

# WAKE FOREST UNIVERSITY



## BOWMAN GRAY SCHOOL OF MEDICINE

300 South Hawthorne Road • Winston-Salem, North Carolina 27103

TELEX: 806449 BGSM WSL

Department of Medicine

Rheumatology

June 14, 1984

Dr. John R. A. Simoons  
Landor Research Corporation  
Pharmaceutical Consultants  
5140 Revere Road  
Durham, NC 27713

Dear John:

Enclosed, as requested by you in your letter of 6-4-84, are four copies of the estimated budget and four copies of the protocol and appendices for our proposed double-blind placebo controlled crossover study of Clotrimazole, 20 mg/KG in q.i.d. dosage two days per week for six weeks in the treatment of rheumatoid arthritis. Please feel free to distribute this protocol, which I have prepared as your consultant, to any members of your organization or to the drug company who will be cooperating in the study. As soon as I have received your comments concerning the proposed protocol and budget, I will submit these through channels at our institution along with preparing the FDA form 1571 and the Clinical Research Practices Committee protocol for review at our institution. Everyone concerned should again be reminded that the institution has not approved this protocol nor should the institutional name be involved with it until it has passed all of these review procedures. I would appreciate your letting me know as soon as you have completed your review of the protocol so that I can go ahead and institute these review procedures. I should further point out that as we commence the study it is school policy that all study results remain the property of the principle investigator with copies of all results to be provided to the sponsoring institutions. All data will be submitted to sponsoring organizations ninety days prior to submission for publication so that the sponsoring institution can comment on these results and use them in any way they see fit.

It has been a pleasure for me to work with you in preparing this possible protocol. I will plan on continuing to work with you as consultant until the time the protocol is approved by your organization, the institution, and the FDA and at that time we will begin the actual study under the budget as estimated if everyone agrees to this. At that time also, my consultant capacity will end since I will be working as principle investigator in the study.

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Dr. John R. A. Simoons

Thank you again for your interest and cooperation. I will look forward to further communications and to completing the final consultant work as soon as everyone has approved everything.

Yours truly,

A handwritten signature in cursive script that reads "Robert Turner".

Robert Turner, M.D.

Professor of Medicine and  
Chief, Section on Rheumatology

RT/mah

Enclosures

Double-Blind Placebo Controlled Crossover Study of Clotrimazole 20 mg/kg in Q.I.D. Dosage Two Days Per Week for Six Weeks in the Treatment of Rheumatoid Arthritis

LAB TESTS

|  |               |               |
|--|---------------|---------------|
| Rheumatoid Factor 5 @ 8.75                   | 43.75         |               |
| ESR 5 @ 6.00                                 | 30.00         |               |
| CBC - 13 @ 26.50                             | 344.50        |               |
| SMAC - 13 @ 19.00                            | 247.00        |               |
| UA - 13 @ 6.25                               | 81.25         |               |
| Hemoccult - 10 @ 3.75                        | 71.25         |               |
| Total  | <u>817.75</u> | 817.75        |
| History & Physical 2 @ 150.00                |               | 300.00        |
| Evaluations - 19 @ 50.00                     |               | 950.00        |
| Data Recording - 19 @ 5.00                   |               | 95.00         |
| Statistical Analysis & Interpretation        |               | <u>150.00</u> |
| Total Per Patient                            |               | 2,312.75      |
| Institutional Overhead @ 20% of Direct Costs |               | <u>462.55</u> |
| Total Grant Per Patient                      |               | 2,775.30      |
| <br>   |               |               |
| Total Grant for 40 Patients                  |               | 111,012.00    |

Terms of Payment: 25% at Inception of Study, 25% at 50% Patient Enrollment, 25% at Enrollment of Last Patient and 25% upon Receipt of Final Reports by the Rheumatoid Disease Foundation \*

Make All Checks Payable To: Bowman Gray School of Medicine  
% Warren H. Kennedy  
Associate Dean of Administration

Mail All Checks To: Robert A. Turner, M.D.  
Rheumatology Section  
Bowman Gray School of Medicine  
300 S. Hawthorne Road  
Winston-Salem, NC 27103

IRS: 1-560-532-138