

Annex 1
AF/01/01-SOP10/01

Continuing Review Application Form

Date: _____

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|-----------------|---|
| Protocol No.: | Assigned No.: <input type="text"/> <input type="text"/> / <input type="text"/> - <input type="text"/> |
| Protocol Title: | |
| PI : | |
| Institute : | |

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| <p>Have there been any amendments since the last review?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Describe briefly in attached narrative)</p> <hr/> <p>Were these protocol amendments approved by IEC</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES</p> <p>If no mention the amendments not approved</p> <hr/> <p>Which protocol amendment is the site following at this date</p> <hr/> <p>Summary of protocol participants:</p> <p>_____ Accrual ceiling set by IEC</p> <p>_____ New participants accrued since last review</p> <p>_____ Total participants accrued since protocol began</p> <p>Accrual exclusions</p> <p><input type="checkbox"/> none</p> <p><input type="checkbox"/> male</p> <p><input type="checkbox"/> female</p> <p><input type="checkbox"/> other</p> <p>(specify: _____)</p> <p>Impaired participants</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Physically</p> <p><input type="checkbox"/> Cognitively</p> <p><input type="checkbox"/> Both</p> <p>Have there been any changes in the participant population, recruitment or selection criteria since the last review?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Explain changes in attached narrative)</p> | <p>Were these ICD amendments approved by IEC</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES</p> <p>If no mention the amendments not approved</p> <hr/> <p>Which ICD amendment is the site following at this date</p> <hr/> <p>Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Discuss in the attached narrative)</p> <p>Have any unexpected complications or SAE been noted since last review at your site?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Discuss in the attached narrative)</p> <p>Have any participants withdrawn from this study during the last one year?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Discuss in the attached narrative)</p> <p>Have any participating investigators been added or deleted since last review?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Identify all changes in the attached narrative)</p> <p>Have any new collaborating sites (institutions) been added or deleted since the last review?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Identify all changes and provide an explanation of changes in the attached narrative)</p> |
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| | <p>Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?</p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES (Append a statement of disclosure)</p> |
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SIGNATURES:

_____ Date:

Principal Investigator

- Assessment of project progress report
 - Comments:

 - Reviewed By _____

- Action requested
 - Renew-New participant accrual to continue
 - Renew-Enrolled participant follow up only
 - Terminate- protocol discontinued
 - Renew after recommendations are incorporated

Sign/date of IEC member