



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

ARM1.950119.008i



SGRD-HR (15-1a)

10 November 1992

MEMORANDUM FOR THE SURGEON GENERAL

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

1. Pursuant to AR 40-7, 4 January 1991; OTSG Regulation 15-2, 11 January 1989; AR 40-38, 1 September 1989 and AR 70-25, 25 January 1990, a meeting of the Human Subjects Research Review Board (HSRRB) was held at 1300 in Room 640, 5109 Leesburg Pike, Falls Church, VA, on 9 November 1992. The HSRRB is the principal body of the Office of The Surgeon General (OTSG) for the assessment of practices and procedures by which DA employs human subjects in research and clinical investigation activities.

a. Voting members present were:

(1) COL Bonnie M. Jennings, AN, TSG Nursing Consultant, SGPS-CP-N (Acting Chairman).

(2) COL Ariel Rodriguez, MC, TSG Surgical Consultant, SGPS-CP-S.

(3) COL J. Pitt Tomlinson, MC, TSG Disease Control Consultant, SGPS-PSP-D.

(4) COL Shannon M. Harrison, MC, TSG Clinical Investigation Consultant, HSHN-I, U.S. Army Health Services Command.

(5) COL George C. Southworth, MS, TSG Laboratory Science Consultant, SGPS-CP-L.

(6) COL James P. Wilson, TSG Pharmacy Consultant, SGPS-PC-P.

(7) LTC John F. Glenn, MS, Executive Assistant to the Commander, USAMRDC.

(8) CHAP (LTC) David M. DeDonato, Department of Ministry and Pastoral Care, Walter Reed Army Medical Center.

(9) MAJ Dale G. Vander Hamm, MS, Chief, Human Use Review and Regulatory Affairs Office, USAMRDC.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

(10) MAJ Intisar A. Abbasi, MS, U.S. Army Medical Materiel Development Activity.

(11) MAJ Michael E. Frisina, MS, SGRD-OP, USAMRDC.

(12) CSM Johnny M. Williamson, Command Sergeant Major, USAMRDC.

(13) Ms. Helen Miller-Scott, U.S. Army Medical Research Institute of Infectious Diseases.

b. Also present were:

(1) COL Harry G. Dangerfield, MC, U.S. Army Medical Research and Development Command.

(2) LTC David N. Taylor, MC, Walter Reed Army Institute of Research.

(3) MAJ Victor McGlaughlin, MC, Womack Army Medical Center.

(4) Ms. Catherine A. Connor, Human Use Review and Regulatory Affairs Office, USAMRDC.

(5) Ms. Martha H. Myers, Human Use Review and Regulatory Affairs Office, USAMRDC (Recorder).

2. After determining that a quorum of eight was present, COL Jennings opened the meeting at 1302.

3. The minutes of the 14 October 1992 meeting of the HSRRB were presented for Board examination and comment (encl 1).

4. The minutes of the 23 October 1992 meeting of the HSRRB Subcommittee for Review of Materiel Test Plans and Protocols were presented for information (encl 2).

5. A list of protocols administratively approved as reported by the Human Use Review and Regulatory Affairs Office since the 14 October 1992 HSRRB meeting was presented (encl 3).

6. Annual reports were presented for the following INDS:

a. BB-IND 365 - Rift Valley Fever Vaccine (encl 4).

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

b. BB-IND 1114 - Bolivian Hemorrhagic Fever Immune Globulin (Human) (encl 5).

c. IND 16666 - Ribavirin (Virazole) (encl 6).

d. IND 30726 - Ketoconazole and Pentostam (encl 7).

7. A report of an incident related to the protocol entitled "Active Immunization of Early HIV Infected Patients with Recombinant gp160 HIV Protein: Phase II Clinical Efficacy," submitted by LTC Robert R. Redfield, MC, WRAMC (Log No. A-5392) was presented for information (encl 8). The Human Use Review and Regulatory Affairs Office was directed to obtain a copy of the additional consent form used for the subject involved in this incident and a copy of the modification to the protocol to allow continuation of a female volunteer who becomes pregnant during course of the study. Questions were raised concerning (a) the right of the mother to consent for her unborn child and (b) whether the father should have the opportunity/responsibility to read and sign the informed consent in cases such as this. The investigator should explain whether the human use committee at Womack Army Medical Center was notified of this incident. The USAMRDC Command Judge Advocate will be consulted on the legal implications of this action. *? need for formal amendment*

8. Report of incident related to protocol entitled "Serologic Response to Anthrax and Botulism Vaccines," submitted by LTC Maria H. Sjogren, MC, USAMRIID (Log No. A-5747) (encl 9). The investigator should explain whether the human use committee at Womack Army Medical Center was notified of this incident. The USAMRDC Command Judge Advocate will be consulted on the legal implications of this action.

9. The following protocols A-D (encls 10-13) were acted upon by the Board. The appropriate review committees will review these studies annually unless otherwise stated. **NOTE:** The question of whether or not the HSRRB's current policy regarding storage of donated blood/tissue/body fluid products samples is adequate was discussed in relation to all the protocols presented at this meeting. Since the legal representative was unable to be present at this meeting, he will be consulted on this matter and the subject will be discussed at the December meeting of the Board.

a. Protocol A - "Phase I Study of Vinblastine Plus Cyclosporin (CSA) and Quinine as Modulators of Multidrug Resistance (MDR)," submitted by Lori J. Goldstein, M.D., Fox Chase Cancer Center (Log No. A-5788) (encl 10).

3RD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

(1) BOARD'S RECOMMENDATION: Deferred. Documentation of review for scientific merit and review and approval by the Fox Chase Institutional Review Board must be submitted. Before resubmission for reconsideration by the HSRRB, the following additional information must be provided and revisions made to the protocol and consent form:

(a) The name and curriculum vitae of the medical monitor must be provided.

(b) A copy of all case report forms must be provided.

(c) With regard to the protocol:

1. Since the use of cyclosporin in this study is not the approved indication for the product, has an Investigational New Drug (IND) application been filed? What is the source of the drug?

2. It is noted that renal toxicity is not being monitored in this study? Has consideration been given to the effect of escalating doses on renal toxicity? *? of on-line monitoring of cyclosporin levels.*

3. Page 7, Section 3.18, change to read "Female patients of reproductive potential must have a negative serum pregnancy test within 48 hours prior to each drug administration (no more than monthly)."

4. Page 11, Section 7.2, Pregnancy test, an "X" should also be placed on the pregnancy test line under the "Every 4 Weeks" column.

5. Page 14, Section 10.0, if females will be removed from the study in the event they become pregnant, this should be stated here and in the consent form.

6. The Human Use Review and Regulatory Affairs Office, USAMRDC, should be included in Section 11.4 on page 15 as an agency to be notified of adverse reactions occurring during the conduct of this study.

(d) With regard to the consent form:

1. The complete title "Phase I Study of Vinblastine Plus Cyclosporin and Quinine as Modulators of Multidrug Resistance (MDR)" should be listed on the consent form.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

2 The location of the study and the principal investigator's name should be listed after the title.

3 The statement under Purpose on page 1 should be rewritten as follows: The purpose of this research study is to determine the best dose of CSA or the dose associated with the fewest unfavorable effects or greatest improvement when given in combination with quinine and vinblastine.

4 The words/phrases "express a protein," "suppress the body's immune system," "action of this protein pump," "intravenously," "indwelling catheter," "mechanism of action," "P-glycoprotein," "bone marrow is involved with tumor cells," "platelet cell count," "red blood cell count," "established toxicity profile," "immunosuppression," "chronically," "dose-dependent nephrotoxicity," "hirsutism" (which is misspelled), "gingival hyperplasia," "lymphomas," "hemolytic uremic syndrome," "hypomagnesemia," "anaphylaxis," "hyperkalemia," "pancreatitis," "chemotherapy," "toxicity," "general anesthesia" and "pneumothorax" should be expressed in lay terms.

5 The following should be added to the consent form: I understand the blood, biopsy tissue and urine samples which I am providing may also be used in other research studies. I will not be personally identified in any publication of the results of these other research studies. In addition, I agree to waive all property rights to these blood/tissue/body fluids.

6 Suggest the volunteer and witness be instructed to date and initial all but the last page of the consent form.

7 Page 2, paragraph 1, line 2, delete "(by vein);"
line 3, change "disease" to "tumor;" line 7, change the second occurrence of the word "day" to "dose." In paragraph 2, the total amount of blood to be drawn during the entire study should be noted in lay terms.

8 It is stated in paragraph 2 on page 2 that tests will be decided by the patient's physician. Page 11 of the protocol shows a schedule of routine tests to be performed. If these tests will be routine, the patient should be informed of the type, duration and frequency of these tests.

9 Page 2, paragraph 3, line 6, change the sentence to read "...tumor increases in size, and if I have a lump...;" line 11, insert "(1 teaspoonful)" after "5 cc." Also, the word "proceeded" in line 13 should be changed to "preceded."

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

10 The word "of" should be inserted after the phrase "... has been used extensively in treatment ..." in line 1 under Vinblastine Toxicity on page 3.

11 Page 3, under Risks, add the risks associated with biopsies.

12 Page 4, paragraph 5 states other alternatives are available. However, it is understood these patients will have exhausted all known treatments before enrollment in this protocol. Please clarify. In paragraph 6, add representatives of the U.S. Army Medical Research and Development Command as those eligible to review research records. In paragraph 7, fourth through sixth sentences should be replaced with "I understand that I will be provided all necessary medical care for injury or disease which is the proximate result of my participation in this research. Other than medical care that may be provided, I will not receive any compensation for my participation in this research study; however, I understand that this is not a waiver of my legal rights."

13 Page 5, paragraph 8, line 2, the word "in" is misspelled. In paragraph 9, delete the second sentence. In paragraph 10, include criteria for removal from the study that are listed on page 14, Section 10.0 of the protocol.

14 What procedures will be followed for obtaining consent in the event the patient becomes comatose during the study? Will third party consent be obtained or will the patient be withdrawn from the study? This should be explained in the consent form and the form should be modified to accommodate third party consent.

(2) BOARD'S VOTE: Twelve in favor (COL Tomlinson not available for vote).

b. Protocol B - "Phase II Study of Vinblastine Plus R-Verapamil as a Modulator of Multidrug Resistance in Metastatic Breast Cancer," submitted by Lori J. Goldstein, M.D., Fox Chase Cancer Center (Log No. A-5789) (encl 11).

(1) COMMENTS: Board members questioned whether the terminally ill patients to be enrolled in this study should be asked to participate in a study to determine toxic dose levels rather than to receive therapeutic benefit. Also, members were frustrated by the overall imprecision of this protocol.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

(2) BOARD'S RECOMMENDATION: Deferred. Documentation of review for scientific merit and review and approval by the Fox Chase Institutional Review Board must be submitted. Before resubmission for reconsideration by the HSRRB, the following additional information must be provided and revisions made to the protocol and consent form:

(a) The name and curriculum vitae of the medical monitor must be provided.

(b) A copy of all case report forms must be provided.

(c) Has an Investigational New Drug (IND) application been filed with the Food and Drug Administration (FDA) for the use of R-Verapamil? If so, the name of the sponsor and the FDA-assigned code number should be provided. Also, the investigational nature of the drug should be described in the consent form, e.g., "The drug, R-Verapamil, is experimental for the purposes to be investigated; it is not approved by the Food and Drug Administration for this purpose."

(d) With regard to the protocol:

1. D-Verapamil and R-Verapamil are both referred to in the proposal. Please clarify whether these are two separate drugs or typographical errors (see pages 17 and 22 of the proposal).

2. The word "response" in 6 of paragraph 4 on page 7 should be changed to "respond."

3. Page 10, change Section 3.20 to read "Female patients of reproductive potential must have a negative serum pregnancy test within 48 hours prior to each drug administration (no more than monthly)."

4. Were the rounding rules used to determine the 360 mg/m² dose (page 11, Section 6.2)?

5. References in Section 7.12 on page 12 to other drugs and references in Sections 7.4 and 7.5 on page 13 to "holding" or "discontinuing" drugs are unclear since their use is not mentioned in the protocol. With reference to Section 7.41 on page 13, what alternative to phenothiazine will be used to treat nausea and vomiting?

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

6 The reference to Verapamil in Section 7.7 on page 14 as a drug which "should not be taken" is unclear. Please clarify.

7 Section 7.9 on page 14 should be deleted.

8 Page 16, Section 9.2, Pregnancy test, an "X" should also be placed on the pregnancy test line under the "Every 4 weeks" column.

9 Section 9.4 should be rewritten. Time zero ("t=0") cannot indicate time prior to beginning treatment. Specify the range, i.e., -15 to -30 minutes. This error also occurs in other places in the protocol. Also, clarify the times for blood collection (Day 24 or at 24 hours).

10 Page 19, Section 12, if females will be removed from the study in the event they become pregnant, this should be stated here and in the consent form.

11 The Human Use Review and Regulatory Affairs Office, USAMRDC, should be included in Section 14.4 on page 20 as an agency to be notified of adverse reactions occurring during the conduct of this study.

(e) With regard to the consent form:

1 The complete title "Phase II Study of Vinblastine Plus R-Verapamil as a Modulator of Multidrug Resistance in Metastatic Breast Cancer" should be listed on the consent form.

2 The location of the study and the principal investigator's name should be listed after the title.

3 The terms/phrases "drug therapy," "chemotherapeutic," "resulted in responses," "express a protein," "chemotherapy," "protein pump," "drug resistance," "experimental model systems of cancer," "heart toxicity," "bone spread," "indwelling port," "intravenously," "indwelling catheter," "intolerable side effects," "biopsies," "bone marrow is involved with tumor cells," "mechanism of action," "white blood cell count," "platelet cell count," "red blood cell count," "hypotension," "bradycardia," "congestive heart failure," "peripheral edema," "avascular necrosis," "cushing syndrome," "edema," "menstrual irregularities," "hypokalemia syndrome," "osteoporosis," "pancreatitis," "peptic ulcer," "steroid myopathy," "poor wound healing," "hyperglycemia," "steroid psychosis," "aspiration,"

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

"anesthetic," "allergic reaction," and "aspiration of ascites" should be expressed in lay terms.

4 A copy of all other consent forms used in the study must be provided for approval.

5 Inform patients why their blood pressure may drop and how the use of Decadron will help.

6 The following should be added to the consent form: I understand the blood, biopsy tissue and urine samples which I am providing may also be used in other research studies. I will not be personally identified in any publication of the results of these other research studies. In addition, I agree to waive all property rights to these blood/tissue/body fluids.

7 Page 2 states that tests will be decided by the patient's physician. Page 16 of the protocol shows a schedule of routine tests to be performed. If these tests will be routine, the patient should be informed of the type, duration and frequency of these tests. In paragraph 4, the total amount of blood to be drawn during the entire study should be noted in lay terms. In paragraph 5, line 5, the word "disease" should be changed to "tumor" and the sentence in that line should be changed to read "...tumor increases in size, and if I have a lump..." In paragraph 5, line 11, insert "(1 teaspoonful)" after "5 cc."

8 Page 3, under Risks, add the risks associated with biopsies.

9 Page 4, under Benefits, the third sentence should read "If this does happen, I might feel better." Under Confidentiality, add representatives of the U.S. Army Medical Research and Development Command as those eligible to review research records. Under Certain Costs, the fourth through sixth sentences should be replaced with "I understand that I will be provided all necessary medical care for injury or disease which is the proximate result of my participation in this research. Other than medical care that may be provided, I will not receive any compensation for my participation in this research study; however, I understand that this is not a waiver of my legal rights." Under Withdrawal, delete the second sentence.

10 Page 5, under Termination, include criteria for removal from the study that are listed on page 19 of the protocol.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

11 What procedures will be followed for obtaining consent in the event the patient becomes comatose during the study? Will third party consent be obtained or will the patient be withdrawn from the study? This should be explained in the consent form and the form should be modified to accommodate third party consent.

(3) BOARD'S VOTE: Twelve in favor (COL Tomlinson not available for vote).

c. **Protocol C - "The Role of Bone Marrow Micrometastases in Breast Cancer,"** submitted by MAJ Kenneth A. Bertram, MC, MAMC (Log No. A-5751) (encl 12).

(1) COMMENTS: COL Harrison noted that this protocol was not submitted through the Clinical Investigation Program Division, Health Care Studies Clinical Investigation Activity.

(2) BOARD'S RECOMMENDATION: Approved, provided the following additional information is submitted and revisions are made to the consent form:

(a) A copy of the medical monitor's curriculum vitae should be submitted, when available.

(b) With reference to the consent form:

1. The terms/phrases "relapse," "blood work" and "bone scan" in paragraph 1 under Introduction should be explained in lay terms. Also, volunteers should be informed how much is meant by "a small amount of blood."

2. If volunteers will be in-patients for these procedures, they should be so informed.

3. The word "separate" in line 3 of paragraph 1 under Procedures is misspelled.

4. With reference to paragraph 2 under Procedures, two-three ml seems a large amount. Is that amount intended?

5. A description of what is meant by "local anesthesia" and "bone marrow aspiration" as well as a description of any pain associated with each should be included. Also, it should be made clear that there will be initial and repeat bone marrow aspirates performed.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

6 A description should be included of the types of "hypersensitivity (allergic) reaction" referred to under Risks, Inconveniences, and Discomforts.

7 The following statements should be included: The blood and bone marrow samples which you are providing may also be used in other research studies. You will not be personally identified in any publication of the results of these other research studies. In addition, you agree to waive all property rights to these blood and bone marrow samples.

(3) BOARD'S VOTE: Twelve in favor (COL Tomlinson not available for vote).

d. Protocol D - "A Randomized, Controlled Field Trial of the Killed Vibrio cholerae Whole Cell Plus Recombinant B Subunit (WC/rBS) Cholera Vaccine to Prevent Cholera in Peru," submitted by Eduardo Gotuzzo, M.D., Cayetano Heredia University (thru WRAIR) (Log No. A-5791) (encl 13).

(1) COMMENTS: LTC Taylor gave a brief summary of the study objectives and the events leading up to the proposed study. Members questioned the ethics of excluding pregnant females if the vaccine is, as LTC Taylor put it, "safer than soda water."

(2) BOARD'S RECOMMENDATION: The Board voted to grant an exception to its policy to require serum pregnancy testing for this study (MAJ Abbasi and CSM Williamson opposed; COL Tomlinson not available for vote). The protocol is recommended for approval, provided the following additional information is submitted and revisions are made to the protocol and consent form:

(a) The curriculum vitae of the medical monitor should be provided, when available.

(b) With reference to the protocol:

1 In Item 4 on page 4, the IND holder should be listed as The Surgeon General of the Army.

2 The word "over" in line 1 of Item 8.7 on page 18 should be deleted.

3 The prefix "663" in Item 16 on page 30 should be changed to "619."

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

4 Will the fact that sample size was based on the number of persons as the observational unit impair any statistical significance equations (page 18)?

5 The phrase "women known to be pregnant" should be deleted from Item 8.8 on page 18.

6 The term "outcome" in lines 13 and 15 of Item 8.11 on page 19 should be changed to "entry." The possibility of "only one dose administered" entry should also be listed. Primary "outcome" possibilities are disease, cultures and immune response.

7 Circulating humoral immunity will be measured as an outcome measure. Will any measure of secretory immunity (e.g., IgA, IgM) be possible or feasible?

8 With reference to Item 8.16.3 on page 24, secondary analyses can reasonably be used for hypothesis testing if proposed before the study and reasonable subsample size is retained.

9 Should the word "second" in line 2 of the paragraph beginning "Booster analysis" on page 25 be changed to "third," (e.g., the second regimen)?

10 The word "note" in line 3 of Item 8.16.3.4 on page 25 should be changed to "not."

11 Is there any seasonality to cholera in this community? Will vaccine recipients develop antibodies before the "high" season begins?

12 Is there any reason to believe that blood group may influence development of antibodies or clinical response to vaccine? Has this analysis been considered?

13 Will the vaccination team members and other personnel be vaccinated assuredly or enrolled in the study?

14 In order to establish clear intent to benefit all subjects in the study, oral vitamins should be added to the treatment regimen of both the vaccine and placebo groups.

15 The reference in Item 24 on page 31 to the WRAIR Human Use Committee should be changed to the Cayetano Heredia

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

Peruvian University Directorate Committee. Also, the word "Committee" in the last line should be changed to "Board."

(c) With reference to the consent form:

1 The form should be rewritten so as to accommodate signature by the subject or the legal representative, e.g., "I/my child."

2 The title and location of the study should be included.

3 The name of the principal investigator should be included.

4 The word "research" should be inserted before the word "study" in line 2 of paragraph 1.

5 Subjects/legal representatives must be provided a copy of the consent form. A statement that they will receive a copy should be included in the form.

6 The investigational nature of this vaccine should be clearly described, e.g., "The vaccine being used in this study is an investigational vaccine. This means it is being tested now, but is not yet approved by the U.S. Food and Drug Administration for use in the general population." Further, it may be prudent to indicate that the vaccine is composed of inactivated cholera bacterial proteins.

7 Statements that the subjects/legal representatives will incur no costs nor receive any compensation for their participation should be included.

8 The facts that half of the subjects will receive placebo (a liquid containing no cholera antigens) should be included and that at the conclusion of the study those who received placebo will be contacted and offered the vaccine.

9 A statement should be included which indicates the total duration of participation.

10 A more complete description of the procedures to be followed should be included, e.g., how will doses be administered? Should subjects be instructed not to eat anything for 90 minutes before and after each dose?

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

11 Since the participants in the pilot study will have blood drawn that should be indicated as well as a description of the risks and discomforts of that procedure.

12 A description of any benefits (e.g., the receipt of vitamins) to the subject or to others which may reasonably be expected from the research should be included.

13 A statement that the vaccine may cause unanticipated side effects (including the possibility of anaphylaxis) should be included. Also, a description of any data from previously conducted studies regarding the effects of this vaccine on the unborn fetus should be included. If no data are available, that should be stated.

14 The statement "You/your child is authorized all necessary medical care for injury or illness which is the direct result of your/his/her participation in this research study" must be included.

15 The following should be included: In any publication that results from this study you/your child will not be personally identified. Representatives of the U.S. Army Medical Research and Development Command, U.S. Naval Medical Research Institute, U.S. Food and Drug Administration, the Ministry of Health of Peru and Cayetano Heredia University may inspect the records of this study due to their support and interest in this vaccine.

16 An explanation of whom to contact for answers to pertinent questions about the research study and in the event of a research-related injury should be included.

17 An explanation of whom to contact for answers to pertinent questions about research subjects' rights should be included. This information should include address and phone number.

18 Paragraph 5 should be replaced with the following: I/my child may refuse to participate or may withdraw my consent from this research study at any time without loss of any benefits to which I/my child am/is entitled. If I/my child need(s) a consultation with the Health Department, I will inform them of my/my child's participation in the study.

19 The following should be included: The body products samples which you are/your child is providing may also be used in

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

other research studies. You/your child will not be personally identified in any publication of the results of these other research studies. In addition, you/your child agree to waive all property rights to these body products samples.

20 The last sentence in paragraph 6 beginning "I understand that only one ..." should be changed to read "I understand that receiving this vaccine does not guarantee protection against cholera."

21 Documentation that the Peruvian version of the revised consent form is accurate should be provided. That documentation should include, on the English version, the statement "I certify that this is an accurate and true translation" as well as the signature, name, address, phone number and FAX number of the translator.

(3) BOARD'S VOTE: Ten in favor; two abstaining (MAJ Abbasi and CSM Williamson); COL Tomlinson not available for vote.

10. COL Dangerfield and MAJ McGlaughlin were welcomed as observers of the Board's proceedings. LTC Glenn and MAJ Vander Hamm were welcomed as new Board members replacing COL Dangerfield and LTC Berezuk, respectively.

11. MAJ Frisina informed members that he had obtained a videotape depicting the obtaining of consent from a prospective volunteer which he will show before or after the December meeting of the HSRRB.

12. Members were reminded to report any conflicts with the proposed 1993 schedule of meetings to the Human Use Review and Regulatory Affairs Office as soon as possible so that the final schedule may be prepared.

SGRD-HR

SUBJECT: Minutes of the Meeting of the Human Subjects Research Review Board, 9 November 1992

13. There being no further business, the meeting was adjourned at 1440. The next regularly scheduled HSRRB meeting is to be held on 9 December 1992.

13 Encls

Marta H. Myers

MARTHA H. MYERS
Investigational Drug Review
Specialist
Human Use Review and
Regulatory Affairs Office
Recorder

RECOMMEND APPROVAL/~~DISAPPROVAL~~

Bonnie M. Jennings

DATE: 12 Nov 92

BONNIE M. JENNINGS
Colonel, AN
Acting Chairman
Human Subjects Research Review Board

APPROVED/~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

F. N. Bussey

DATE: 14 Nov 92

FREDERICK N. BUSSEY
Major General, MC
Deputy Surgeon General

13 November 1992

MEMORANDUM FOR SGRD-HR

SUBJECT: Human Subjects Research Review Board - 9 November 1992

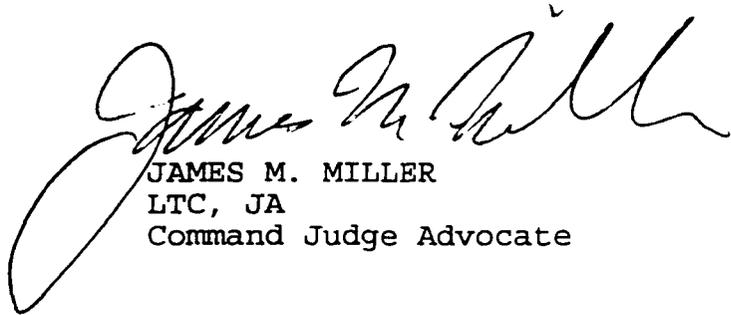
1. Pursuant to regulatory guidance, the protocols submitted for review at subject meeting have been reviewed and the following comments are provided.

a. Log Nos. A-5788 (A) and A-5789 (B). It would appear that both of these protocols will be run in Pennsylvania where I believe the age of majority is 21 years of age. Therefore, it is recommended that the volunteer group be 21 years and older vice 18 years. In the alternative, the consent forms could be adopted to include guardian permission. In this instance, benefit would need to be shown/discussed for the minors involved to ensure compliance with 10 USC 980.

b. Log No. A-5751 (C). No comment.

c. Log No. A-5791 (D). Concur with the comments made by HURRAO. Further, I vote that the protocol be rejected because the use of minors and placebos make it impossible to demonstrate the benefits of this protocol to all minors. This deficiency is fatal due to the fact that it violates the provisions of 10 USC 980.

2. If further information/discussion is desired, please contact the undersigned.



JAMES M. MILLER
LTC, JA
Command Judge Advocate

17 NOV 92 08 37

RECEIVED
U.S. ARMY MEDICAL DEPT.
HUMAN USE REVIEW OFFICE