

Certificate of Action

Investigator Name: Andreas M. Kogelnik, MD, PhD	Board Action Date: 02/08/2020
Investigator Address: Building #2, 2500 Hospital Drive Mountain View, CA 94040, United States	Approval Expires: 03/07/2021 Continuing Review Frequency: Annually
Sponsor: Centers for Disease Control and Prevention Institution Tracking Number:	Sponsor Protocol Number: OMI-14-1024 Amended Sponsor Protocol Number:
Study Number: 1150798	IRB Tracking Number: 20142223
Work Order Number: 1-1248290-1	Panel: 4 Note: Panel 18 is a shared panel of CGIRB and WIRB. Panel 19 is a shared panel of Aspire and WIRB.
Protocol Title: Multi-site Clinical Assessment of Chronic Fatigue Syndrome (CFS): Natural Killer Cell Testing	

THE FOLLOWING ITEMS ARE APPROVED:

Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

Please note the following information:

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

Open Medicine Institute, 2500 Hospital Drive, Bldg 2, Mountain View, California 94040
 Sierra Internal Medicine, 926 Incline Way, Suite 150, Incline Village, Nevada 89451
 Bateman Horne Center, 24 South 1100 East, Salt Lake City, Utah 84102
 Hunter-Hopkins Center, P.A., 7421 Carmel Executive Park Drive, Suite 320, Charlotte, North Carolina 28226
 Richard Podell, M.D. P.A., 11 Overlook Road, Suite 140, Summit, New Jersey 07901

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
 - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- For research subject to continuing review, submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
 - The protocol is permanently closed to enrollment
 - All subjects have completed all protocol related interventions and interactions
 - For research subject to federal oversight other than FDA:
 - No additional identifiable private information about the subjects is being obtained
 - Analysis of private identifiable information is completed
- For research subject to continuing review, if research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”) without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP’s requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator’s Brochures, an approval action indicates that the IRB has the document on file for the research.

If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by the IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. ”

For research subject to continuing review, you will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

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Contact, Company

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