**Yenepoya Ethics Committee-1**

**Ann03/SOP7A/v4**

**Checklist to review placebo justification (Source SOP7A/v4)**

|  |  |  |
| --- | --- | --- |
| A | Protocol No. |  |
| B | Title of the protocol  |  |
| C | Name of the PI |  |
| D | Name of the primary reviewer: |  |
|  |  | To be filled by the PIYes/ No (Please justify either answer with detailed explanation. Do not simply write yes/no) | For reviewer use only Explanation adequate/ inadequate (If inadequate justify with details) |
|  | Is there a standard treatment for condition under study? |  |  |
|  | Is the standard treatment available locally? |  |  |
|  | Please provide evidence of the standard treatment in either national, international or society guidelines or in a standard reference textbook ? | Yes/NoEvidence annexed: Yes/No |  |
|  | In healthcare setting, would newly diagnosed patients with this condition be put on this standard treatment  |  |  |
|  | What is the treatment rationale ?1. Pathophysiologic
2. Symptomatic
 |                                           Yes/NoYes/No |  |
|  | Are most (more than 85%) of the patients with this condition responsive to standard treatment? |  |  |
|  | Are the side effects of the standard treatment severe? | Yes/No (Explain in detail) |  |
|  | Does standard treatment have undesirable side effects? |  |  |
|  | Does   standard   treatment   have   contraindications   that   prevent some participants from being treated? |  |  |
|  | Is there substantial (at least 25%) placebo response in this disease treatment? |  |  |
|  | Is the risk of using placebo instead of treatment life threatening? |  |  |
|  | Is the use of placebo instead of treatment likely to lead to permanent disability? |  |  |
|  | Is the risk of using placebo instead of treatment likely to cause irreversible disease progression? |  |  |
|  | Can the use of placebo instead of treatment lead to an acute emergency? |  |  |
|  | Can   risk  of  using  placebo  instead  of  treatment  cause the  persistence  of  distressing symptoms? |  |  |
|  | Can the risk of using placebo instead of treatment cause severe physical discomfort or pain? |  |  |
|  | Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo? | *.* |  |
|  | Is there benefit in the overall management of the research participants? |  |  |
|  | In this study, are research participants at high risk for the use of placebo excluded? |  |  |
|  | Is the study duration the minimum necessary in relation to action of the drug? |  |  |
|  | Are there clearly defined rules to withdraw the participant in case of no improvement? |  |  |
|  | Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences? |  |  |
|  | Are there defined rules to withdraw the participants before the advent of severe disease progression? |  |  |
|  | If the risk of placebo is an acute emergency, are rescue medication/emergency treatment available? |  |  |
|  | If  the  risk  of  placebo  is  the  persistence  of  distressing  symptoms,  is  concurrent medication to control them allowed? |  |  |
|  | If  the  risk  of  placebo  is  severe  physical  discomfort  or  pain,  is  there  rescue medication? |  |  |
|  | Are the risks of getting placebo instead of active treatment fully disclosed in the participant information sheet/informed consent form? |  |  |
|  | Are the risks of the test drug disclosed? |  |  |
|  | Are advantages of alternative treatments explained? |  |  |
|  | Is there some kind of assessment of comprehension of the participant to document that he/she has understood the implication of the use of placebo? |  |  |

*Note: The use of placebo is ethically acceptable when*

1. *The research participants are not exposed to severe or permanent harm by the use of placebo.*
2. *The research participants under placebo will benefit from the overall treatment of the disease.*
3. *The risks of the use of placebo are minimized.*
4. *The risks are adequately disclosed in the consent form.*

|  |
| --- |
| Assessment key for primary reviewers/reviewers (confidential)Items 1 to 6: If the answers are “yes”, placebo is not recommended.  If one or more answers are “no”, placebo may be possible.Items 7 to 10: If the answers are “no”, placebo is not recommended. If one or more answers are “yes”, placebo may be possibleItems 11 to 17: If the answer to any is “yes”, placebo is not acceptable.Items 18 to 26: If answers are “yes”, consider placebo. If no, placebo not recommendedItems 27 to 30: If answers are  ‘yes’, consider placeboProvisional Decision of the primary reviewer/reviewer:• Placebo acceptable • Placebo not acceptable • Discussion in YEC-1 Meeting: Name and signature of the reviewerDate:  |
| Final decision of YEC-1 • Placebo acceptable • Placebo not acceptable • Recommendation to the PI: Signature of the Member-Secretary/ ChairpersonDate:  |

Primary /Reviewer’s signature with date: