

BROWN UNIVERSITY



CNS RESEARCH, INC.

15 Years of Excellence

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ACRP

Association of Clinical
Research Professionals

April 4, 2011

Research Coordinator
123 Main Street
Town, State, ZIP

A 6-month, Randomized, Active Comparator, Open-label, Multi-Center Study to Evaluate Patient Outcomes, Safety and Tolerability of Fingolimod 0.5 mg/day in Patients with Relapsing Forms of Multiple Sclerosis who are candidates for MS therapy change from Previous Disease Modifying Therapy (EPOC)

Dear Research Coordinator:

This letter sets forth the contract between you and CNS Research, Inc, relating to your services and the compensation you will receive as CRC, Clinical Research Coordinator on the above referenced study.

Enclosed please find two copies of the agreement and the CRC budget. Please review the material carefully making sure that your compensation per visit meets with your approval. Once you are in agreement, please sign both copies of the agreement and return one to CNS Research.

We are looking forward to working with you on this study. If you have any questions regarding this agreement, please do not hesitate to contact me at 1-800-707-6013.

Sincerely,

Patricia J. Epple
Research Director
CNS Research, Inc.

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Terms and Conditions

Nature of Relationship. This agreement is not intended to create nor shall it be deemed or construed to create any relationship other than that of independent contractors that are contracting with one another solely for the purpose of carrying out the purposes of this agreement. As an independent contractor, you will be responsible at all times for your own liability insurance, malpractice insurance, workers compensation insurance, health insurance and taxes. CNS assumes no responsibility for any of these items as you are working as an independent contractor. Both parties understand that this is a non-exclusive relationship, and that you are free to work with other clients during your period of engagement with CNS Research, Inc.

Scope of Services. You agree to provide services as Clinical Research Coordinator ("CRC") to CNS Research, Inc., referred to as "CNS" according to the terms of this agreement. You agree to perform the services called for in this agreement in a professional manner and in accordance with applicable clinical trial protocols, applicable guidelines and regulations, and current Good Clinical Practice ("GCP") standards. For patient care and safety matters, you will be directed by the Principal Investigator. As the Research Coordinator it is however your responsibility to know the protocol, the Inclusion/Exclusion Criteria and be able to apply the principals of GCP with sufficient authority to point out to the Principal or Sub-Investigators when they are in violation of the provisions guiding Clinical Research.

Credentials. You have represented that you have all of the credentials, certifications and licenses required to carry out the activities called for under this agreement. Upon request, you agree to provide CNS with written documentation that shows that all necessary certifications, credentials and licenses have been obtained and are in full force and effect. You agree to notify CNS in writing within forty-eight (48) hours of any change in status of any certification, credential and/or license required under this agreement.

Insurance. You shall at all times maintain, at your sole cost and expense, professional liability insurance with a reputable and financially stable insurance carrier (as determined in CNS's sole and absolute discretion) in the amount of at least One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) annual aggregate. Said professional liability insurance shall provide insurance coverage for all professional services provided by you in connection with your participation in a clinical trial under this agreement. Upon request, you agree to provide CNS with (a) the most current copy of any such insurance policies and (b) notice at least five (5) days prior to any cancellation, termination, or material alteration of any such insurance policies, including changes in carriers, changes in coverage, notification of claims against, denials of, restrictions on, termination of, or other changes in such insurance.

Confidentiality. At all times during the term of this agreement and thereafter, you agree to keep confidential any of CNS's or a clinical trial sponsor's Confidential Information (as defined herein) which may come into your possession or knowledge. You agree to not disclose said Confidential Information to any third party without CNS's prior written consent. "Confidential Information" means all information not generally known to the public relating to CNS's or any clinical trial sponsor's business, including but not limited to: (1) clinical trial and budget agreements, protocols, procedures, investigator brochures, or reporting forms; (2) any quality assurance program documents, operations manuals and bulletins, and other information announcing or containing policies, procedures and requirements; (3) any lists of clinical trial investigators or clinical trial sponsors or prospective investigators or sponsors; (4) any information concerning CNS's or a clinical trial sponsor's data base(s); and (5) any other information which CNS or any clinical trial sponsor identifies as proprietary or confidential. Any disclosure or use of Confidential Information in violation of this provision shall be grounds for immediate termination of this agreement, and shall subject you to damages for breach of this provision and/or other remedies available at law or in equity, including, without limitation, the right to injunctive relief to prevent any pending or threatened disclosure or use of information in violation of this provision. If you are in doubt as to whether certain information is considered confidential by CNS or a clinical trial sponsor, CNS, upon your request, will advise you as to whether such information is confidential.

Budget Agreement

This Budget Agreement sets forth the financial terms for your working on the above reference study. CNS Research, Inc. shall coordinate all financial and payment issues with you and is solely responsible for payment to you for your work on the Study.

A. Itemized Per Patient Budget

You will be paid for the services you provide in the Study on a per patient, per visit basis according to Schedule A. **Payment shall be made only for "Qualified Patients"**, and only for the actual number of patient visits completed by said Qualified Patients. "Qualified Patients" are defined as evaluable patients who have satisfied all protocol requirements, including compliance with dosing regimen and visit schedule, and can be included in the statistical analysis for the study. Questions pertaining to a patient's eligibility must be addressed to and resolved by the Sponsor's Medical Monitor prior to that patient's entry into the study.

B. Payments are subject to the following terms:

1. If a Qualified Patient participating in the study withdraws from the study or administration of the study drug, does not comply with the protocol requirements, or is otherwise discontinued in a particular case for good reasons outside of your control you will be paid on a prorated basis on the number of patient visits actually completed by the patient.
2. Screen failures or partial completers will be reimbursed according to actual assessments conducted in accordance to the allowances in the protocol.
3. Your training on the study will include work alongside Patricia J. Epple until you feel comfortable performing the study procedures by yourself, during this training time your compensation will be half the amount per visit indicated below:

Visit #	1	2	3	4	5	6	Total
CRC	\$600	\$600	\$300	\$300	\$300	\$500	\$2,600

<u>DMT Arm Extension Visits</u>	
Visit # 7 (Ext. V1)	\$ 400
Visit # 8 (Ext. V2)	\$ 400
Visit # 9 (Ext. V3)	\$ 500
Total	\$ 1,300

Payment Schedule

- 1.) Monitor visits will require your meeting with the representative in the beginning and or the end of the visit. You will be compensated for such visits at a flat rate per occurrence.
- 2.) In the event of an audit by the FDA, IRB or Sponsor you agree to actively assist the auditor in person. For you efforts you will be compensated at the flat rate.

Term. This agreement shall be deemed effective as of the date it was signed and continue for the duration of the study until closed out by the Monitor and until all data queries are resolved. Either party may terminate this agreement on thirty (30) days written notice.

Amendments. This agreement supersedes all prior agreements, both written and oral, between the Coordinator and CNS Research, Inc. The laws of the State of Rhode Island shall govern this agreement. This agreement can be amended only in writing and by joint agreement of the parties.

**BY MY SIGNATURE BELOW, THE CLINICAL RESEARCH COORDINATOR
HEREBY ACCEPTS AND AGREES TO THE TERMS OF THIS AGREEMENT:**

Research Coordinator

Date

CNS Research, Inc.

Patricia J. Epple, CCRC, President

Date