBMISSION TYPE: | Continuing Review/Progress Report |
| STUDY TITLE: | [795906-8] Stem cells of the oral cavity |
| CORIHS#: | 2015-3236-R3 |
| ACTION: | APPROVED |
| SUBMISSION APPROVAL DATE: | July 17, 2018 |
| PROJECT EXPIRATION DATE: | July 16, 2019 |
| REVIEW TYPE: | Expedited Review |
| EXPEDITED REVIEW CATEGORY: ( IF APPLICABLE ) | *#3* |

Thank you for your submission of Continuing Review/Progress Report materials for this research study. Stony Brook University IRB (CORIHS A) (FWA #00000125) has deemed that your study can proceed.

- Study qualifies for a waiver of documentation of consent per 45CFR46.117.c.
- Approval includes:
- Protocol version date: 2/3/2017

**Before you begin your research, you need to:**

**1) Download the stamped consent(s) / assent form(s) located in IRBNet.** Go to your project. Immediately under the first heading is a link called "Designer". Click on "Designer", which will bring you to the next screen. To get stamped documents and approval letters, click on "Review details".

- Consent is an on-going process. You should continue to assess the subject's capacity to consent and the subject's willingness to continue to be in the study. Use only the current CORIHS-stamped forms in the consent process and ensure that each subject receives a copy of his/her signed consent/permission/assent document.

**You are reminded that:**

1. Your approval to conduct this research will expire on the date above. You must apply for and be granted continued approval for this study before that date in order to be able to conduct your study in an uninterrupted manner. If you do not receive approval before this date, you must cease and desist all research involving human subjects, their tissue and their data until such time as approval is granted.
2. All research must be conducted in accordance with this approved submission. Any modifications to the study as approved must be reviewed and approved by CORIHS prior to initiation.

3. Unanticipated problems (including serious adverse events) must be reported to the Office of Research Compliance in accordance with SBU Policy at http://research.stonybrook.edu/humansubjects-standard-operating-procedures/unanticipated-problems-involving-risks-subjects-or.
4. Any complaints from subjects or issues of non-compliance must be immediately reported to the Office of Research Compliance.
5. Consent forms signed by subjects in this study must be kept by the investigator for 7 (seven) years from study termination, or indefinitely (if so indicated in the consent form).

**For studies involving minors, please note:**

- Inclusion of minors in this study is acceptable in accordance with 45 CFR 46 404.
- Verbal parental permission from one parent and minor assent is obtained in accordance with 45 CFR 46.408. Minor assent is also obtained in accordance with SBU Assent Policy, Category 1.

**If you have any questions or comments about this correspondence, please contact (include your study title and CORIHS number):**

Office of Research Compliance
Division of Human Subject Protections
Stony Brook University Stony Brook, NY 11794-3368.
Phone: 631-632-9036
Fax: 631-632-9839

We are interested in receiving feedback regarding your experience with the Office of Research Compliance, SBU's IRBs (CORIHS), or any other aspect of our Human Research Protection Program. Please feel free to e-mail Margaret McNurlan, Interim Assistant Vice President for Research Compliance, at Margaret.McNurlan@stonybrook.edu.