

FROM: SGS (Mrs Whitaker/7143)

23 Oct 92

SUBJ: Minutes of the Institutional Review Committee (IRC) Subcommittee
on Potential Scientific Misconduct in GP160 Phase I Immunotherapy Study

TO: WHMC IRC
SG-2

1. PLACE: Clinical Investigation Conference Room
2. DATE AND TIME OF MEETING: 23 Oct 92, 0800 hours
3. ATTENDANCE:

a. Members:

Col John H. Classik, BSC	SGS	Chairman
Lt Col Frank J. Criddle, MC	SGH	Dep. Dir., Hospital Services Dir.
Maj Paul M. Dankovich, JD	SGJ	Dir, Medical Law
Capt Steven G. Davis, BSC	SGHDP	Chief, Clinical Pharmacy
Dr Clifford A. Butzin, PhD	SGS	Consultant (non-voting member)
Mr James M. Wilbourn, GS-12	LTC/XR/3	Research Psychologist
Mrs Nancy K. Whitaker, GS-6	SGS	Recorder (non-voting member)

b. Visitors:

Col R. Neal Boswell, MC	SGHM	Assoc. Chief, Div of Medicine
Maj Craig W. Hendrix, MC	SGHMI	Director, HIV Program
Capt Stewart R. Wirebaugh	SGHDP	Clinical Pharmacist
Dr George Kelling, PhD	SGPA	Historian/Public Affairs Rep

4. DISCUSSION:

a. This subcommittee was convened under the auspices of AFR 169-8, "Human Use in Clinical Investigations," and WHMC MCR 169-11, "Scientific Fraud and Misconduct," to address an alleged incidence of misconduct by Lt Col Robert Redfield, an Army researcher involved in the Phase I GP160 Immunotherapy Study, assigned to the Walter Reed Army Institute of Research (WRAIR). Maj Hendrix presented a chronological overview of events leading up to a letter he and Col Boswell forwarded to Col Donald Burke, Director of WRAIR, on 21 Oct 92. Maj Hendrix's point paper and a copy of the letter are attached. For clarification, the following five groups involved in the Military Medical Consortium for Applied Retroviral Research (MMCARR) and key people are identified:

(1) Walter Reed Army Medical Center, Col Charles N. Oster, Chief, Infectious Disease Service

(2) Wilford Hall Medical Center Clinical Unit, Maj Craig Hendrix, Director, HIV Program

(3) National Naval Medical Center, Capt Walter Karney, Manager, HIV Navy Program

(4) Walter Reed Army Institute of Research (WRAIR), Col Don Burke, Director; Lt Col Robert Redfield, Principal Investigator of Phase I Study; Dr Maryanne Vahey, researcher in Dr Redfield's lab; Dr John Brundage, Epidemiologist.

(5) Henry M. Jackson Foundation Lab, Dr Bill McCarthy, Statistician; Dr John Brundage, Epidemiologist.

b. The committee discussed Maj Hendrix's allegation that Dr Robert Redfield may have either misled or deceived the scientific community in several presentations of the GP160 Phase I Immunotherapy Study. His 21 Oct 82 letter makes three recommendations:

(1) There must be widest possible public correction of the record to show that findings presented by Dr Redfield are premature and/or unsubstantiated.

(2) Dr Redfield should be censured for scientific misconduct, if this is proven.

(3) An independent investigation of the Phase I study should be conducted.

CONCLUSION: It was noted that no Wilford Hall patients or investigators have been involved in the Phase I study in question. The committee agreed the information presented by Dr Redfield seriously threatens his credibility as a researcher and has the potential to negatively impact AIDS research funding for military institutions as a whole. His allegedly unethical behavior creates false hope and could result in premature deployment of the vaccine. The need for Phase II studies, which stand to answer questions raised in this controversy, could also come into question.

RECOMMENDATIONS/ACTION: The committee voted unanimously to take the following action:

(1) Through the chain of command, address the fact that the triservice agreement stating a HMJF statistical group must evaluate all data presented for oral presentation or publication has not been adhered to. Evaluations must be done with no exceptions; and

(2) address the fact that papers/data from any MMCARR source must be reviewed in-house prior to release (this also has not been adhered to).

(3) Dr Hendrix and Dr Boswell should be officially tasked to conduct a fact-finding visit to WRAIR along with Col Oster (USA) and Capt Karney (USN). Based on their findings, they may recommend an audit by an outside agency. A full disclosure in the form of a written report should be presented to the IRC and to HQ AFMOA/SG. If an outside evaluation is requested, the agency should attempt to gather video/audiotapes of presentations made in public settings by Dr Redfield.

(4) While the focus of investigation is the Phase I GP160 study, the appearance of impropriety in one study raises into question the entire process of data analyses and presentation for all protocols which have been activated at WHMC through the MMCARR mechanism. The findings of internal or external review should be considered by the WHMC IRC in the context of potential impact on all consortium protocols.

(5) Dr Hendrix should be appointed in writing as principal representative from WHMC to the MMCARR, and for all HIV-related issues. The committee believes Dr Hendrix should be officially commended for his concern and for his thorough and timely response to this issue.

(6) WHMC should continue to participate in the GP160 Phase II studies, since it is anticipated these studies will answer questions about efficacy of the GP160 vaccine.

FOLLOW-UP: OPEN: 27 Oct 92, OPR: Maj Hendrix

5. ADJOURNMENT: 0945 hours

Nancy K. Whitaker
NANCY K. WHITAKER
Protocol Coordinator
Clinical Investigations

- 3 Atch
1. Point Paper
2. SGHMI-H Ltr, 21 Oct 92
3. Science article, 9 Oct 92

John H. Cissik
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Director, Clinical Investigations