**IRB Meeting Minutes**

«committee.name»
«dateTimeStart»

**ATTENDANCE**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Regular/Alternate Member[[1]](#footnote-1)** | **Representative Capacity(ies)** | **Status****(Member or Alternate)** | **If Voting Alternate, Member Substituting For** | **Present by Tele-conference?** |
| «TableStart:getPotentialAttendees()»«fullName()» | Choose an item.Choose an item. | Choose an item.Choose an item. |  | Yes«TableEnd:getPotentialAttendees()» |

**Reporting of Expedited Reviews:**

A report of completed review conducted via the Expedited procedure for the previous 45 days was made available to the IRB. The IRB was asked if there were any questions about the reviews and *[no questions or comments were raised OR include description if there were any questions.]*

**Adequate Expertise:**

Prior to the meeting, WORKSHEET: Quorum and Expertise (HRP-305) was referenced in consultation with the IRB chairperson to ensure that the meeting would be convened with appropriate expertise. Further, at the panel meeting, the IRB affirmed that members present were sufficiently qualified through experience and expertise to review all research activities on the agenda and that expert consultants have contributed, when applicable.

**OTHER ATTENDEES**[[2]](#footnote-2)

1. <*List other attendees and their role here>*

**MEETING INFORMATION**

|  |  |
| --- | --- |
| Number of IRB members on the roster[[3]](#footnote-3): # | Number required for quorum: # |
| Meeting start time: «dateTimeStart» | Meeting end time: XX:XX a.m./p.m. |

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

**ATTENDANCE KEY**

|  |  |
| --- | --- |
| **Vote Type** | **Description** |
| FOR: | A vote for the motion. |
| AGAINST: | A vote against the motion. |
| ABSTAIN: | Present for the vote, but not voting “For” or “Against.” |
| ABSENT: | Absent for discussion and voting for reasons other than a conflicting interest. |
| RECUSED: | Absent from the meeting during discussion and voting because of a conflicting interest. |
| SUBSTITUTION: | When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member substitutes for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote.  |

**OTHER BUSINESS**

1. Items on this agenda were not necessarily reviewed in the order in which they appear.
2. A non-scientist member was in attendance during the discussion and voted on all action items on this convened IRB agenda.
3. This meeting was conducted remotely via Zoom Meeting Teleconference.
4. A copy of the completed WORKSHEET: Quorum and Expertise (HRP-305) can be found in the supporting documents section of the meeting minutes.
5. No members reported any conflicting interest with items on the agenda. OR Member, <Member Name> stepped out of the convened meeting from <Time Left> to <Time Returned> for the review of <Submission ID> due to a conflict of interest and was recused from the action taken on <Submission ID>.
6. A brief educational discussion was led by <insert education statement>. OR No education was provided at this meeting.
7. Member <Member Name> stepped out of the convened meeting from <Time Left> to <Time Returned>; no actions were taken during their absence <or> he/she was absent from the action taken on <Submission ID>. OR No voting members had to step out of the convened meeting.

**REVIEW OF PROTOCOLS**

1. **Protocol Review:**

|  |  |
| --- | --- |
| **Type of Review:** | «project.submissionType» |
| **Title of Study/Submission:**  | «project.name» |
| **Investigator:**  | «project.investigator.studyTeamMember.ful» |
| **IRB ID:**  | «project.ID» |
| **Funding[[4]](#footnote-4):** | «project.customAttributes.irbSubmissionCu» *<Indicate “None” if there is none.>*☐ Internal UMN Funding☐ Funding Management Outside the University |
| **Proposal/Award ID:** | «project.customAttributes.irbSubmissionCu»*<Indicate “None” if there is none.>* |
| **Safety Monitoring[[5]](#footnote-5):** | Choose an item. |
| **IND or IDE or HDE Number:** | «project.getDeviceOrDrugNumbersMergeStrin»*<Indicate “None” if there is none.>* *<*If this is an NSR IDE, indicate “NSR IDE”> |
| **Submission Description:** | «project.irbSubmissionCustomExtension.get» |
| **Documents Reviewed:**  | The documents reviewed for this submission are listed in the Documents tab in ETHOS. |

* 1. **Notes:**

The committee evaluated the submission by utilizing the WORKSHEET: Criteria for Approval (HRP-314). The following is a summary of the committee’s discussion:

Criteria for Approval Discussion Summary:

«putItemIntoWomContext()»«project.getWordMergeProperty(notes)»

Scientific Review: <Summarize the IRB’s discussion related to scientific review.>

Financial Conflict(s) of Interest: <Summarize the IRB’s discussion regarding any disclosed conflicts of interest. OR indicate “NA” if no conflict has or was disclosed. OR insert "This submission does not impact the prior assessment of the conflict of interest disclosed in this study." >

<If approved, include “The IRB determined that all criteria for approval were met.”>

<If modifications required to secure approval, include “The IRB reviewed the submission and determined that the criteria for approval continue to be met, based on the assumption that the modifications required are satisfied.”>

* 1. **Controverted issues and their resolution[[6]](#footnote-6):**

«project.getWordMergeProperty(controverte»

*<Indicate “None” if there is none.>*

* 1. **Consultant report[[7]](#footnote-7):**  Choose an item.
	2. **Scientific assessment[[8]](#footnote-8):** Choose an item.
	3. **Study Level of risk[[9]](#footnote-9):** «project.getWordMergeProperty(riskLevel)»
	4. **Determinations and findings that require documentation:**

«project.getWordMergeProperty(determinati»

*<Include language regarding determinations when applicable or indicate “None.”>*

*<Append completed checklist(s) when applicable.>*

* 1. **Significant/non-significant device determination:**

[ ]  Not applicable as there is no medical device involved.

[ ]  Not applicable as the medical device is exempt from the IDE regulations.[[10]](#footnote-10)

[ ]  Not applicable as a prior determination has already been made by the IRB.[[11]](#footnote-11)

[ ]  Non-Significant Risk. See completed checklist (HRP-418: Non-Significant Risk Device).

[ ]  Significant Risk Device.

[ ]  Unable to assess.[[12]](#footnote-12)

* 1. **IRB Decision:** «project.getWordMergeProperty(determinati»
	2. **Last Day of Approval Period[[13]](#footnote-13):** «project.getWordMergeProperty(dateExpirat»
	3. **Required changes & reasons)[[14]](#footnote-14):**

«project.getWordMergeProperty(modificatio»

<Indicate “There are no recommended changes for this submission.” if none.>

* 1. **Tabled reason:**

<Indicate “NA” if not applicable.>

<Indicate reason for tabling submission review. Otherwise indicate “NA.”>

* 1. **Vote:**

**For:** «project.getWordMergeProperty(votesYesCou»

**Against:** «project.getWordMergeProperty(votesNoCoun»

**Abstain:** «project.getWordMergeProperty(votesAbstai»

**Absent:** «project.getWordMergeProperty(votesAbsent»

**Recused:** «project.getWordMergeProperty(votesRecuse»

**Substitutions:** «project.getWordMergeProperty(substitutio»

* 1. **Supporting documents:**

«htmlcontent:project.generatedListOfDocum»

«TableEnd:getAgendaItemsBySubmissionType(»

**REVIEW OF REPORTABLE NEW INFORMATION**

1. **Reportable New Information:**

|  |  |
| --- | --- |
| RNI ID: | «project.ID» |
| RNI Short Title: | «project.name» |

* 1. **Related Submissions:** «TableStart:project.reportableNewInformat»

|  |  |
| --- | --- |
| **Related Study Submission ID(s):** | «ID» |
| **Study Title:** | «name» |
| **Investigator(s):**  | «investigator.studyTeamMember.fullName()» |
| **Funding:** | «customAttributes.irbSubmissionCustomExte»*<Indicate “None” if there is none.>*☐ Internal UMN Funding☐ Funding Management Outside the University |
| **Proposal/Award ID:** | «customAttributes.irbSubmissionCustomExte»*<Indicate “None” if there is none.>* |
| **IND or IDE or HDE Number:** | «getDeviceOrDrugNumbersMergeString();»*<Indicate “None” if there is none.>* *<*If this is an NSR IDE, indicate “NSR IDE”> |
| **Submission Description:** | «irbSubmissionCustomExtension.getDescript» |

«TableEnd:project.reportableNewInformatio»

* 1. **Notes:**

The committee evaluated the submission by utilizing the WORKSHEET: New Information (HRP-321). The following is a summary of the committee’s discussion:

«putItemIntoWomContext()»«project.getWordMergeProperty(notes)»

* 1. **Controverted issues and their resolution:**

*<Indicate “None” if there is none.>*

* 1. **Consultant report:** Choose an item.
	2. **IRB Decision:** «project.getRNIDeterminationMergeString()»
	3. **Required action(s) and reason(s):**

«project.reportableNewInformation.actionR»

«project.reportableNewInformation.origina»

<Indicate “None” if no additional action was required.>

* 1. **Suspension/termination reasons:**

NA

<Indicate reason for suspension/termination. Otherwise indicate “NA.”>

* 1. **Tabled reason:**

NA

<Indicate reason for tabling submission review. Otherwise indicate “NA.”>

* 1. **Vote:**

**For:** «project.getWordMergeProperty(votesYesCou»

**Against:** «project.getWordMergeProperty(votesNoCoun»

**Abstain:** «project.getWordMergeProperty(votesAbstai»

**Absent:** «project.getWordMergeProperty(votesAbsent»

**Recused:** «project.getWordMergeProperty(votesRecuse»

**Substitutions:** «project.getWordMergeProperty(substitutio»

* 1. **Supporting documents:**

«htmlcontent:project.generatedListOfDocum»

«TableEnd:getAgendaItemsBySubmissionType(»

1. Document the attendance of any member (regular or alternate) in attendance who voted during the meeting. Any member (regular or alternate) who did not vote at least once during the meeting must be documented under “Other Attendees.” IRB staff supporting the meeting, must be reflected as a “Regulatory Expert” in the attendance table. [↑](#footnote-ref-1)
2. Any non-voting individuals (including IRB staff, consultants, Investigators, etc.) in attendance at the meeting for any reason or any amount of time. If a guest is present (not IRB AD/IRB/HRPP staff), the [Confidentiality Agreement for Attendance](https://research.umn.edu/units/irb/toolkit-library/templates-forms#forms) must be completed and uploaded as a supporting document. [↑](#footnote-ref-2)
3. Document the number of regular IRB members listed on HRP-601 - DATABASE - IRB Roster, not including alternates. [↑](#footnote-ref-3)
4. IRB staff must manually select “Internal Funding” or “Funding Managed Outside the University” [↑](#footnote-ref-4)
5. If the submission is deferred or a modification, N/A should be selected. At time of continuing review, the monitoring plan should be re-affirmed. If a minimal risk study is reviewed by the convened IRB, this section still must be completed. [↑](#footnote-ref-5)
6. Controverted issues are those issues that cause controversy or dispute among IRB members during the meeting. This includes situations where there is a difference of opinions, questions or concerns, that cause debate or a formal disagreement (e.g. voting ‘no’ to a motion). [OHRP IRB Meeting Guidance](https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0#_Toc491772345) [↑](#footnote-ref-6)
7. Consultant reports are stored in the ETHOS submission as a private ancillary review. [↑](#footnote-ref-7)
8. The IRB must determine whether the scientific review requirement has been satisfied for non-exempt research. Research requiring IRB determination regarding NSR IDE do not require scientific review documentation prior to the IRB review. IRB staff should select “N/A” for continuing review submissions or modification submissions where the scientific assessment remains unchanged. [↑](#footnote-ref-8)
9. Indicate “Unable to Assess” if the initial study submission is deferred. [↑](#footnote-ref-9)
10. For studies that are exempt from the IDE regulations, the IRB does not need to decide whether the study poses a significant risk or nonsignificant risk. [↑](#footnote-ref-10)
11. IRB staff should select this option for submissions (modifications, continuing reviews) where the NSR/SR device determination remains unchanged. [↑](#footnote-ref-11)
12. For initial submissions, if deferred or disapproved, “Unable to assess” should be selected. [↑](#footnote-ref-12)
13. Indicate “NA” if the initial study submission is deferred. [↑](#footnote-ref-13)
14. Must be prescriptive in order to qualify as a modification required to secure approval (see [Stipulation Examples for Meeting Minutes - Letters](https://docs.google.com/document/d/1lpqK9SnEPX73LKL91ej5EvpaOAJ46yP1kM5KokW3Bhk/edit?usp=share_link)). [↑](#footnote-ref-14)