MINUTES[1]

Brown University

[Insert date of meeting]

ATTENDANCE

Name of Regular/Alternate Member[2]	Status (Member or Alternate)	If Voting Alternate, Member Substituting For	Present by Tele-conference ?

Reporting of Expedited Reviews:

A report of completed review conducted via the Expedited procedure during *[date range]* 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.]*

OTHER ATTENDEES[3]

Name of Attendee	Title/Role	Present by Tele-conference ?

MEETING INFORMATION

Number of IRB members on the roster[4]:
Number required for quorum:
Meeting start time:
Meeting end time:

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

[1] This template satisfies AAHRPP elements I-9, II.1.D, II.1.E, II.2.D, II.2.E-II.2.E.2, II.5.B
[2] 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.”
[3] Any non-voting individuals (including IRB staff, consultants, Investigators, etc.) in attendance at the meeting for any reason or any amount of time.
[4] Document the number of regular IRB members listed on HRP-601 - DATABASE - IRB Roster, not including alternates.

ATTENDANCE KEY

Vote Type	Description
FOR:	Voting for the motion.
AGAINST:	Voting 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. May be deleted if there are no substitutions.

OTHER BUSINESS

1. Item
2. Item
3. Item

REVIEW OF PROTOCOLS

1. **Protocol Review:**

Type of Review:	*<Indicate Initial, Continuing, Modification>*
Title:	
Investigator:	
IRB ID:	
Funding:	*<Indicate "None" if there is none.>*
Grant Title:	*<Indicate "None" if there is none.>*
Grant ID:	*<Indicate "None" if there is none.>*
IND or IDE:	*<Indicate "None" if there is none.>*
Documents Reviewed:	

   a. **Notes:**

      <If approved, include statement that the IRB determined that all criteria for approval were met.>

   b. **Consultant report:**

   c. **Controverted issues and their resolution:** *<Indicate "None" if there is none.>*

   d. **Level of risk:** Minimal Risk/Greater than Minimal Risk

   e. **Determinations and findings that require documentation:** *<Append completed checklist(s) when applicable.>*

   f. **Rationale for a significant/non-significant device determination per FDA:**

   g. **Motion:**

   h. **Modifications required to secure approval:**

Required Change	Reason

   i. **Deferral/disapproval reasons and recommended changes:**

Recommendation	Reason

   j. **Suspension/termination reasons and recommended changes:**

Recommendation	Reason

   k. **Tabled reason:**

   l. **Vote:**

      For:
      Against:

Abstain:
Absent:
Recused:
Substitutions:

REVIEW OF REPORTABLE NEW INFORMATION

2. Reportable New Information:

Type of Review:	*<Indicate Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval>*
Title:	
Investigator:	
IRB ID:	
Funding:	*<Indicate "None" if there is none.>*
Grant Title:	*<Indicate "None" if there is none.>*
Grant ID:	*<Indicate "None" if there is none.>*
IND or IDE:	*<Indicate "None" if there is none.>*
Documents Reviewed:	

a. Notes:

b. Consultant report:

c. Controverted issues and their resolution: *<Indicate "None" if there is none.>*

d. Motion:

e. Required action(s):

Required Action(s)	Reason

f. Request for additional information:

Requested Information	Reason

g. Suspension/termination reasons and recommended changes:

Recommendation	Reason

h. Tabled reason:

i. Vote:

For:
Against:
Abstain:
Absent:
Recused:
Substitutions:

POSSIBLE CONTINGENCIES FOR DETERMINATIONS AND PROTOCOL-SPECIFIC FINDINGS THAT REQUIRE DOCUMENTATION

Research Involving Pregnant Women or Neonates that is Not Otherwise Approvable (45 CFR §46.207)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and requires OHRP approval.
The research may proceed only after the Director, Defense Research (DOD) and Engineering has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and requires approval by the Director, Defense Research and Engineering.
The research may proceed only after organizational officials have conducted a review in accordance with the HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.	The research is not conducted or funded by DHHS and requires an external review as an additional ethical protection.

Research Involving Prisoners as Subjects (45 CFR §46 Subpart C)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and falls into the 45 CFR §46.306(2)(C), which requires OHRP approval.
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and falls into the 45 CFR §46.306(2)(D) category and prisoners are assigned to control groups which may not benefit from the research, which requires OHRP approval.
The research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled.	The research is conducted or funded by DHHS and OHRP requires certification of such research before it may proceed.
The research may proceed only after the Director, Defense Research and Engineering (DOD) has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and falls into the 45 CFR §46.306(2)(C), which requires approval by the Director, Defense Research and Engineering.
The research may proceed only after the Director, Defense Research and Engineering (DOD) has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and falls into the 45 CFR §46.306(2)(D) category and prisoners are assigned to control groups which may not benefit from the research, which requires approval by the

	Director, Defense Research and Engineering.
The research may proceed only after the institution has certified to the Director, Defense Research and Engineering (DOD) that the duties of the Board under this section have been fulfilled.	The research is conducted or funded by Department of Defense (DOD) and the Director, Defense Research and Engineering requires certification of such research before it may proceed.

Research Involving Children as Subjects (21 CFR §50.54/45 CFR §46.407)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and requires OHRP approval.
The research may proceed only after the Director, Defense Research (DOD) and Engineering has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and requires approval by the Director, Defense Research and Engineering.
The research may proceed only after Commissioner of Food and Drugs has reviewed and approved the research.	The research is FDA regulated and requires FDA approval.
The research may proceed only after organizational officials have conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.	The research is not conducted or funded by DHHS and not FDA regulated, and requires an external review as an additional ethical protection.