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**The Bowman Gray**

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**School of Medicine**

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Department of Medicine  
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May 29, 1985

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

Dear John:

This letter is in response to all of your letters and to our telephone conversation on 5-28-85. As we discussed, there are now 10 patients who have entered the study and four who have dropped out from side effects. Of the four who dropped out from side effects, two dropped prior to one month and therefore, according to our original agreement, can not be used for efficacy and will be replaced. As agreed and discussed, we will replace these type drop outs at no cost to the Foundation. Also as discussed, we will hold bills for added tests or travel until the end of the study rather than billing you during the course of the study for this.

You should also be aware that I have again instructed the patients, CRU personnel, and physicians involved regarding the "Herxheimer" problem, including all of the various manifestations and the fact that many people feel strongly that this heralds a good response to the medication. As we discussed, we are encouraging such people to stay on the study and informing them of your group's feelings concerning this matter. You should also be aware that it is possible in studies such as this that the four people who dropped out with side effects were on placebo, since we do see a certain number of placebo drop outs with side effects on most of our studies. Your group should also be aware that with all of our studies there is a lag period until everyone gets familiar with the study and the most efficient way to handle matters. I do not see any particular problems with this study and believe we will finish it to the satisfaction of all concerned within the next year and one-half.

We are certainly attempting to accelerate the admissions to the study and you and I should take a look at this in the next several months and decide whether further strategies are in order for accomplishing this.

Thank you again for your concern and help in these efforts. I will look forward to further communications and comments as things move along.

Yours truly,

  
Robert Turner, M.D.

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