

Attachment 6 CDC IRB Approval

DATE: 5/1/2008

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #2805, "Exposure to Aerosolized Brevetoxins During Red Tide Events" (Expedited)

TO: Lorraine Backer, PhD, MPH [LFB9]
NCEH/EHH

CDC's IRB A has reviewed and approved your request to continue protocol #2805 for the maximum allowable period of one year and it will expire on 5/22/2009. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories 3 & 7.

NOTE: We need the current local approval's for the University of Miami, the Florida Department of Health and All Children's Hospital of the University of South Florida and they should be sent as soon as possible to our office.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 5/22/2009.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

John A. Valosen
Administrator IRB A

cc:
NCEH/ATSDR Human Subjects
Dee Williamson

DATE: 8/8/2008

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Amendment to Protocol #2805, "Exposure to Aerosolized Brevetoxins During Red Tide Events" (Convened Board - A)

TO: Lorraine Backer, PhD, MPH [LFB9]
NCEH/EHH

CDC's IRB A has reviewed and approved your request to amend protocol #2805 by the addition of a component to this study to assess whether loratidine, an antihistamine available in over-the-counter products, such as Claritin, can relieve the upper respiratory symptoms induced by inhaling aerosolized brevetoxins during Florida red tides; and the addition of an Informed consent to be obtained using the Impact of Loratidine Consent Form.

NOTE: This request for approval was met with a great deal of discussion and there were dissenting votes to its approval. If you would like to view some of the comments from the negative report please let me know and I can supply you with them.

Also, the board wishes to see the study results and any of the PI's recommendations before they go into print/media as a condition of this approval.

Reminder: IRB approval of protocol #2805 will still expire on 5/22/2009. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

John A. Valosen
Administrator IRB A

cc:
NCEH/ASTDR Human Subjects
Anne Latimer
Dee Williamson
Scott Campbell