APPENDIX 6: MIRERC Continuing Review Form F-1-39-5

PROTOCOL/PROPOSAL NO.	**MIRERC NO.**
STUDY TITLE:	
NAME OF CORRESPONDING PRINCIPAL INVESTIGATOR:	**MIRERC APPROVED SITES:**
DATE OF INITIAL APPROVAL:	**DATE OF LAST ANNUAL RENEWAL:**
ACTION REQUESTED: □ Renew – New subjects enrollment to continue □ Renew – Enrolled subjects follow up only	**TRIAL DURATION (MONTHS):** _____ Recruitment Duration _____ Trial Duration
SUMMARY OF STUDY SUBJECTS (MIRERC APPROVED SITES): _____ Enrolment ceiling set by MIRERC (Target Number during time of approval) _____ New subjects enrolled since initial approval / last annual renewal _____ Total subjects enrolled since study started.	**HAS ANY SUBJECT WITHDRAWN FROM THIS STUDY SINCE THE LAST MIRERC APPROVAL?** □ NO □ YES (Discuss in the attached narrative)
ENROLLMENT EXCLUSIONS: □ NONE □ MALE □ FEMALE	**IMPAIRED SUBJECTS:** □ NONE □ PHYSICALLY □ COGNITIVELY □ BOTH
IONIZING RADIATION USE (X-RAYS, RADIOISOTOPES, ETC) □ None □ Medically indicated only	**INVESTIGATIONAL NEW DRUG / DEVICE** □ NO □ IND □ IDE FDA Number …….. Name: …….. Sponsor: …….. Holder: ……
HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA 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 MIRERC'S EVALUATION OF THE RISKS / BENEFITS ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS STUDY?** □ NO □ YES (Discuss in the 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)	**HAVE ANY CO- / SITE INVESTIGATORS BEEN ADDED OR REMOVED SINCE THE LAST REVIEW?** □ NO □ YES (Identify all changes in attached narrative)
HAVE ANY INVESTIGATOR DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS STUDY WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? □ NO □ YES (Append a statement of disclosure)	**HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR REMOVED SINCE THE LAST REVIEW?** □ NO □ YES (Identify all changes and provide an explanation of changes in attached narrative)
HAVE THERE BEEN ANY OTHER AMENDMENTS SINCE THE LAST REVIEW? NO □ YES (Explain changes in attached narrative)	**HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW?** □ NO □ YES (Discuss in the attached narrative) □ NA *

SIGNATURE:

_____ _____

*** For non-clinical studies**

It is compulsory to renew your ethical approval every year unless otherwise specified. Please note that your ethical approval is valid for only a specified time based on the risk benefit assessment by the MIRERC .This time period is specified in the approval letter by MIRERC. To avoid delay, please submit your renewal application ***at least two months*** *in advance before expiry. If your ethical approval is not renewed you are not to continue the study until approval is obtained*

(CORRESPONDING PRINCIPAL INVESTIGATOR) **(DATE)**

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