## EXHIBIT 1

A. MEDICAL MONITOR

1. The following duties and conditions of the Medical Monitor (M/M) shall apply when Dr. Raper participates in Restricted Clinical Activity:

   a. M/M shall not be affiliated with Dr. Raper, the University of Pennsylvania, its related institutions or, in the event Dr. Raper leaves the University of Pennsylvania, his current employer.

   b. M/M will have the expertise to fully understand the subject matter of the Restricted Clinical Activity.

   c. M/M will meet in person with Dr. Raper and gain a thorough understanding of the hypothesis, goals, risks and benefits of the Restricted Clinical Activity.

   d. The M/M will review and approve the enrollment of each research participant in any Restricted Clinical Activity.

   e. M/M will review all of Dr. Raper's required filings and reports of adverse events to the sponsor, governmental agencies and IRB(s) for the Restricted Clinical Activity.

   f. M/M will have unilateral authority to take whatever action s/he deems appropriate, including, but not limited to:

      (1) Contacting the IRB for the Restricted Clinical Activity and any appropriate entity with responsibility for oversight of clinical activities and protection for human research participants in Clinical Trials.

      (2) Contacting the sponsor for the Clinical Trial and reporting a concern.

      (3) Contacting the appropriate federal agency and reporting a concern.

      (4) Halting the Clinical Trial temporarily.

      (5) Stopping the Clinical Trial.

   g. If the M/M reports a concern to the IRB relating to the Restricted Clinical Activity and issues a report, Dr. Raper will provide a copy of all IRB communications to the M/M. The M/M will report to the government the actions taken by the IRB and provide an assessment of the action taken by the IRB to address the concern. The M/M shall provide a copy of this report to Dr. Raper.

h. The M/M will determine whether Dr. Raper has sufficient time available to perform Restricted Clinical Activity. If the M/M determines that Dr. Raper does not have sufficient time available to perform Restricted Clinical Activity, Dr. Raper shall modify his schedule to the satisfaction of the M/M or withdraw his application. Any change in the level of Dr. Raper's participation in Restricted Clinical Activity shall be immediately reported to the appropriate federal agency.

i. The M/M will make semi-annual reports to the government concerning Dr. Raper's compliance with applicable regulations related to Restricted Clinical Activity and his compliance with this agreement. The M/M shall provide a copy of the reports to Dr. Raper. The semi-annual reports shall include, at a minimum:

Grant Number
Title of Project
Budget and project period dates of grant
Dr. Raper's role
Update on activities performed (including dates and nature of meetings with Dr. Raper)
Concerns identified during reporting period (including actions taken)
Proposed resolutions to concerns identified
Certification of compliance with all regulatory requirements
Certification of compliance with agreement
Any additional comments/concerns

B. CONTRACT RESEARCH ORGANIZATION

1. In addition to the M/M, a Contract Research Organization (CRO) will be designated to oversee the regulatory compliance of all Restricted Clinical Activity involving Clinical Trials. Dr. Raper will ensure that no conflicts of interest exist between the CRO, himself, and/or his employer. The duties of the CRO will include, but not be limited to, the following:

   a. Review all submissions and reports to the sponsor, IRB, and government agencies, for compliance with applicable regulations and ensure they are submitted in a timely manner. In addition, the CRO will review all source data generated or utilized by Dr. Raper as part of its review. The CRO will also ensure that the appropriate approved informed consent form is used and that the clinical trial is conducted in accordance with approved protocols and investigational plans.

   b. Review all information from other sites participating in the clinical trial that is relevant to the conduct of the clinical trial in which Dr. Raper is participating in Restricted Clinical Activity.

   c. The CRO will have unilateral authority to take whatever action s/he deems appropriate, including, but not limited to, the following:

(1) Contacting the IRB for the Restricted Clinical Activity and any appropriate entity with responsibility for oversight of clinical activities and protection for human research participants in Clinical Trials.

(2) Contacting the sponsor for the Clinical Trial and reporting a concern.

(3) Contacting the appropriate federal agency and reporting a concern.

(4) Halting the clinical trial temporarily.

(5) Stopping the clinical trial.

2. The CRO will make semi-annual reports to the government concerning Dr. Raper's compliance with applicable regulations relating to Restricted Clinical Activity and his compliance with this agreement. The CRO shall provide a copy of these reports to Dr. Raper. The reports shall include, at a minimum:

Grant Number
Title of Project
Budget and project period dates of grant
Dr. Raper's role
Update on activities performed (including dates and nature of meetings with Dr. Raper)
Concerns identified during reporting period (including actions taken)
Proposed resolutions to concerns identified
Certification of compliance with all regulatory requirements
Certification of compliance with agreement
Any additional comments/concerns

C. SPECIAL MONITOR

A Special Monitor shall be employed in accordance with the Agreement. The Special Monitor shall not be affiliated with Dr. Raper, the University of Pennsylvania, its related institutions or, in the event Dr. Raper leaves the University of Pennsylvania, his current employer. The Special Monitor shall have the expertise to fully understand the regulatory requirements applicable to Dr. Raper's research and will perform the following functions:

1. ascertain whether Dr. Raper's involvement constitutes Restricted Clinical Activity; and

2. ascertain whether Dr. Raper communicates information, developed by Dr. Raper and related to the safety of human research participants involved in that related research, to the investigator responsible for conducting the clinical trial and to the sponsor or grantee; and

3. ascertain whether Dr. Raper complies with this agreement and applicable regulatory requirements, such as the nature, content and timeliness of submissions to be reported to the appropriate entities and receiving approval by the appropriate regulatory oversight committees; and

4. report to the government on a semi-annual basis concerning subsections 1-3. The Special Monitor shall provide a copy of these reports to Dr. Raper.

The report shall include, at a minimum:

Grant number
Title of project
Budget and project period dates of grant
Indication of whether Dr. Raper is involved with human research participants
Dr. Raper's role
Update on activities performed (including dates and nature of meetings with Dr. Raper)
Concerns identified during reporting period (including actions taken)
Proposed resolutions to concerns identified
Certification of compliance with all regulatory requirements
Certification of compliance with agreement
Any additional comments/concerns

D. ADMINISTRATION

1. All costs associated with the M/M, CRO and Special Monitor will be borne by the sponsor/grant recipient.

2. The NIH Division of Grants Compliance and Oversight and the FDA will have the right to conduct inspections, audits or reviews of the activity addressed in this Agreement.