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| **FORM 3.1 PROTOCOL AMENDMENT REVIEW** |

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| --- | --- | --- | --- | --- |
| URERC Protocol Number |  | Sponsor Protocol Number |  | Date of Submission |
|  |  |  |  |  |
|  |  |  |  |  |
| Principal Investigator/Researcher |  | Sponsor |  | Date of Initial Approval |
|  |  |  |  |  |

|  |  |
| --- | --- |
| Title |  |

| **Items to be Amended**  ***(Previous Version)*** | **Amended Version**  *(Please indicate page and section)*  *\*All amended versions should be highlighted* | **Reasons for Amendment** |
| --- | --- | --- |
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***FOR URERC USE:***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Amendment: | Major |  | Minor |  |  |
|  |  |  |  |  |  |
| Does the amendment increase the risk to participant? | Yes |  | No |  |  |
|  |  |  |  |  |  |
| Is there favourable benefit/risk ratio | Yes |  | No |  |  |

|  |  |
| --- | --- |
| Comments of Primary Reviewers |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Primary Reviewer |  | Signature |  | Date |
|  |  |  |  |  |
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| **URERC Final Decision** | | |
|  |  | Approval |
|  |  | Major Revisions to the protocol/informed consent form |
|  |  | Minor Revisions to the protocol/informed consent form |
|  |  | Disapproval |
|  |  |  |

Form 3.1 Rev.: 001

11/11/2019