**REVIEW ASSESSMENT FORM**

**UMMC-MREC**

**MREC ID:**

**STUDY TITLE:**

**Principal Investigator:**

**Primary Reviewers: Scientific: Non-Scientific:**

**Date of UMMC-MREC meeting:**

**PART A: REVIEW OF RESEARCH PROTOCOL (SCIENTIFIC MEMBER ONLY)**

*\** ***Ref****: You may refer to the relevant question(s) in the online application form submitted by the researcher.*

*\*\*****Y****: Yes;* ***N****: No;* ***NA****: Not Applicable*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Assessment Criteria for Protocol** | **\*Ref** | **\*\*Y / N / NA** | **Comments** |
| **Suitability of Investigators** |
| 1 | Do the investigators have the necessary experience and skills to conduct the study? | 12,15 |  |  |
| 2 | Is there a physician (or dentist when appropriate) in the study team who is responsible for study related medical decisions? | 12,15 |  |  |
| **Adequacy of Background Information** |
| 3 | Is there acceptable information on the investigational product(s) where appropriate? | 35 |  |  |
| 4 | Is there a clear summary of available non-clinical and clinical information relevant to the study? | 17 |  |  |
| 5 | Is there a clear summary of the known and potential risks and benefits to subjects? | 41, 42 |  |  |
| 6 | Is there acceptable review of the study treatment(s) especially route of administration, dosage, dosage regimen and treatment period? | 24 |  |  |
| 7 | Is there a clear description of the study population? | 24, 31 |  |  |
| 8 | Is the literature review current and appropriate? | 24 |  |  |
| **Project Information** |
| 9 | Are the objectives and outcomes clear? | 20 |  |  |
| 10 | Does this study answer an important question? | 19 |  |  |
| 11 | Have similar studies been done before? | 18 |  |  |
| **Study Design** |
| 12 | Are the study endpoints stated? | 21 |  |  |
| 13 | Is the study design appropriate? Is there a schematic diagram of the study design? | 24 |  |  |
| 14 | Is there a description of how bias is minimized, including randomization, and blinding? | 24 |  |  |
| 15 | Is it stated how randomization codes are maintained and procedure for breaking code? | 24 |  |  |
| 16 | Is the expected duration of subjects’ participation, and description of the sequence and duration of study periods, acceptable? | 34 |  |  |
| 17 | Are stopping rules or discontinuation criteria for study, stated? | 24 |  |  |
| 18 | Are the accountability procedures for the investigational product(s), stated? | 24 |  |  |
| **Selection and Withdrawal of Subjects** |
| 19 | Are subject inclusion and exclusion criteria, acceptable? | 31 |  |  |
| 20a | Does the study involve vulnerable subjects?  | 30 |  |  |
| 20b | Are steps taken to ensure they are not being disadvantaged? | 30 |  |  |
| 21 | Are subject withdrawal criteria, stated? | 24 |  |  |
| **Study Treatment** |
| 22 | Is there acceptable information on all treatment(s) administered, dose, dosing schedule, route of administration, and treatment periods? | 24 |  |  |
| 23 | Are permitted and not permitted medications/treatments before and during study period, clearly stated? | 36 |  |  |
| 24 | Is there information on how compliance of subjects is monitored? | 24 |  |  |
| **Assessment of Efficacy** |
| 25 | Are efficacy parameters specified? | 24 |  |  |
| 26 | Are methods and timing for assessing, recording, and analysis of efficacy parameters, stated? | 24 |  |  |
| **Assessment of Safety** |
| 27 | Are safety parameters specified? | 24 |  |  |
| 28 | Are methods and timings for assessing, recording, and analyzing safety parameters, stated? | 24 |  |  |
| 29 | Are procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses, stated? | 24 |  |  |
| 30 | Are the type and duration of follow-up of subjects after adverse events, stated? | 24 |  |  |
| **Statistics** |
| 31 | Is the statistical method for analysis, described? | 29 |  |  |
| 32 | Is the number of subjects planned to be enrolled, acceptable? | 29 |  |  |
| **Direct Access to Source Data** |
| 33 | Is it stated who are the individuals who have direct access to source data? | 46 |  |  |
| **Ethical Issues** |
| 34 | Are there benefits to the subjects? | 41 |  |  |
| 35 | a. Are risks to the subjects acceptable?  | 42 |  |  |
| b. Are actions taken to minimize them? |  |  |
| 36 | Are the participants’ information anonymized?  | 44 |  |  |
| Is the data kept securely? |  |  |
| 37 | Are the subjects compensated appropriately? | 54 |  |  |
| 38 | Is Data Handling and Record Keeping acceptable? | 45, 46 |  |  |
| 39 | Is the storage period of data/ records acceptable? | 47 |  |  |
| **Study Insurance** |
| 40 | Is there insurance to pay for treatment of study-related injuries? | 55 |  |  |

**PART B: REVIEW OF PATIENT/PARTICIPANT INFORMATION SHEET (NON-SCIENTIFIC MEMBER)**

*\** ***Ref****: You may refer to the relevant question(s) in the online application form submitted by the researcher.*

*\*\*****Y****: Yes;* ***N****: No;* ***NA****: Not Applicable*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Assessment Criteria for Protocol** | **\*Ref** | **\*\*Y / N / NA** | **Comments** |
| 1 | Is it stated that the study involves research? | Intro |  |  |
| 2 | Is the purpose of the study stated clearly? | 1 |  |  |
| 3 | Are the study treatment(s), possibility of randomization and blinding stated clearly? | 3 |  |  |
| 4 | Is the information on study procedures, especially invasive ones, acceptable? | 4 |  |  |
| 5 | Are subjects’ responsibilities stated clearly? | 9 |  |  |
| 6 | Is it stated which aspects of the study are experimental? | - |  |  |
| 7 | Is the information on foreseeable risks and inconveniences to the subjects acceptable? | 11 |  |  |
| 8 | Are the expected benefits stated? | 12 |  |  |
| 9 | Are alternate procedures or treatments stated if patients do not consent to participate? | 16 |  |  |
| 10 | Is the information on compensation and treatment for study-related injuries appropriate? | - |  |  |
| 11a | Is the prorated payment for participation clearly stated?  | - |  |  |
| 11b | Is the amount acceptable? | - |  |  |
| 12 | Is there information on the anticipated expenses to the subject for participating in the study? | - |  |  |
| 13 | Is it stated that participation of the subject is voluntary and that the subject may refuse to participate or withdraw from the study without any penalty or loss of benefits? | 8, 16 |  |  |
| 14 | Is there acceptable information on the individuals who have access to the subject’s medical records and study data? | 13 |  |  |
| 15 | Is there acceptable information on how confidentiality of the subjects’ records can be ensured? | 14 |  |  |
| 16 | Is it stated that the subject will be informed of new information that may affect the subject’s willingness to continue in the study? | 17 |  |  |
| 17 | Is there information on who the subject should contact for further information on the study, their rights as subjects, and reporting study-related injuries? | 22, 23 |  |  |
| 18 | Is the circumstances or reasons for terminating a subject’s participation stated clearly? | - |  |  |
| 19 | Is the expected duration of the subject’s participation stated? | 10 |  |  |
| 20 | Is the number of subjects in the study stated? | - |  |  |
| 21 | Is there information on whether the source(s) and component(s) of the investigational product are culturally acceptable? | 5 |  |  |
| 22 | Is the language of the PIS understandable? | - |  |  |
| 23 | Is the language of the consent form understandable? | - |  |  |
| 24 | Is the procedure for obtaining informed consent appropriate? | - |  |  |

**PART C: REVIEWERS’ COMMENTS**

**Should the researcher be interviewed?** Yes/No

**Brief account of the study and its objectives (by Scientific Primary Reviewer only):**

**Points of note or concern:**

1. **Review of scientific aspect:**

1. **Review of non-scientific aspect:**

**Recommendation:**

1. **Review of scientific aspect:**

1. **Review of non- scientific aspect:**

**Scientific Primary Reviewer (Name):                                 Date of review:**

**Non-Scientific Primary Reviewer (Name):                                 Date of review:**

**PART** **D: SECRETARY’S NOTES**

**PART E: DECISION BY MREC:   Accept/ Modify/ Reject**

**Chair (Name):**