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The Bowman Gray

School of Medicine

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Department of Medicine  
Section on Rheumatology  
Robert A. Turner, M.D., Section Head  
Professor of Medicine  
(919) 748-4209  
May 9, 1985

Dr. John Simoons  
The Rheumatoid Disease Foundation  
5140 Revere Road  
Parkwood  
Durham, NC 27713

Dear John:

Thank you for your letter of 4-25-85 concerning Rheumatology protocol R-1120. I am enclosing a copy of Ms. Crater's report to me dated 3-25-85 so you will have it for your records. I am asking her to give me an updated report which I will get to you within the next several weeks. I have just received a letter from Dr. Pybus expressing concern similar to that you have expressed about the "Herxheimer reaction". As you and I have discussed, this study is not designed to determine the severity of this problem, but is designed purely to test the efficacy of Clotrimazole vs. placebo in the treatment of rheumatoid arthritis. The "Herxheimer reaction" will be recorded if this is a problem to the patients and will certainly be recorded if the problem is severe enough to cause drop-outs. This was clearly pointed out in the protocol and has been accepted by our institutional review board and IRB and your organization as is and I do not believe a redesigning of the reporting sheets or other action should be taken at this time concerning this matter. I have alerted my staff again to carefully record these symptoms, but I do not believe further action is warranted concerning this at present.

I will look forward to further communication and will certainly try to keep you updated as to the progress of the study. Both Ms. Crater and myself will welcome any questions you might have or a visit if you wish to compile further data prior to your presentation in Birmingham.

Yours truly,



Robert Turner, M.D.

BT/mam

Enclosure

cc: Ms. Sue Crater  
Dr. Paul K. Pybus

10 South Hawthorne Road, Winston-Salem, North Carolina 27103

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