*202101/V8*

**REVIEW FORM TiSEM IRB**

*(for use by IRB reviewers)*

*Please write your comments in English and in the same tone and style as a peer review of a manuscript submitted to an academic journal, as if you are addressing the researcher/author directly.*

1. **General information**

|  |  |
| --- | --- |
| Project ID |  |
| Name of PI |  |
| Department |  |
| Project title |  |
|  | |
| Name IRB Committee member |  |
| Date review |  |
| Signature Committee member |  |

1. **Fit with TiSEM IRB Scope**

|  |  |
| --- | --- |
| 1. Is the TiSEM IRB the right body to review this research proposal? | |
| O | YES |
| O | NO |
| If **NO**, specify (e.g., because it falls under Medical Research Ethics Committee (MREC)):  <add information> | |

1. **Data Collection**

|  |  |
| --- | --- |
| 1. Are there issues with the sampling procedure? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

|  |  |
| --- | --- |
| 1. Are there issues with the intervention(s) in the research? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

|  |  |
| --- | --- |
| 1. Are there issues with the participant information letter and/or the Informed Consent Form (see part 4 of the submission form)? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

|  |  |
| --- | --- |
| 1. Are there issues with respect to sufficiently informing participants before, during, and after their participation? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

|  |  |
| --- | --- |
| 1. Are there issues with respect to risks to the well-being and/or health of the participants? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

|  |  |
| --- | --- |
| 1. Are there issues with respect to a good balance between the burden on the participants on one hand and the remuneration of the participants on the other hand? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

1. **Data Management *(to be reviewed by the Data Representative IRB member and optional to the other reviewers)***

|  |  |
| --- | --- |
| 1. Are there issues with respect to processing, storing, and/or archiving the data? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

1. **Compliance with GDPR (*to be reviewed by the Data Representative IRB member and optional to the other reviewers*)**

|  |  |
| --- | --- |
| 1. Are there issues with respect to protecting the privacy of participants AND maintaining confidentiality of their data? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

1. **General comments and other Issues**

|  |  |
| --- | --- |
| 1. Are there other issues regarding the proposed research, and should these be included in the TiSEM IRB letter to the research team? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

**FOR EVALUATION OF SRPs SEE APPENDIX BEFORE PROCEEDING TO G.**

1. **Recommendation**

|  |  |
| --- | --- |
| 1. Provide your recommendation | |
| O | Approval |
| O | Conditional approval: <*add condition(s)*> |
| O | Revision needed: <*add revision(s) needed*> |
| O | Rejection: <*add ground(s) for rejection*> |

**IN CASE OF REVIEWING A REVISED RESEARCH PROPOSAL**

1. **Previous issues/questions**

|  |  |
| --- | --- |
| 1. Have the issues/questions on the previous version of the research proposal been adequately addressed/answered? | |
| O | YES |
| O | NO |
| If **NO**, specify:  <add information> | |

1. **New issues/questions**

|  |  |
| --- | --- |
| 1. Are there new issues/questions that you want to raise based on the revised research proposal? | |
| O | NO |
| O | YES |
| If **YES**, specify:  <add information> | |

1. **Recommendation**

|  |  |
| --- | --- |
| 1. Provide your recommendation | |
| O | Approval |
| O | Conditional approval: <*add condition(s)*> |
| O | Revision needed: <*add revision(s) needed*> |
| O | Rejection: <*add ground(s) for rejection*> |

**APPENDIX A**

**ADDITIONAL EVALUATION CRITERIA FOR SRPs**

**A1. SCOPE**

|  |  |
| --- | --- |
| Is the Standard Research Protocol **broad enough** to cover various specific research proposals by multiple researchers? | |
| O | Yes |
| O | No, because: <*provide details*> |

**A2. FOCUS**

|  |  |
| --- | --- |
| Is the Standard Research Protocol **specific enough?** Are the (expected) research proposals within the SRP sufficiently similar compared to each other and sufficiently different from (expected) research proposals within other SRPs? | |
| O | Yes |
| O | No, because: <*provide details*> |

**A3. DETAIL**

|  |  |
| --- | --- |
| Is the Standard Research Protocol **detailed enough?** Is the SRP described in sufficient detail to be able to have a clear idea and evaluate the specifics of the research proposals within the SRP? | |
| O | Yes |
| O | No, because: <*provide details*> |