**Navigating the Regulatory Steps in**

**Biotherapeutic Translation Workshop.**

Workshop Date: January 16-17, 2020

Location: University of Ottawa, Ottawa, Canada

**Workshop and Bursary Application Form**

All applications should be directed to Rebecca Cadwalader, Stem Cell Network by emailing info@stemcellnetwork.ca by **11:59pm (sender’s time), *November 25, 2019***.

Section 1: Project Overview

**1.1 Project Title:**

**1.2 Project Leader:**

**1.3 Host Institution:**

### Section 2: Project Team

**2.1 Team Members:** In Table I below, please list the principal investigator, plus **two (2)** team members, who are integral to the described work that will accompany the project leader. These additional team members can include individuals such as a research clinician collaborator, senior research staff, project managers or research coordinators, and must include one trainee (graduate student or postdoctoral fellow). For each person, provide their name, position, institutional affiliation and email address. Provide two to three sentences that describe the role of each team member in the research project and their respective areas of expertise.

All team members including the project leader (Investigator) must be present in person for the entirety of this workshop.

**CVs:** In a separate PDF, provide a max 2-page CV for each of the members listed in Table I.

#### Table I: Team Members

|  |  |  |
| --- | --- | --- |
| Name | Position and Institution | Phone and Email Address |
| 1. |  |  |
| Role in project and area of expertise: |
| 2. |  |  |
| Role in project and area of expertise: |
| 3. |  |  |
| Role in project and area of expertise: |

### Section 3: Project Description

**3.1 Please describe the discovery to which you will be applying the knowledge gained at the workshop (250 words max)**. *Please note that we will be circulating these descriptions to the course instructors, and may also be included in the program book. The description you include here will be used for adjudication purposes, but if successful, you will be given an opportunity to update your description prior to circulation.*

 **3.2 Please briefly describe the stage of your discovery in terms of translational development (250 words max).**

**3.3 Please indicate the where you are in the translational process:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Discovery stage \_\_\_ | Pre-CTA meeting scheduled within next 6 months \_\_\_ | Pre-CTA Meeting has taken place \_\_\_ |  Phase I anticipated to start within 6 months \_\_\_ | Phase I initiated \_\_\_ | Phase 2 \_\_\_ |

**3.4 Please indicate the where cell and/or vector manufacturing will occur:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Manufactured by research team \_\_\_ | Manufactured in research institute facility (please specify what facility):  | Contract Manufacturing (please specify):  | Purchase of cells from company (please specify):  | Manufacturing will take place within Canada\_\_\_ | Manufacturing will take place outside of Canada\_\_\_ |

**3.5. In reference to the discovery listed above, please indicate below your grant status or provide the requested details:**

**BioCanRx**

|  |  |  |  |
| --- | --- | --- | --- |
| Current holder \_\_\_ | Previous holder \_\_\_ | LOI submitted \_\_\_ |  Applied but not successful \_\_\_ |

**OIRM**

|  |  |  |
| --- | --- | --- |
| Current Disease Team awardee \_\_\_ | Previous Disease Team awardee \_\_\_ | Other (please describe):  |

**SCN**

Please describe if/how previous SCN funding contributed to the development of the discovery you are seeking to translate. If you applied for funding through SCN’s 2019 funding competition to support the work you are seeking to translate, please provide the title of the application(s):

|  |
| --- |
|  |

**Section 4: Anticipated Outcomes**

**4.1 Please describe what your goals are for attending this workshop (max 250 words).** In your response, please describe your greatest challenges in moving your technology forward and how this workshop may alleviate these challenges.

**4.2 Please describe how the learning outcomes from this workshop will be disseminated to your team (max 250 words).** Please describe how the information gained through this workshop will be put into practice.

**4.3 Please describe the long-term ambitions of this project (max 250 words).** Please describe the projects sustainability plan and long-term goals.

### Section 5: Institutional Resources

**5.1 Please use table below to indicate (Y/N) which resources you have access to at your or a collaborator’s facility.** Please note that this will facilitate our networking capabilities and will not be used to adjudicate successful applications.

***Table 2. Please check which of the follow you have access to:***

|  |  |  |
| --- | --- | --- |
|  | You (Y/N) | Collaborator (Y/N)If yes, please indicate your collaborator and collaborator institution.  |
| Animal care facility  |  |  |
| Assay Development |  |  |
| Charitable foundations  |  |  |
| Clinical specimen analysis |  |  |
| Clinical trial data management  |  |  |
| Clinical trial design support |  |  |
| Clinicians  |  |  |
| GLP Laboratory  |  |  |
| GMP Laboratory  |  |  |
| Health economist  |  |  |
| Process development space |  |  |
| Regulatory affairs experts  |  |  |
| Statistical methods centre  |  |  |
| Technology transfer office |  |  |

**5.2 Please add any additional comments relating to institutional resources here (250 words max):**