Dr. Daren Heyland and project staff at the Clinical Evaluation Research Unit (CERU) at Queen's University would like to assess your interest in participating as a site investigator in the VICToRY trial, a clinical trial examining the effects of high dose (200mg/kg/day x 96 hours) vitamin C administration compared to placebo as part of resuscitation in adult patients with severe thermal burn injuries. See accompanying protocol for details.

We request that this questionnaire is completed by the physician or delegated research team member and returned to the Project Lead via email: Maureen.dansereau@queensu.ca.

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| --- | --- | --- | --- |
| **PART A: Physician Contact Details** | | | |
| Last Name: |  | First Name: |  |
| Affiliated Hospital: |  | Affiliated University: |  |
| Address: |  | Tel: |  |
| City |  | Fax: |  |
| Province/State: |  | Email: |  |
| Postal/Zip Code: |  | Best Method of Contact: |  |
| Country: |  |  |  |

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| **PART B: Burn Unit/ICU Demographics** | | |
| 1 | Type of institution: | Academic  Community |
| 2 | Administrative Structure: | Open  Closed |
| 3 | Total number of patients age 18 years or older with > 20 % TBSA burn admitted to your Burn Unit or ICU annually: | # \_\_\_\_\_\_\_\_\_\_ |
| 4 | Of the patients age 18 years or older with > 20 % TBSA burn admitted to your Burn Unit or ICU annually, **how many are transferred to your facility post resuscitation**? | # \_\_\_\_\_\_\_\_\_\_ |
| 5 | Number of Burn Unit beds: | #\_\_\_\_\_\_\_\_\_\_\_ |
| **Part C: Clinical Trials Expertise and Resources** | | |
| 6 | Are the physician and research team familiar with Good Clinical Practice Guidelines for conducting clinical trials? | Yes  No |
| 7 | How many clinical trials are ongoing in your Burn Unit or ICU?  Please list the type/nature of studies (RCT vs. observational):  1) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry  Academic  2) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry  Academic  3) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry  Academic  4) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry  Academic  5) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry  Academic | # studies: \_\_\_\_\_\_ |
| 8 | Will you be available for oversight of study patients? | Yes  No |
| 9 | Will you be available for resolution of issues pertaining to the study? | Yes  No |
| 10 | Will you be available for regulatory and essential document signatures? | Yes  No |
| 11 | Are you planning to use any physician sub-investigators? If yes, please list:  a) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes  No |
| 12 | Do you have a research coordinator or research nurse?   1. If yes, please provide contact details:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. If no, please indicate who will complete the daily study tasks?   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes  No |
| 13 | Has your site ever been audited by Health Canada, US FDA, BfArM or other regulatory agency? If “Yes”, please provide details on a separate document or in email. | Yes  No |
| 14 | Does your Pharmacy have resources to support research activities (e.g. randomization, dispensing study product, study product accountability)? | Yes  No |
| 15 | Do you or your staff have experience obtaining regulatory approval for academic studies in your country? | Yes  No |
| 16 | Does your institution have a FWA (FederalWide Assurance) number?  If ‘No’, will you be able to register for an FWA (there is no cost to register)?  *(The FWA application form, terms of FWA and instructions can be accessed at:*  [http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html) .) | Yes  No  Yes  No |
| **PART D: VICToRY Study** | | |
| 17 | a) Is high dose vitamin C administration (≥ 66mg/kg/hr), as part of resuscitation, standard of care for burn patients in your Burn Unit or ICU?  b) If yes, do you have equipoise such that you/your site will be willing to change your practice and allow patients to be randomized? | Yes  No  Yes  No |
| 18 | The study intervention must be applied within hours of admission to your hospital, during the resuscitation phase. If burn patients are resuscitated elsewhere and then transferred to your unit, this protocol may not work. Is your clinical team directly involved in resuscitating severely burned patients? | Yes  No |
| 19 | Your local pharmacy will need to source IV vitamin C locally. Will this be a problem? | Yes  No |
| 20 | The IV vitamin C and placebo (saline) will need to be available in the Emergency Department (or wherever resuscitation takes place). Will this be a problem? | Yes  No |
| 21 | Will your research or clinical teams have access and capacity to administer the Study Solution (active or placebo) within a few hours of admission (maximum 24 hours)? | Yes  No |
| 22 | Approximately how many patients do you feel you could enroll in a 12-month period? | #\_\_\_\_\_\_\_\_\_\_\_ |

Please provide any comments that help clarify any issues identified above or any suggestions for improving the feasibility of the protocol:

Thank you for taking the time to complete this questionnaire.