INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: May 12, 2006

TO: Scott P. Carroll, Ph.D.
Carroll-Loye Biological Research

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Independent Investigational Review Board, Inc.
Procedures for review of EPA monitored Studied

This summary is prepared in response to a request from William Jordan of the US EPA, forwarded to the Independent Investigational Review Board, Inc. (IIRB) by Scott P. Carroll, Ph.D. of Carroll-Loye Biological Research. In this report excerpt from Rule and Regulations of the IIRB is addressed in *italics.*

The following information is intended to serve an introduction to the response that is to be provided to the EPA reviewer:

1. ***FUNCTION OF THE BOARD***

The Independent Investigational Review Board (IIRB) is an institutional review committee structured in compliance with both the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (2ICFR 50 and 56) and in accordance with regulations described in 45 CFR 46, Department of Health and Human Services (DHHS). The IIRB provides Assurance of Compliance with human subjects regulations as required by the DHHS when the research involves human subjects and is conducted by DHHS or supported in whole or in part by DHHS.

In addition, ICH/GCP guidelines are observed and review is conducted in compliance with 45 CFR Parts 160 and 164, the Privacy Rule, implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Independent Investigational Review Board, Inc. will review studies regulated by the Environmental Protection Agency (EPA) within the scope of regulations included in 40 CFR Parts 9 and 26; Protections for Subjects in Human Research; Final Rule.

The primary function of the Independent Investigational Review Board, Inc. (IIRB) is to protect the rights and welfare of human subjects involved in clinical investigations, as defined by Federal Regulation. The IIRB reviews research activities including but not limited to; Phase I, II, III or IV or Device studies (as defined by FDA regulations) and research regulated by the EPA. Review is conducted in accordance with regulations described in 21 CFR Parts 50 and 56, 45 CFR 46 and 40 CFR Parts 9 and 26in accordance with the policies and procedures adopted by the Board. In the review of research involving human subjects conducted by DHHS or supported in whole or in part by DHHS, and review of research regulated by the EPA involving human subjects where both the FDA regulations and the DHHS Regulations apply or EPA regulations apply, the more stringent requirements will be met.

The Communication received from Scott Carroll included a request to respond to:

(1) As required by §26.1115(a)(2): Minutes of IRB meetings . . . in sufficient detail to show
- o attendance at the meetings;
- o the basis for requiring changes in or disapproving research; and
- o a written summary of the discussion of controverted issues and their resolution.

4. BOARD RECORDS, MINUTES AND FILES

B. *Meeting Records/Minutes*

The Board will maintain minutes of each meeting and will review and vote on the Approval of the minutes of the previous meeting before consideration of any other business. Prior to approval, members may request changes in the minutes, however, all changes shall require Board approval. The Chairman shall report to the Board on new Board appointments or changes, new or updated guidelines pertinent to IIRB functions, proposed policy and procedure changes, expedited actions taken by the Chairman since the previous meeting, and on any other matters deemed appropriate by the Chairman.

Minutes shall record the date, time and place of all Board meetings. Minutes shall record the total attendance at all Board meetings, including non-members, consultants, clinical investigators, and others attending the meeting. The voting results cast for all initial and continuing protocol reviews shall be recorded; votes for, against and abstaining on these actions will be noted.

Consent form and procedure changes/discussion may be included in the documentation maintained in the study file.

The minutes shall accurately reflect appropriate comments and discussion regarding votes and the decision-making process. The Minutes shall include the reasons for any disapprovals of clinical investigations. The minutes shall document Board actions on continuing review, adverse reports, protocol and informed consent modifications after initial review, suspensions and termination of Board approvals, completed clinical investigation reports and other business relating to previously approved research studies. Minutes shall include any comments members may specifically request to appear in the minutes. The minutes will also address any other business brought before the Board.

* If the EPA reviewer requires specific copies of the minutes related to the review of any research study, an inquiry from the the EPA reviewer to the Chairperson of the IIRB is required.

(2) As required by §26.1115(a)(4), copies of all correspondence between the IRB and the investigators (including application forms and all attachments).

4. BOARD RECORDS, MINUTES AND FILES

A. *Protocol Files*

The Chairman or designee shall create a protocol file for each clinical investigation reviewed. The protocol file will contain, but not be limited to; copies of the research protocol, amendments (if applicable), Investigator's Brochure (if applicable or refer to where the information is filed), for studies regulated by the EPA, applicable MSDS information, approved informed consent documents, approval/disapproval memoranda, correspondence and reports of injuries to subjects. The protocol file shall also contain copies of opinions from consultants requested by the Board and other documents as described in policies and procedures adopted by the Board. The Chairman/President shall be responsible for the maintenance of these files.

An Informed Consent Check List (sample attached) or other checklists as developed will be used as a guidelines in the review process. The forms are intended to minimize the opportunity for Board error and improve documentation of compliance. The Check Lists should be kept filed with the protocol file.

The Investigators C-V (and Site Questionnaire) will be held on file and updated when changes occur.

(3) As required by §26.1115(a)(5):

- A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations;

* A current Membership Roster is posted on the Independent Investigational Review Board, Inc. website (www.iirb.com) and is attached to this summary for reviewer convenience.

2. BOARD COMPOSITION

The IIRB shall have no less than five (5) members of various backgrounds; consideration will include gender and racial and cultural backgrounds of members. The IIRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in non-scientific area.

At each meeting there shall be at least one member that is not otherwise affiliated with the Institution. If the IIRB regularly reviews research involving a vulnerable category of subjects (such as children, prisoners, pregnant women or the handicapped) consideration shall be given to the appointment of an individual knowledgeable and experienced in working with those subjects. A Board Membership List is maintained and will include enough information to reflect the education and background of each member. A file will be kept that includes the C-V, license and certification (as warranted), and Disclosure/Conflict of Interest documents.

- o any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

    * All members of the IIRB serve as consultants to the Board and are not employees, governing board/panel members or stockholders.

(4) As required by §26.1115(a)(6), written procedures for the IRB in the same detail as described in §26.1108(a) and (b).

    * The Policies and Procedures of the IIRB fully provide written procedures for each area outlined in §26.1108(a) and (b) and are available for inspection by representatives of the EPA if more detailed review is warranted.

(5) Section 26.1125 specifies the information that must be submitted in connection with a proposal to conduct new research with human subjects covered by the rule. This information generally includes (1) certain records that the Institutional Review Board (IRB) is required to maintain [see section 26.1115(a)]; (2) to the extent not covered in the IRB's records, a discussion of key issues which the IRB is required to consider and resolve in approving proposed research [see section 26.1125 (a) - (d)]; and (3) documentation of the IRB's approval of the proposed research [see section 26.1125(f)].

    * The Policies and Procedures of the IIRB fully provide written procedures for each area outlined in §26.1125 and are available for inspection by representatives of the EPA if more detailed review is warranted.

I hope this response addresses the areas of inquiry from the EPA reviewer. If you have any questions or if any additional clarification is required, please let me know.

Thank you.

Chairman, Kim Lerner, B.S.
Ms. Lerner is co-founder of the Independent Investigational Review Board and has acted as Chairman for the past 16 years. She has transformed her experience as Director of the IRB at a large teaching hospital into directing a large and diverse independent IRB. Her experience serving as the Director of a Hospital Quality Assurance Program provides the foundation for implementation of the Independent IRB's continuous quality improvement and regulatory compliance programs

Vice Chairman, Anita Mc Sharry, RN (scientific)
Ms Mc Sharry is co-founder of the Independent Investigational Review Board and has acted as President for the past 16 years. She has extensive knowledge of principles of medical research, regulatory compliance and clinical safety. Previous experience included development of Research Study budgets, liaison between the Pharmaceutical Sponsor and the Principal Investigator at the University of Miami, Department of Clinical Pharmacology.

David D. Wells, MD (physician/scientific)
Dr. Wells graduated from the University of Havana, is English-Spanish bilingual and brings this international experience to the IRB. He has served as the Emergency Medicine Department Chairman at a local hospital, has health care Clinic experience working with financially disadvantaged patients and is presently volunteering as a Family Practice Physician serving migrant farm workers. This hands-on experience enables him to clearly assess overall research risks and benefits and understand vulnerable population issues.

Rabbi Akiva D. Mann, M.A. (non-scientific)
Rabbi Mann is presently the Spiritual Leader of the Hallandale Jewish Center and is the Director of the Institute of Jewish Knowledge and Learning. He has served on Mayorial Commissions addressing the issues of Medical Ethics and Geriatric Care, as well as having served on Hospital Ethics Committees.

Edward Wiederhorn (non-scientific)
Mr. Wiederhorn is the community representative to the IIRB and is a member of the American Association of Retired Persons (AARP). Mr. Wiederhorn has longstanding experience as a Civic Activist and has been a member of Fraternal and Charitable Organizations, at present he is actively involved in support of the City of Hope.

Shari Somerstein, B.S., R. Ph. (scientific)
Ms. Somerstein has served as a member of the Independent IRB for more than 6 years and has extensive experience in the interpretation and assessment of clinical research findings and study design. She brings extensive clinical pharmacy experience in a Hospital setting and in the community. She has broad administrative experience in IRB activities including, protocol review, assessment of adverse drug experiences and informed consent form development.

George J. Garbarino (non-scientific)
Mr. Garbarino has been an advocate for Labor Union members and brings a wide range of experience in the area of worker's rights and contract negotiations. He is the Business Manager of the Tile, Marble and Stone Workers Local 121 and is associated with the School Board of Broward County.

Glenn K. Moran, DO, FACOFP (Alternate for: physican/scientific)
Dr. Moran is Board Certified in Family Practice and is presently in private practice. He maintains privileges at local hospitals and is active in the areas of Medical Quality Assurance and Peer Review and other community organizations. He is an Assistant Clinical Professor at Nova Southeastern College of Osteopathic Medicine and is familiar with current medical research requirements.

Marcos Rejtman, DO, (Alternate for: physican/scientific)
Dr. Rejtman is Board Certified in Family Practice, Geriatric Medicine and Hospice &Palliative Medicine and is presently the Medical and Team Director for VITAS Innovative Health Care (Hospice) and provides in hospital patient management for a multi-specialty group. He also has recent experience in Emergency Department Medicine. He maintains privileges at local hospitals and is active in the areas of Medical Quality Assurance and Peer Review and other community organizations. He is English-Spanish bilingual.

Maria L. Rodriguez, MS, CCRC,RHIT (Alternate for: non-scientific)
Ms Rodriguez brings to the Board extensive experience in the clinical research field and knowledge of regulatory requirements, policy and procedure development, and the implementation of the quality assurance function. Her educational background focuses on education and training in the clinical research field. She is English-Spanish bilingual.

Elsie P. Remy, MSN, ARNP-c (Alternate for: scientific)
Ms Remy has an extensive background in nursing as an educator and clinical nurse manager. Her experience includes acute and primary care. She is an Assistant Professor in the Nursing Department at Miami Dade Community College. Her responsibilities include curriculum development and she serves as an Academic Adviser and Adviser to student organizations.

Robert Lettman, Esq. (non-scientific)
Mr. Lettman is a practicing Attorney in South Florida with extensive experience in civil litigation and serves as a resource in the consideration of the legal aspects of the informed consent process. Having been in the community for 30 years he brings insights and knowledge of the needs of the community.

MEMBERSHIP CHANGES FROM PREVIOUS ROSTER (Dated: 05/10/05)
George Garbarino had been serving as "Alternate for Non-Scientific Member" and is now serving as "Member (Non-Scientific)".

Robert Lettman had been serving as "Member (Non-Scientific)" and is now serving as "Alternate for Non-Scientific Member".