Expanded Access Protocol Registration Template

For more information, see How to Register Your Study at https://clinicaltrials.gov/ct2/manage-recs/how-register.

* Required
§ Required if Study Start Date is on or after January 18, 2017
[ ] Conditionally Required

### 1. STUDY IDENTIFICATION

<table>
<thead>
<tr>
<th>*Unique Protocol Identification Number:</th>
<th>*Brief Title:</th>
</tr>
</thead>
</table>

[*] Official Title (Optional if Expanded Access Type is "Individual Patients"):

[*] Acronym (if any):

*Study Type (select one):  Interventional  observational  observational—Patient Registry  Expanded Access

If Expanded Access does not involve a U.S. FDA-regulated drug product, select "Not Applicable".

*§ Expanded Access Type (select all that apply):  Not Applicable  Individual Patients  Intermediate-size Population  Treatment IND/Protocol

More than one Secondary ID can be entered. If more than two are needed, more space is available in the PRS.

[*] Secondary ID 1 (if any) (Optional if Expanded Access Type is "Individual Patients"):

[*] Secondary ID 1 Type (select one):  U.S. National Institutes of Health (NIH) Grant/Contract Award Number  Other Grant/Funding Number  Registry Identifier  EudraCT Number  Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*] Description 1:

[*] Secondary ID 2 (if any) (Optional if Expanded Access Type is "Individual Patients"):

[*] Secondary ID 2 Type (select one):  U.S. National Institutes of Health (NIH) Grant/Contract Award Number  Other Grant/Funding Number  Registry Identifier  EudraCT Number  Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*] Description 2:

### 2. STUDY STATUS

*Record Verification Date: Month: Year:

*§ Expanded Access Status (select one):  Available  No longer available  Temporarily not available  Approved for marketing

### 3. SPONSORS/COLLABORATORS

* Responsible Party, by Official Title (select one):  Sponsor  Principal Investigator  Sponsor-Investigator

Investigator Information is required only for "Principal Investigator" or "Sponsor-Investigator."

[*] Investigator Information:

Investigator Name:

Investigator Official Title: Investigator Affiliation:
3. SPONSORS/COLLABORATORS (CONTINUED)

* Name of the Sponsor

Enter as many Collaborators as needed. Additional fields are available in the PRS.

Collaborators (if any):

Name of Collaborator 1: ____________________________  Name of Collaborator 2: ____________________________

4. OVERSIGHT

* U.S. Food and Drug Administration IND or IDE (select one):

- [ ] Yes
- [ ] No

If Yes, provide information below:

[*] FDA Center (select one):  CDER  CBER  CDRH

[*] IND/IDE Number: ____________________________  [*] IND Serial Number: ____________________________

5. STUDY DESCRIPTION

* Brief Summary (using lay language):

Detailed Description:

6. CONDITIONS AND KEYWORDS

Enter as many Conditions as needed. Additional fields are available in the PRS.

[*] Conditions or Focus of Study (Optional if Expanded Access Type is "Individual Patients"):

1. ____________________________
2. ____________________________

Enter as many Keywords as needed. Additional fields are available in the PRS.

Keywords:

1. ____________________________
2. ____________________________

7. INTERVENTIONS

Enter as many Interventions as needed. Additional fields are available in the PRS.

Intervention 1:  * Intervention Name:

[*] Other Intervention Name 1 (if any) (Optional if Expanded Access Type is "Individual Patients"): ____________________________

[*] Other Intervention Name 2 (if any) (Optional if Expanded Access Type is "Individual Patients"): ____________________________

[*] Intervention Description (Optional if Expanded Access Type is "Individual Patients"): ____________________________

Intervention 2:  * Intervention Name:

[*] Other Intervention Name 1 (if any) (Optional if Expanded Access Type is "Individual Patients"): ____________________________

[*] Other Intervention Name 2 (if any) (Optional if Expanded Access Type is "Individual Patients"): ____________________________

[*] Intervention Description (Optional if Expanded Access Type is "Individual Patients"): ____________________________
### 7. INTERVENTIONS (CONTINUED)

- **Intervention Name:**

- **Other Intervention Name 1 (if any) (Optional if Expanded Access Type is “Individual Patients”):**

- **Other Intervention Name 2 (if any) (Optional if Expanded Access Type is “Individual Patients”):**

- **Intervention Description (Optional if Expanded Access Type is “Individual Patients”):**

### 8. ELIGIBILITY

- **Sex/Gender (Optional if Expanded Access Type is "Individual Patients"):**

  - **Sex (select one):** All, Female, Male

- **Gender Based (if any):** Yes, No

  If Yes, provide descriptive information about the Gender Based criteria.

- **Gender Eligibility Description:**

- **Age Limits: (Optional if Expanded Access Type is "Individual Patients"):**

  - **Minimum Age:**
  - **Unit of Time:**
  - **Maximum Age:**
  - **Unit of Time:**

  Provide bulleted lists (one criterion per bullet) below the headers "Inclusion Criteria" and "Exclusion Criteria."

- **Eligibility Criteria (Optional if Expanded Access Type is "Individual Patients"):**

### 9. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

- **Central Contact Person:**
  - First Name:
  - Middle Initial:
  - Last Name or Official Title:
  - Degree:
  - Phone:
  - Ext.:
  - Email:

- **Central Contact Backup:**
  - First Name:
  - Middle Initial:
  - Last Name or Official Title:
  - Degree:
  - Phone:
  - Ext.:
  - Email:

Enter as many Overall Study Officials as needed. Additional fields are available in the PRS.

- **Overall Study Official 1:**
  - First Name:
  - Middle Initial:
  - Last Name:
  - Degree:
  - Organizational Affiliation:
  - Official’s Role (select one): Study Chair, Study Director, Study Principal Investigator
### 9. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION (CONTINUED)

<table>
<thead>
<tr>
<th>Overall Study Official 2:</th>
<th>First Name:</th>
<th>Middle Initial:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Degree:</strong></td>
<td><strong>Organizational Affiliation:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Official’s Role (select one):</strong></td>
<td>Study Chair</td>
<td>Study Director</td>
<td>Study Principal Investigator</td>
</tr>
</tbody>
</table>

#### Facility Information:
- **Facility Name:**
- **City:**
- **State/Province:**
- **ZIP/Postal Code:**
- **Country:**

#### Facility Contact:
- **First Name:**
- **Middle Initial:**
- **Last Name or Official Title:**
- **Degree:**
- **Phone:**
- **Ext.:**
- **Email:**

#### Facility Contact Backup:
- **First Name:**
- **Middle Initial:**
- **Last Name:**
- **Degree:**
- **Phone:**
- **Ext.:**
- **Email:**

Enter as many Investigators as needed. Additional fields are available in the PRS.

<table>
<thead>
<tr>
<th>Investigators:</th>
<th>First Name:</th>
<th>Middle Initial:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Degree:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Role (select one):</strong></td>
<td>Site Principal Investigator</td>
<td>Site Sub-Investigator</td>
<td></td>
</tr>
</tbody>
</table>

#### 10. REFERENCES

Enter as many Citations and Links items as needed. Additional fields are available in the PRS.

<table>
<thead>
<tr>
<th>Citations:</th>
<th>PubMed Identifier:</th>
<th>Citation:</th>
</tr>
</thead>
</table>

Results Reference (select one):
- [ ] Yes
- [ ] No

<table>
<thead>
<tr>
<th>Links:</th>
<th>URL:</th>
</tr>
</thead>
</table>

| Description: | |
|--------------| |