



**DEPARTMENT OF THE AIR FORCE**  
 HEADQUARTERS JOINT MILITARY MEDICAL COMMAND - SAN ANTONIO (ATC)  
 WILFORD HALL USAF MEDICAL CENTER  
 LACKLAND AIR FORCE BASE TX 78236-5300

REPLY TO  
 ATTN OF SGHMI-H/Maj Melcher (DSN 554-7444)

28 May 92

SUBJECT Revised Consent Form for Study Entitled, "HMJF #RVOI-08, A Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium Avium Complex Disease in HIV-Infected People."

HARRY G. DANGERFIELD, M.D., Colonel, MC  
 Acting Chairman  
 Human Subjects Research Review Board

We are submitting for approval the above local Wilford Hall USAF Medical Center formatted consent form for your approval. It does not look exactly the same as the Pfizer consent which Col Berman processed through your committee because we are required to use USAF guidelines, however, we have included the identical information in the WHMC format. The following is a paragraph by paragraph, line by line correlation of the two consent forms. A "comments" section will follow this table. Also attached is WHMC IRB approval of this consent form.

HSRRB/Pfizer Approved Consent			Wilford Hall MC Approved Consent		
<u>Paragraph</u>	<u>Line</u>	<u>Comment</u>	<u>Paragraph</u>	<u>Line</u>	<u>Comment</u>
1 ✓	1 ✓		1 ✓	1 ✓	
	2 ✓		2	12	
	3		2	13	
	4		1	6	
	6		1	10	
	8		1	2	
	9-23	1			
	24		1	6	
	25-28		1	7-10	
	28-30		2	2	
2.a.	1-13		2	1-19	
2.b.	1		2	14	
	2		2	17	
2.c.	1		2	3	
	2		3	9	
	4		7	1	
	7		1	3	
3	1-39	2	3	1-18	
4	1-9		3.a.	1-5	3
5	1-3		9	5	

HSRRB Approved Consent

Wilford Hall MC Approved Consent

<u>Paragraph</u>	<u>Line</u>	<u>Comment</u>	<u>Paragraph</u>	<u>Line</u>	<u>Comment</u>
6	1-5		4	1-4 4-7	3
7	1-3		5	1-2	3
8	1-4		9	1-11	3
9	1-4		8	1-3	
10	1-11		6	1-5	3
11	1-2		7	1-6	3
12	1-4		3	5-12	
13	1		7	1-6	3
14	1-9		7	1-6	3
15			7	1-6	3
16			9,10		3

COMMENTS:

1. This patient population has been fully informed about the history of the HIV virus. The purpose of the study is stated clearly in paragraph 1.
2. Side effects experienced heretofore with this drug are summarized in sufficient detail in paragraph 3. We make it very clear how safety monitoring will be performed and all previously noted toxicities have been described.
3. These paragraphs are all formatted in the required standard U.S. Air Force format as designated by our Institutional Review Board and must be included for local approval.

We hope the above explanations will satisfy the HSRRB. Please call me at the above number if you have any questions.



GREGORY P. MELCHER, Maj, USAF, MC  
Chairman, Department of Infectious Diseases

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1. WHMC approved consent
  2. HSRRB approved consent
  3. WHMC IRB approval memo