SUBMISSION LETTER

Date _____

Valerie Golembiewski, (520) 298-7494
Chairperson
Argus Independent Review Board
6668 S. Hidden Flower Way
Tucson, AZ 85756

Regarding:

protocol: # _____
name_____
sponsor _____
investigator _____
approximate start date _____
subjects:
sex : ☐ male ☐ female
ethnicity: ☐ any ☐ white ☐ Hispanic ☐ African American
☐ Asian American ☐ Native American
☐ other _____

Dear Ms. Golembiewski:

With this letter, I request that Argus IRB review the protocol that is identified above, under the provisions of 21 CFR, Parts 50 and 56. An attached **Argus Site Questionnaire**, one for each site, gives details and our assurances about the study: the subject population (and whether or not they are composed of groups requiring special safeguards), how emergencies are handled, identification and qualifications of the study personnel, recruitment and informed consent procedures, and subject compensation. The **Questionnaire** further documents the community's concerns about this type of research, including all relevant laws.

I hereby affirm that I will select subjects equitably, monitor the informed consent process, and fulfill my research and clinical responsibilities as Principal Investigator under the Code of Federal Regulations. I will report promptly any serious adverse events (SAEs) to the sponsor and Argus IRB.

The following names and phone numbers will be entered into the Informed Consent:

Study Doctor: _____

24-hour number _____ pager number _____

IRB chairperson: Valerie Golembiewski

24-hour number ***at study site*** _____ pager _____
The person contacted at the site will call Ms. Golembiewski at (520) 298-7494.

Unless otherwise noted and explained, the documents that are listed below have been completed and are attached.

Submission Checklist

- ☐ Site Questionnaire: Investigator (1 for each site) with all relevant attachments
- ☐ Indemnification Agreement
- ☐ Billing Information
- ☐ Principal Investigator's curriculum vitae & license
- ☐ Co-Investigators' curricula vitae & licenses
- ☐ Recruitment materials: ads, other
- ☐ Study protocol
- ☐ Informed Consent
- ☐ Translations of Consent with signature of translator, if applicable

---

Sincerely,

_____ _____

signature of Principal Investigator date

_____

printed name of Principal Investigator

Additional signature if required by the site:

_____ _____

signature of Medical Director date
or other organizational representative

_____

printed name

_____

title