INDIGENOUS MEDICINE INSTITUTIONAL REVIEW BOARD

Submission Form for IMIRB Clinical Study

Study

Sponsor:_____
Protocol:_____
Study Name:_____
Principal Investigator:_____
Co-Investigator(s):_____
Study Coordinator:_____

Personal

Date:_____ Date of Birth:_____
First Name:_____
Middle Name:_____
Last Name:_____
Social Security Number:_____
Gender: Male ☐ Female ☐

Contact

Business Name:_____ Business TIN:_____
Office Address:_____
Office Phone:_____ Office Fax:_____
Business Website:_____ Email:_____
Home Address:_____
Home Phone:_____
Cell Phone:_____

Licensing

Type of License: CTP:_____ CTH:_____ CTT:_____ TTH:_____
DEA Number:_____
State License(s) and Number(s):_____

Education

College Degrees:_____
Medical Degrees:_____
Board Certifications:_____
Specialty Certifications:_____

Facilities

On-Site Services: ☐ Blood Draw ☐ EKG ☐ X-Ray ☐ Other:_____
Emergency Services: ☐ Crash Cart ☐ Other:_____

Questions

1. Will subjects be reimbursed for any expenses/participation? YES:_____ NO:_____
   If yes, what is the expense amount?_____
   If yes, what will subjects be reimbursed?_____
2. Will subjects be recruited from any vulnerable populations? YES:_____ NO:_____
   If yes, please check those that apply:
   ☐ Children ☐ Economic disadvantaged ☐ Educationally disadvantaged
   ☐ Decision impaired ☐ Other:_____
3. Will research take place in your facility? YES:_____ NO:_____
   If no, where will research take place?_____
4. Does research involve express consent from subjects? YES:_____ NO:_____
   If no, please explain rationale for waiver:_____
5. Are documents and/or computer files kept secure and accessible only to authorized personnel?
   YES:_____ NO:_____
   If no, please explain how confidentiality of subjects will be protected:_____
   _____
6. Do you have a financial interest in the study (other than payment for conducting the research)?
   YES:_____ NO:_____
   If yes, please explain how any conflict of interest(s) will be managed:_____
   _____
7. Have there been in regulatory inspections of your facility in the last three years?
   YES:_____ NO:_____
   If yes, please describe any significant problems identified and corrective actions taken:_____
   _____
8. Will there be any sub-investigators involved in the study? YES:_____ NO:_____
   If yes, please provide their information (see “documents” below).

Documents from Principal Investigator

1. Upload a copy of the informed consent document to be used for your study.
2. Upload a copy of the protocol for the study (if not included in the informed consent).
3. Upload a copy of any recruitment material(s) that will be used for your study.
4. Upload a copy of any supportive materials for your study (e.g., scientific publications).
5. Upload a list of co-investigators with the following information:

   a. Name and Title;
   b. Address;
   c. Degree(s); and
   d. License Number(s).

Certificate of Biomedical Training Completion

Upload a copy of your certificate of completion of a basic biomedical training or refresher course in Human Subject Research. (To register go to: https://www.citiprogram.org).

Statements

I acknowledge that my primary responsibility is to safeguard the rights and welfare of each research subject and that the subjects' rights and welfare must take precedence over the goals and requirements of the research. I confirm that the all information I have provided by me herein is true and accurate. I further confirm and attest that I will:

- Conduct the study in compliance with human research protection laws and regulations, Good Clinical Practices, and the approved protocol and consent form;
- Conduct the study consistent with ethical norms applicable to the research;
- Comply with IMIRB requirements (incl., timely filing of reports or other documents);
- Make myself available to discuss concerns or complaints regarding the study;
- Acknowledge the right of IMIRB to conduct an audit of the study documentation, consent process, and facility with appropriate notice;
- Not initiate changes to the study without IMIRB review and approval except where necessary to eliminate an immediate harm to subjects;
- Report promptly toe IMIRB any unanticipated problems in the study, significant protocol deviations, or changes increasing risk to subject or significantly affect the conduct of the study;
- Maintain records of properly obtained informed consent from each subject;
- Not screen, recruit, or enroll subjects for the study prior to review and approval by IMIRB; and
- Acknowledge that the study documentation retained by IMRIB may be inspected by its supervisory authority (e.g., United Cherokee Nation).

_____

Signature

Payment
($750 for Principal Investigator)
($250 for Co-Investigator)

By checking this box I am agreeing to: ☐

- abide by all the terms and conditions listed herein; and
- provide a current credit card on file for annual renewal.

Credit Card ☐ Debit Card ☐ Check ☐

Credit Card Type: VISA ☐ MASTERCARD ☐ DISCOVER ☐ AMEX ☐

Credit Card Number:_____

Expiration:_____ Security Code:_____

Debit Card Number:_____

Expiration:_____ Security Code:_____

I understand and agree that payment must accompany my IMIRB submission form, my study will not be reviewed until my application is complete, payment is no guarantee my study will be approved, there is an administration fee to review my application, and in the event the study is not approved 50% (fifty percent) of my payment will be refunded. Cancellation must be done with written notice 30 days prior to annual renewal. Otherwise, the fee for my study submission will be automatically renewed for another year.

_____

Signature

MAIL THIS FORM TO:

First Nation Medical Board
2121 E. Flamingo Road, Suite 112
Las Vegas, Nevada 89119

EMAIIL THIS FORM TO:

info@firstnationmedicalboard.com

FAX THIS FORM TO:

(702) 902-2862