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(360) 252-2500 • 1-800-562-4789 • Fax (360) 252-2498
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WIRB INITIAL REVIEW SUBMISSION REQUIREMENTS

The following is a general list of items needed by WIRB to begin the review process for your research study. You will need to submit the Initial Review Submission Form with each protocol you submit for review. If you have questions, call 1-800-562-4789 or e-mail clientservices@wirb.com for assistance.

ALL INITIAL REVIEW REQUESTS must include one copy of the following:

- **Current version of the WIRB Initial Review Submission Form** (posted at www.wirb.com)
- **Protocol***
- **Current professional license** for Principal Investigator, showing the expiration date**
- **Curriculum Vitae (CV)** for Principal Investigator and each Sub-Investigator**
- **Consent form***
- **Other materials to be provided to the subjects** which are not included in the protocol, such as advertisements, questionnaires, subject diaries, etc. **

If a DRUG/BIOLOGIC study, a copy of the following:

- **Investigator's Drug Brochure***
- **Background Information for Food Supplements***
- **FDA Form 1572** (if applicable)
- **Canadian Research Ethics Board Attestation Form and Qualified Investigator Undertaking Form** (Canadian sites)
- **A request for WIRB Institutional Biosafety Committee (IBC) review** or the **IBC approval information** from the review of your study, if applicable. (Gene Transfer Protocols)

If a DEVICE study, provide device manual and <u>ONE</u> of the following:

- **FDA Letter** granting the Investigational Device Exemption (IDE)* and a copy of the **signed Investigator Agreement**; OR
- **Letter from sponsor** stating that the study is a non-significant risk device study;* OR
- **Letter explaining why the investigation is exempt** from the IDE requirements under 21CFR 812.2(c) or otherwise exempt. **

***Material may be omitted if WIRB is already in receipt of a current version.**

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Initial Review Submission Form

Sponsor Agricultural Handlers Exposure Task Force, L.L.C. **Sponsor Protocol No.** AHE36

I. PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h)]

1.	PI Name: **Eric D. Bruce**		Gender: ☒ M ☐ F	
1a.	PI Company Name: **None; Independent Contractor**			
1b.	PI Mailing Address: (street, city, state/province, postal code, country) **21 Oak Knoll Court** **Walnut Creek, California 94596** **United States**			
1c.	PI Phone: (**925**) **939-4987**	PI Fax: (**925**) **939-4987**	PI E-mail: **eybruce@pacbell.net**	
1d.	How would the PI prefer to receive study documents? (check one) ☐ Fax ☒ E-mail ☐ Regular Mail			
1e.	PI Degree(s): **B.S. in Toxicology**	PI Specialty(ies): **Worker exposure to pesticides**		
1f.	If this research will be conducted through an organization which requires use of WIRB for IRB services, please provide the name of the organization:			NA ☒
2.	Study Coordinator Name: **David R. Johnson, Ph.D.**		Gender: ☒ M ☐ F	
2a.	Study Coordinator Phone: (**660**) **395-9590**	Study Coordinator Fax: (**660**) **395-9593**	Study Coordinator E-mail: **davejohn@marktwain.net**	
2b.	Does the study coordinator need to receive a copy of the regulatory documents in addition to the copy sent to the PI? *If Yes, How would the coordinator prefer to receive study documents? (check one) ☐ Fax ☐ E-mail		*Yes ☐	No ☒
3.	Has the PI ever received an FDA Warning Letter or Health Canada Inspection Report that has not been previously submitted to WIRB?		Yes ☐	No ☒
4.	Has the PI ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority or is the PI currently involved in such a proceeding? *If Yes, please attach explanation		*Yes ☐	No ☒
5.	***Licensing Information:*** *Please fill in the information requested below and attach legible copies of all pertinent current licenses and registrations (if not on file at WIRB). If necessary, please enlarge the copy of the license for legibility.*			
5a.	Medical or Professional License #: State/province: Expiration Date:			N/A ☒
5b.	If this PI will conduct research involving an investigational drug in the state of Massachusetts, provide the PI's Massachusetts Research Registration number:			N/A ☒

6.	Please attach a signed copy of each of the following (if applicable): • U.S. FDA form 1572, • Canadian Research Ethics Board Attestation Form and Qualified Investigator Undertaking Form; • Your country's equivalent.		N/A ☒
7.	Does the PI, PI's family, the study staff, or the study staff's family have any financial relationship with the sponsor or manufacturer of the product under investigation other than payment for the conduct of clinical research? *****If Yes, please describe the relationship on the Financial Interest Disclosure Form provided at the end of this document. (Examples include speaking fees, consultation fees, stock ownership or other equity interest, patents, trademarks, copyrights, licensing agreements.) Report interests valuing over $10,000 and interests representing a greater than 5% ownership in an enterprise.	*Yes ☐	No ☒
8.	For this protocol, how many of the following will the PI supervise? Sub-Investigators **0** Sites **2** Research Coordinator(s): **0** (Do not leave any spaces blank)		
9.	How many of the following does the PI currently supervise? (total for all research projects) Open Research Studies **1** Sites **2** Physician Sub-Investigators **0** Research Coordinator(s) **0** Approx. Number of active subjects **10** (Do not leave any spaces blank)		
10.	Based on WIRB's accreditation and NIH requirements, Investigators must ensure each member of the research study team/staff has had training in the protection of human subjects. Training must be completed prior to performance of study related-procedures. Has each member of the team completed such training?	Yes ☒	No ☐
10a.	Indicate what type(s) of training were completed: (mark at least one, and all that apply) ☐ NCI Human Participant Protections Education for Research Teams ☐ Institutional Human Subject Protection Training requirements satisfied ☐ Tri Council Policy Statement online training (for Canadian sites) ☒ Collaborative IRB Training Initiative (CITI) ☐ WIRB-sponsored Investigator or GCP course ☐ Other: (specify) _____ A list of potential sources, including web-based tutorials, books, and in-person training courses is available at www.wirb.com or by contacting WIRB's Client Services.		
11.	Will a Site Management Organization (SMO) be involved in this research? If No, proceed to question 12.	Yes ☐	No ☒
11a.	SMO Name:		
11b.	SMO Address: (street, city, state/province, postal code, country)		
11c.	SMO Contact Name:	Gender: ☐ M ☐ F	
11d.	SMO Contact Phone: ( )	SMO Contact Fax: ( )	SMO Contact E-mail:
11e.	How would the SMO contact prefer to receive documents from WIRB? (check one) ☐ Fax ☐ E-mail ☐ Regular Mail		

II. SPONSOR & PROTOCOL INFORMATION: Please tell us about the research to be conducted.

12.	Protocol Number and Version Date: **AHE36; April 3, 2006**		
13.	Is this research investigator-initiated? (i.e., no separate sponsor is involved)	Yes ☐	No ☒

14.	Sponsor Name: **Agricultural Handlers Exposure Task Force, L.L.C. (AHETF)**		
14a.	Sponsor Contact Name: **David R. Johnson, Ph.D.**		Gender: ☒ M ☐ F
14b.	Sponsor Contact Address: (street, city, state/province, postal code, country) **1720 Prospect Drive** **P.O. Box 509** **Macon, Missouri 63552** **United States**		
14c.	Sponsor Contact Phone: (**660**) **395-9590**	Sponsor Contact Fax: (**660**) **395-9593**	Sponsor Contact E-mail: **davejohn@marktwain.net**
14d.	How would the sponsor contact prefer to receive documents from WIRB? (check one) ☐ Fax ☒ E-mail ☐ Regular Mail ☐ N/A		
14e.	Medical Monitor Name: **N/A**		Gender: ☐ M ☐ F
14f.	Medical Monitor Phone: ( )	Medical Monitor Fax: ( )	Medical Monitor E-mail:

15.	Is a Contract Research Organization (CRO) involved in this research? If No, proceed to question 16.	Yes ☐	No ☒
15a.	CRO Name:		
15b.	CRO Address: (street, city, state/province, postal code, country)		
15c.	CRO Contact Name:		Gender: ☐ M ☐ F
15d.	CRO Contact Phone: ( )	CRO Contact Fax: ( )	CRO Contact E-mail:
15e.	How would the CRO contact prefer to receive documents from WIRB? (check one) ☐ Fax ☐ E-mail ☐ Regular Mail		

16.	Please list each item for which the PI is seeking Board review and approval. List all rating scales, questionnaires, and forms that subjects will be asked to fill out and include a copy if a copy is not included in the protocol. Also, for standardized rating instruments, please indicate if the site will use the standard version or an altered version. **Study Protocol** **Research Subject Information and Consent Form - English**

17.	Has another IRB declined to review, disapproved or terminated this research study at your site prior to submission to WIRB? *If Yes, please provide the IRB correspondence.	*Yes ☐	No ☒
18.	Is this study being transferred to WIRB from another IRB? *If Yes, please fill out the IRB Transfer form posted at www.wirb.com.	*Yes ☐	No ☒
19.	Is this research federally funded entirely or in part? If No, proceed to question 20.	Yes ☐	No ☒
19a.	What federal agency(ies) is funding this research?		N/A ☐
19b.	Provide a copy of the complete grant (if applicable).		N/A ☐
19c.	If this grant funds multiple protocols, please list those protocols previously reviewed by WIRB.		N/A ☐

19d.	Provide the federal contract (if applicable).		N/A ☐
20.	Does this research involve a Drug, Biologic or Dietary Supplement? If No, proceed to question 21.	Yes ☐	No ☒
20a.	Provide the Investigational New Drug (IND) number assigned by the FDA and/or the Health Canada Clinical Trial Control Number (Canadian sites). Under most circumstances, WIRB requires an IND for research involving dietary supplements.		N/A ☐
20b.	If an IND number is not available, please attach an explanation of why an IND was not obtained.		N/A ☐
20c.	Provide a copy of the Investigator's Drug Brochure (unless previously sent to WIRB), applicable package inserts, or the background information for food supplements.		N/A ☐
21.	Does this research involve an Investigational Device? If No, proceed to question 22.	Yes ☐	No ☒
21a.	Provide one of the following: • FDA letter granting an Investigational Device Exemption for the proposed use, • Letter from sponsor stating that the study is a non-significant risk device study, or • Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt.		N/A ☐
22.	Does this research involve any form of **Gene Transfer**? If No, proceed to question 23.	Yes ☐	No ☒
22a.	Has this been submitted to the Recombinant DNA Advisory Committee (RAC)?	Yes ☐	No ☐
22b.	If available, attach the Response to Appendix M of the National Institutes of Health (NIH) Guidelines.		N/A ☐
22c.	If available, attach copies of the RAC correspondence regarding the protocol.		N/A ☐
22d.	Has there been an Institutional Biosafety Committee (IBC) review? *If Yes, please attach the IBC recommendations. **IBC services are available through WIRB. Contact IBC Services at (360) 252-2850 for fee schedule and IBC submission form.**	*Yes ☐	No ☐

III. RESEARCH SITE LOCATIONS & INFORMATION (*must match submitted 1572 or Canadian REBA form, if applicable*): Please tell us where the research will take place by completing this section for each site. If you will be conducting the research at more than one site, complete and attach the Additional Site Listing form at the end of this document for each additional site. *Each site listed below and on the 1572 (or REBA) will be listed on the consent form.*

If site information changes during the course of the study, you will need to notify WIRB. Please request the necessary changes using the Change In Research/Subject Recruitment Submission Form available on the WIRB web site.

23.	**Site #1:** If Site #1 is the same as the mailing address listed above in the PI section (section I), write "same" below and proceed to question 23b. (List only sites at which subjects will be seen.) Name of Research Location: **Coastal Research Services** Physical Address: (street, city, state/province, postal code, country) **(*must match box 3 of submitted 1572 or part 3 of Canadian REBA form, if applicable*)** **1661 Mulberry Lane** **Paso Robles, California 93446 United States**
23a.	**Site #1** Phone: (**805**) **239-5875**

23b.	What type of facility is this site? ☐ Medical office ☐ Hospital ☐ University ☐ Psychiatric Institution ☐ Nursing home ☒ Other *(specify):* Agricultural Research Facility ☐ Research Clinic ☐ Dialysis Center			
23c.	What resources are available at this site to treat emergencies resulting from study-related procedures? ☐ ACLS trained personnel and crash cart ☐ Emergency drugs and supplies to stabilize subject until emergency personnel arrive ☐ Emergency response team within facility ☒ Call 911 ☐ Other *(specify):* _____ ☐ N/A			
23d.	If this site is not a hospital, please name the medical facility to be used in an emergency: **Mee Memorial Hospital (King City, California), or nearest ER facility**			N/A ☐
23e.	Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? *If No, attach a separate sheet of paper describing the following: • How subjects would be referred for hospitalization, • Name, address and telephone number of physician who has agreed to attend these patients, and • What measures would be taken to assure communication between the investigator and the attending physician		Yes ☐	*No ☒

23f.	For each additional site, please copy, complete and attach the Additional Site Listing form at the end of this document.	N/A ☒

24.	Does the PI have an obligation to use another IRB for any site in this study? *If Yes, WIRB will need a written statement from the other IRB acknowledging WIRB's review of this research. Please call Client Services for more information.		*Yes ☐	No ☒
25.	What is the local attitude toward human subject research? ☒ Positive ☐ Negative If other than positive, please explain:			
26.	Are there laws governing medical research in your state/province? If No, proceed to question 27.	Yes ☐	No ☐	un-known ☒
26a.	Have the laws governing research in your state/province changed in the past year?	Yes ☐	No ☐	un-known ☒
27.	What precautions will be used to maintain the confidentiality of identifiable health information? ☐ Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. ☐ Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. ☐ Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information. ☐ Whenever feasible, identifiers will be removed from study-related information. ☒ Other *(specify):* Names of subjects will be identified in the raw data, but not in the final report. Each subject will be identified in the final report as replicate and worker (e.g., Replicate M1, Worker A).			

28. Please describe the roles of those members of the study team who have substantive interaction with subjects.

Name/Site(s)	Title	Role
Example: *John Doe, M.D., Sites #1 & #2*	*PI*	*Provide medical oversight for study subjects. Responsible for all study related issues*
Eric D. Bruce	**Study Director, PI**	**Overall responsibility for the scientific aspects of the study, including: protocol and final report preparation; approval of amendments and deviations; obtaining signed consent forms; interpretation of results; and dealing with any unexpected occurrences.**

Attach an additional page, if necessary.

IV. RECRUITMENT, CONSENT & SUBJECT PAYMENT INFORMATION: Please provide information about how subjects will be recruited, the consent form subjects will be asked to sign, and what type of payment subjects will receive.

29. Do you intend to enroll any subjects from the following "vulnerable" categories?

*If Yes, please list all vulnerable subject groups, even those clearly identified in the protocol inclusion criteria.

			*Yes	No
☐ Mentally ill	☐ Prisoners	☐ Wards of the state (e.g., foster children)		
☐ Institutionalized	☐ Chronic condition	☐ Terminally ill		
☐ Hospitalized	☐ Limited or non-readers	☐ Minors		
☐ Poor/uninsured				
☐ Pregnant women (If yes, you must complete question 29a)			☐	☒
☐ Nursing home residents recruited in the nursing home				
☐ Cognitively Impaired (If yes, you must answer question 29b)				
☐ Students of PI or study staff				
☐ Students to be recruited in their educational setting , i.e. in class or at school.				
☐ Employees directly supervised by PI or sub-investigator				
☐ Employees of Research Site or Sponsor				
☐ Military personnel to be recruited by military personnel				
☐ Others Vulnerable to Coercion (Specify) _____				

29a. If you plan to enroll pregnant women, **complete the following:**

As required by Federal Regulations, I assure the Board of the following: (45 CFR 46.204 (h), (i), (j))

- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

N/A ☒

_____ _____
Signature of PI date

_____ _____
Signature of Co-PI (if applicable) date

29b.	If some or all subjects will be cognitively impaired, describe how capacity for consent will be determined: ☐ Capacity Assessment using the following method or instruments: _____ ☐ Other (specify): _____		N/A ☒
30.	WIRB expects that the subject consent process will be conducted under the following conditions: • Will take place without undue influence or coercion. • Will allow the subjects adequate time to consider the research before signing. • Will be conducted in a private place and manner. • Will be conducted with words understandable to subjects. • The person obtaining consent will invite questions from the subjects. • The subject will be allowed to take home an unsigned copy of the consent form to share with family and friends prior to enrollment. • The subject will be given a signed and dated copy of the consent form for their records if enrolled. • Non-English speaking subjects will be provided with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB. Indicate one of the following and attach written explanation where instructed: ☒ The consent process will meet all of the above conditions. ☐ N/A, waiver of consent requested. ☐ The consent process will not satisfy all of the above conditions, as it will **take place in emergency situations**; **a written explanation of the proposed consent process is attached**. Note: Please contact WIRB's Client Services department for an explanation of WIRB's submission requirements. ☐ The consent process will not satisfy all of the above conditions, and the consent **will not be obtained in an emergency situation**. **A written explanation of the proposed consent process and the reason one or more conditions cannot be met is attached** (for example, research subjects are to be recruited in an outdoor public setting where a private consent discussion is not practicable).		
31.	Check any of the following methods that the PI will use to recruit subjects for this study: ☐ Advertising *(All recruitment materials must be approved by WIRB before use)* ☐ From a database for which subjects have **given prior permission to be contacted** for research studies ☐ From Personal Contact (e.g., patients, students) ☐ Referrals *(referral fees are not allowed by WIRB)* ☒ Other (specify): **Experienced agricultural chemical handlers will be recruited from growers near the research site and/or local professional pesticide applicators will be recruited** U.S. SITES: PLEASE NOTE – for HIPAA compliance, you may need an authorization from the subject or a waiver of authorization before you can use or disclose identifiable health information for research screening or recruitment purposes. This may affect your ability to recruit subjects into this study. For more information on HIPAA requirements for research and additional HIPAA-related forms, go to www.wirb.com.		
32.	Are recruitment materials or subject materials attached? *If Yes, check all that are attached: ☐ Newspaper ☐ Letter ☐ Brochure ☐ Web Site ☐ Public Service Announcement ☐ **Video *(recordings will not be reviewed without scripts)* ☐ Posting ☐ **Audio *(recordings will not be reviewed without scripts)* ☐ Other _____ **To avoid unnecessary additional production costs due to re-work, it is strongly recommended that submitters seek WIRB pre-approval of scripts before producing the recordings. Any Board-required modifications to the material must be reflected in the final version of the recording.	*Yes ☐	No ☒
32a.	Have any of these or similar recruitment materials been previously approved by WIRB for this protocol or other protocols? *If Yes, please attach a copy of the previously-approved item(s). WIRB support staff will provide the Board with information about the previous Board review, so that the previous decision of the Board can be taken into account when the materials are reviewed.	*Yes ☐	No ☒

33.	Who will perform the screening examination of the patients to determine if they are eligible for the research? (if applicable)		N/A ☒
34.	Are you using any written or verbal screening materials to screen subjects prior to enrollment in the research (such as telephone call scripts, written or web-based questionnaires or pre-screening forms)? *If Yes, please include them for review and describe the screening plan on the Screening Procedures Information Form provided at the end of this document. WIRB reviews screening materials in the same fashion as consent documents. WIRB's requirements for screening scripts are listed at the bottom of the Screening Procedures Information form.	*Yes ☐	No ☒
35.	Approximate ethnic makeup of population to be recruited for this research: **If your site is in the U.S. or Canada:** _____% African-American **20**% Asian _____ % Pacific Islander _____% Middle Eastern **40** % Caucasian **40**% Hispanic _____% Native American/First Nations _____ % Other: _____		
	If your site is located elsewhere: Please indicate the names and percentages of the applicable ethnic populations.		
36.	Please indicate the language(s) of the subjects the PI plans to enroll. *All the consent forms and other subject materials must be in a language easily understood by the subject, and all translations must be approved by WIRB.* ☒ English ☐ French Canadian ☐ Spanish ☐ Other _____		
37.	If you are enrolling non-English speaking subjects, would you like WIRB to provide translation of your consent forms or other subject materials? *(extra fee)* *If Yes, please list each item you would like translated and indicate the languages requested: Items: _____ Languages: _____ *If you will provide the translation(s), contact the WIRB translations department for requirements.*	*Yes ☐	No ☐ NA ☒
38.	For **multicenter studies**, it is likely a consent form for this protocol has already been approved by WIRB. If available, would you like to use it? WIRB will incorporate any institutionally-required language and your site-specific contact information, payment information, locations, etc. from this submission form into the previously approved consent. Selecting "yes" can significantly reduce the processing time and you will receive your documents more quickly. To verify that a previously approved consent form is available for this protocol, please call Client Services at 1-800-562-4789. If answering Yes, proceed to question 39, and you do not need to submit a consent form with your review materials.	Yes ☐	No ☒
38a.	If you prefer **not** to use the previously approved WIRB consent form for this protocol or this is not a multicenter study, indicate your consent form preference by checking one of the following: ☒ Use enclosed *(if on disk, Microsoft Word compatible).* If you are using a sponsor's template consent form, please underline any changes you have made. ☐ Request WIRB write consent form ***(extra fee)***		N/A ☐

39.	Contact information to be listed in the Consent Form: Contact name and phone number for **questions about the study**: Name **Eric D. Bruce** Phone number(s): (925) 939-4987 (home office) ☒ Office Hours ☒ 24 hours ☐ Pager (check all that apply) (925) 708-5538 (cell) ☒ Office Hours ☒ 24 hours ☐ Pager (check all that apply) Contact name and phone number for use in the event of **research-related injury**: Name **Eric D. Bruce** Phone number(s): (925) 939-4987 (home office) ☒ Office Hours ☒ 24 hours ☐ Pager (check all that apply) (925) 708-5538 (cell) ☒ Office Hours ☒ 24 hours ☐ Pager (check all that apply) If the contact information listed above changes, you will need to notify WIRB (a consent form modification fee will apply). Please request the necessary changes using the Change In Research Submission Form available at www.wirb.com.	N/A ☐ (sites requesting waiver of consent only)

40.	Would you like names of the sub-investigators you provided in question 28 listed on the cover page of the consent form? (If you would like additional names listed on the cover page of the consent form, please submit a list of all the names, including anyone listed in question 28) If the sub-investigators change, you will need to notify WIRB (a consent form modification fee will apply). Please request the necessary changes using the Change In Research/Subject Recruitment Submission Form available at www.wirb.com.	Yes ☐	No ☒

41. Please provide subject payment information: If subjects are to be paid, state specifically for which visits subjects will receive payment and when such payment will be made; for example, "payment will be made at the end of each study visit", "payment will be made at the end of the last study visit" or "payment will be made within one month after the last study visit". Please be as specific as possible to minimize confusion.

☐ Subjects will **not be paid**.

☐ Subjects will present receipts and be reimbursed **for travel and or parking** as follows:

_____

☐ Subjects will be **paid according to attached payment schedule or as stated in submitted consent form**. *Note*: the sponsor's consent form template generally does not include specific payment amounts.

OR

☒ Subjects will be **paid as follows**:

Amount per completed visit: $**100.00** Comments: **Up to one visit per day**
Number of visits in this study: **1.00** Comments: **May be up to two visits per worker**
List any visits not paid: **0** Comments: _____
☐ Total, $_____ Comments: _____
or
☒ Do not list a total in the consent form

Sponsor Protocol # AHE36 **Investigator Last Name:** Bruce

V. BILLING INFORMATION: Please tell us who should be billed for this review. *(If this section is not completed, the PI will be billed)*

42.	If you have listed someone other than yourself as the billing contact, please attach written verification from that person indicating he or she will pay for these services.			
42a.	Company Name: **Agricultural Handlers Exposure Task Force L.L.C. (AHETF)**			
42b.	Attn.: **David R. Johnson**			
42c.	Address: (street, city, state/province, postal code, country) **1720 Prospect Drive** **P.O. Box 509** **Macon, Missouri 63552** **United States**			
42d.	Phone: (**660**) **395-9590**	Fax: (**660**) **395-9593**	E-mail: **davejohn@marktwain.net**	
42e.	Mail Stop/Cost Center:			
42f.	Purchase Order number (P.O.#), if applicable:			N/A ☒
42g.	Cost of the requested WIRB translation services will be paid by: (if applicable)			N/A ☒
42h.	Please describe any special billing instructions:			N/A ☒

VI. NAME OF PERSON COMPLETING THIS FORM: Please tell us who you are and how we can contact you if we have questions about this form.

43.

Eric D. Bruce — Printed or Typed Name of Person Completing This Form

Independent Contractor — Company & title

(**925**) **939-4987** — Phone number

(**925**) **939-4987** — Fax number

eybruce@pacbell.net — E-mail address (optional)

Initial Review Submission Form – *Additional Sites Listing* WIRB®

Sponsor Protocol # AHE36 **Investigator Last Name:** Bruce

Submit additional copies of this page to list additional sites. List only sites at which subjects will be seen. Each site will be listed on the consent form.

a.	**Additional Site # 2:** Name of Research Location: **Research For Hire** Physical Address: (street, city, state/province, postal code, country) **(*must match box 3 of submitted 1572 or part 3 of Canadian REBA form, if applicable*)** **1696 South Leggett Street** **Porterville, California 93257 United States**	N/A ☐
b.	**Site #2** Phone: (**559**) **784-5787**	
c.	What type of facility is this site? ☐ Medical office ☐ Hospital ☐ University ☐ Psychiatric Institution ☐ Nursing home ☒ Other *(specify):* Agricultural Research Facility ☐ Research Clinic ☐ Dialysis Center	
d.	What resources are available at this site to treat emergencies resulting from study-related procedures? ☐ ACLS trained personnel and crash cart ☐ Emergency drugs and supplies to stabilize subject until emergency personnel arrive ☐ Emergency response team within facility ☒ Call 911 ☐ Other *(specify):* _____ ☐ N/A	
e.	If this site is not a hospital, please name the medical facility to be used in an emergency: **Sierra View District Hospital (Porterville, Californit) or nearest ER facility**	N/A ☐
f.	Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? *If No, attach a separate sheet of paper describing the following: • How subjects would be referred for hospitalization, • Name, address and telephone number of physician who has agreed to attend these patients, and • What measures would be taken to assure communication between the investigator and the attending physician	Yes ☐ *No ☒
g.	Approximate distance from main site: **130 miles** If more than 50 miles from the main site, please explain how the PI will provide adequate oversight of the distant sites: **Subject participation will not overlap; that is, all subjects will complete participation at one site before subjects start participation at the other site.**	

WIRB® Financial Interest Disclosure FORM
(For Sites Answering Yes to Question 7)

Information to be filled in by Investigator Site:

Drug or Device Name: _____ Sponsor Name: _____

Investigator Name: _____ Date: _____

Party with the Financial Interest:

(Please provide a separate form for each individual with a financial interest.)

Name: _____

Party's Position:

- ☐ Investigator
- ☐ Sub-Investigator
- ☐ Other Research Staff
- ☐ Family Member
- ☐ Institution (e.g., Hospital, University, etc.)
- ☐ Other Party: _____

Nature of Financial Interest: (check box and fill in information)

☐ Equity (stock, options, etc. - Does not include diversified mutual funds or similar instruments in which shareholder has no control over the equities held by the fund.)

Number of Shares, etc.: _____ $ value: _____

- ☐ Consulting Fees during last 365 days (or indicate alternative period) $ value: _____
- ☐ Speaking Fees during last 365 days (or indicate alternative period) $ value: _____
- ☐ Gifts during last 365 days (or indicate alternative period) $ value: _____
- ☐ Corporate Officer or Board of Directors $ value: _____
- ☐ Other Employment Relationship $ value: _____
- ☐ Trademarks $ value: _____
- ☐ Copyrights $ value: _____
- ☐ Licensing Agreements $ value: _____
- ☐ Royalty Payments $ value: _____
- ☐ Patent Holdings $ value: _____
- ☐ Other (describe) _____ $ value: _____

Commentary:

Information to be filled in by Western Institutional Review Board:

WIRB Protocol No.: _____ WIRB Study No.: _____

Prepared for Board By: _____ Investigator No.: _____

Present to Panel Number(s): _____ Date: _____

Screening Procedures Information Form

WIRB®

(For Sites Answering Yes to Question 34)

1.	How is screening initiated? ☐ Incoming response to an ad or web site ☐ Site or call center initiating a call to a patient whose name was obtained from a database or list Please note: Provincial, state, or federal laws may prohibit unsolicited calls to people who have not given prior permission to be contacted.			
2.	How is information stored? ☐ In a database Describe the security measures in place: _____ ☐ On paper How and where is the paper stored? _____ Who has access to the paper? _____			
3.	How long is information stored?			
4.	How is information destroyed at the end of the designated storage time?			
5.	Are screening failure records kept with the other study records? *If No, please describe how and when they will be destroyed:		Yes ☐	*No ☐
6.	Are the names of screened subjects sold to or shared with other entities? *If Yes, please explain:		*Yes ☐	No ☐
7.	Does your site utilize a call center? *If Yes, please forward a copy of the call center's privacy policy if available or summarize how your office will receive subject information from the call center (e.g., e-mailed, faxed, received directly from the caller who was provided with your office's phone number, etc.)		*Yes ☐	No ☐
	If the call center faxes information to your site, is the fax machine accessible only to authorized study personnel? Comments:	Yes ☐	No ☐	NA ☐

WIRB Screening Requirements:

(If you plan to screen Canadian citizens, please call Client Services for more information about Canadian screening requirements.)

- The script must include an introductory statement that informs the subject of the purpose of the questions and that they do not have to answer any questions they do not want to answer.
- The script must not describe the type of questions that will be asked as "confidential;" i.e., rather than saying "we would like to ask you some *confidential* questions," say "we would like to ask you some questions." It is acceptable to say "personal questions" or "sensitive questions." The purpose of this policy is to prevent any possible misunderstanding that the answers will be held in complete confidence.
- When appropriate, the script must include an introductory statement warning the subjects of the sensitive nature of the questions that might make the subject uncomfortable, and preferably include an example (for instance, "We are going to ask you about drug or alcohol use.") This will generally be limited to questions about mental illness, substance abuse, and sexual abuse. For these types of screening scripts, it may be appropriate to not collect any identifying information until after the questions are asked (i.e., collect the name and other identifying information at the end of the conversation and the form).

Body of Screening Form

- The Board expects to see the actual questions that will be asked, not just a general statement such as "inclusion/exclusion criteria addressed."

Closing Statement

- The script must include a closing statement informing the subject of whether or not they have met the preliminary screening requirements.
- The script must address in a closing statement whether the information received from the subject will be destroyed immediately, or whether it will be stored, and if so for how long and where.
- If the site would like to keep information for future contact for new studies, this must be described to the subject as well, and the subject must have an opportunity to decline.

Additional Issues

- The screening script must be in language understandable by lay people. If complicated medical terms must be included in the screening script, please provide WIRB with an explanation of how they will be explained to the subjects.
- WIRB realizes that the script may not be followed verbatim, as subjects may ask additional questions or stray from the topic. This is acceptable, but WIRB expects that the interviewer will keep as closely as possible to the spirit and letter of the script.
- It is useful to WIRB if the investigator informs WIRB of the use of the recruitment screen; e.g., if it is going to be used with subjects calling in from advertisements, for calling patients listed in a database, or for conducting cold calls.