# Form 5: Continuing Review Application Form

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| PROTOCOL No.: | | | Date: |
| PROTOCOL TITLE: | | | |
| PRIMARY INVESTIGATOR: | | | |
| ACTION REQUESTED:   * Renew – Protocol Amendments * Renew – Expiring ERC approval * Terminate - Protocol discontinued * Others   HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?   * NO * YES (Describe briefly in attached narrative)   SUMMARY OF PROTOCOL PARTICIPANTS:  Accrual ceiling set by ERC  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 ERC 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   * NO * YES (Discuss in the attached narrative)   HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST ERC APPROVAL?   * NO * YES (Discuss in the attached narrative)   USE OF INVASIVE MODALITIES OR TECHNIQUES (Dry needling, needle EMG, and the like)   * None * Medically indicated only   HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?   * NO * YES (Identify all changes in the attached narrative)   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) | |