**III. IRB Application and Consent Form(s)**

**IV. Data Safety Monitoring Plan:**

Frequency of Safety Monitoring:

Please indicate the appropriate mechanism of safety monitoring before filling out the table below. If you have any questions regarding the following section, please contact CRC Research Subject Advocate, Milda Saunders, MD: [msaunder@bsd.uchicago.edu](mailto:msaunder@bsd.uchicago.edu) (702-5941).

|  |  |
| --- | --- |
|  | The PI will perform safety monitoring. The protocol has been determined not to require a Data and Safety Monitoring Board/Committee. How often will your study be monitored?  annually  bi-annually quarterly  If selected, complete section A below. |
|  | A designee (independent monitor) will perform the safety monitoring. The protocol has been determined not to require a Data and Safety Monitoring Board/Committee. If selected, complete section A below. |
|  | An “internal” Data and Safety Monitoring Committee will perform the safety monitoring. If selected, complete sections A and B below. |
|  | An “external” Data and Safety Monitoring Board provided by the protocol sponsor or agency will perform the safety monitoring. If selected, please provide a copy of the members of the board including name, title, affiliation, and role on board. Members should not have conflicts with this study or study personnel. Attach copy as additional sheets. Complete section A and B below. |

1. List below at least two University of Chicago PHYSICIANS who will be performing safety assessments. Rationale: should a CRC nurse need medical advice concerning the health of a research subject or their suitability for the study, either of the two physicians will be readily available by pager/telephone, or can visit the subject in the CRC. Attach additional sheets as necessary.

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Title | Affiliation | Role on Project |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. Specify, if necessary, any sub-specialists who will be needed on the Data & Safety Monitoring Committee for this protocol. *Note: Members should not have conflicts of interest with this study or study personnel.*

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Title | Department | Role on Committee |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |