Supplement C

**EXPANDED ACCESS STATUS**

1. **Expanded Access Status: Status indicating availability of an experimental drug or device outside any clinical trial protocol. This data element is only applicable for Expanded Access records (see Expanded Access under Study Type). Select one.**

\_\_ Available: expanded access is currently available for this treatment

\_\_ No longer available: expanded access was available for this treatment previously but is not currently available and will not be available in the future

\_\_Temporarily not available: expanded access is not currently available for this treatment, but is expected to be available in the future

\_\_Approved for marketing: this treatment has been approved for sale to the public

1. **Will NIH be the “responsible party”for registering the protocol with CT.gov?**

\_\_ Yes \_\_ No

If yes, select they type:

\_\_ Sponsor (Specify Institute):

Provide point of contact:

\_\_ Sponsor-Investigator (Specify investigator):

\_\_ Investigator (Specify investigator):

If no, provide the name of the organization who will register the protocol:

1. **Study Interventions:**

|  |
| --- |
| Interventions |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  | Type (select from choices below\*) | Name | Description (cover key details of the intervention) limit 1000 characters |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |

 |
| \*Type selections include: Drug, Genetic, Biological/Vaccine, Behavioral, Device, Radiation, Procedure/Surgery, Dietary Supplement or Other. |