# ANNEX – 1

**AF/01-015/01**

**Continuing Review Application Form**

|  |  |  |
| --- | --- | --- |
| PROTOCOL No.: | PROTOCOL TITLE: | |
| Principal Investigator: Site……………… | | |
| Action Requested:   * Renew - New Participant Accrual To Continue * Renew - Enrolled Participant Follow Up Only * Terminate - Protocol Discontinued   Have There Been Any Amendments Since The Last Review?   * No * Yes (Describe Briefly In Attached Narrative)   Summary of Protocol Participants:  Accrual Ceiling Set By IRB  New Participants Accrued Since Last Review  Total Participants Accrued since Protocol Began  Accrual Exclusions   * None * Male * Female * Other (Specify: )   Impaired Participants   * None * Physically * Cognitively * Both   Have There Been Any Changes In The Participant Population, Recruitment Or Selection Criteria Since The Last Review?   * No * Yes (Explain Changes In Attached Narrative)   Have There Been Any Changes In The Informed Consent Process Or Documentation Since The Last Review?   * No * Yes (Explain Changes In Attached Narrative) | | Has Any Information Appeared In The Literature, Or Evolved From This Or Similar Research That Might Affect The IRB’s Evaluation Of The Risk/Benefit Analysis Of Human Subjects Involved In This Protocol?   * No * Yes (Discuss In The Attached Narrative)   Have Any Unexpected Complications Or Side Effects Been Noted Since Last Review?   * No * Yes (Discuss In The Attached Narrative)   Have Any Participants Withdrawn From This Study Since The Last IRB Approval?   * No * Yes (Discuss In The Attached Narrative)   Investigational New Drug/Device  □ None □ Ind □ Ide  Dra No. …………………………..  Name: ……………………………  Sponsor: …………………………  Holder: ……………………………  Ionizing Radiation Use (X-Rays, Radioisotopes, Etc)   * None * Medically Indicated Only   Have Any Participating Investigators Been Added Or Deleted Since Last Review?   * No * Yes (Identify all changes in the attached narrative and submit the CV of the new investigator(s)   Have Any New Collaborating Sites (Institutions) Been Added Or Deleted Since The Last Review?   * No * Yes (Identify All Changes And Provide An Explanation Of Changes In The Attached Narrative) |
| HAVE THERE BEEN ANY CHANGES IN SUPERVISOR / INVESTIGATOR?   * NONE * DELETE:………………………………………… * ADD: …………………………………………….. | | HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?   * NO * YES (Append A Statement Of Disclosure) |

**SIGNATURES:**

Date: ………………. Protocol Chairperson (if applicable)

Date: ……………….

*INSTITUTE....* SUPERVISOR

Date: ………………. *INSTITUTE....* Director

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(For use by IRB)

COMPLETION

Date:………………… Member-Secretary, IRB

(For IRB use)

Complete the following section if there are no changes or amendments. If there are changes or amendments refer “Review of Protocol Amendments” SOP/013.

Member’s Recommendation:

⬜ Approved ⬜ Approved with Recommendation

⬜ Resubmission ⬜ Disapproved

Comments, if any: .............................................................................................................................

…………………………………………………………………………………………………………………...

FINAL DECISION of IRB:

1. By Chairperson

⬜ Approved ⬜ Approved with Recommendation

⬜ Resubmission ⬜ Disapproved

Comments, if any: .............................................................................................................................

…………………………………………………………………………………………………………………...

1. By Full Board

⬜ Approved ⬜ Approved with Recommendation

⬜ Resubmission ⬜ Disapproved

Comments, if any: .............................................................................................................................

…………………………………………………………………………………………………………………...