# 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 BeganAccrual 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Have Any Participants Withdrawn From This Study Since The Last IRB Approval?* No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

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(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: .............................................................................................................................

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