

**From:** Burnett, Donald M. [burnetdm@bp.com]

**Sent:** Tuesday, February 18, 2003 11:19 AM

**To:** Patsy Clegg

**Subject:** FW: Interactions with the Ethics and Scientific Review Panels

Patsy, the e-mail communication below from Patrick Beatty to Richard Irons and Otto Wong is the "letter" which you and I just discussed. The attached Word document is referenced in the last paragraph of Patrick's e-mail and was sent to Irons and Otto to clarify the roles and responsibilities of the various consortium committees, including the SRP and ERP. Financial oversight of the project is an explicit responsibility of the Oversight Committee.

Don

-----Original Message-----

**From:** Beatty, Patrick (PatrickBeatty) [mailto:PatrickBeatty@ChevronTexaco.com]

**Sent:** Thursday, January 30, 2003 6:03 PM

**To:** Burnett, Donald M.

**Subject:** FW: Interactions with the Ethics and Scientific Review Panels

Don,

Sorry that you did not get the original version of this message. I have two versions of your e-mail address in my computer address book, and I clicked on the wrong one. This is what I sent including the attachment.

Patrick

-----Original Message-----

**From:** Beatty, Patrick (PatrickBeatty)

**Sent:** Thursday, January 30, 2003 3:53 PM

**To:** 'Richard.Irons@UCHSC.edu'; 'OttoWong@aol.com'

**Cc:** 'Dr. Baruch Brody'; 'Jmricewas@aol.com'; 'Burnetdm@bp.com'; Beatty, Patrick (PatrickBeatty)

**Subject:** Interactions with the Ethics and Scientific Review Panels

Dear Richard and Otto,

Because of recent events which have necessitated changes in the study protocols and informed consent documents, I feel the need to clarify from the perspective of the Benzene Health Research Consortium (BHRC) members our expectations for the roles of the Ethics Review and Scientific Review Panels. These panels have been established as part of the BHRC structure both to reassure the consortium members that the studies are being conducted in the highest ethical and scientific manner possible and to provide top-tier independent review. This review operates in conjunction with traditional and legally mandated reviews by IRBs affiliated with the principal investigators' parent institutions as well as relevant Chinese institutional and governmental reviews. The combined purpose of all of these reviews, including those of the ERP and the SRP, is enhanced scientific credibility and universal acceptance of the study.

The BHRC members recognize that the relevant IRBs are the final arbiter of what is legally acceptable from a scientific or ethics perspective. However, this does not preclude either the SRP or the ERP from requiring additional conditions or wording that goes beyond the requirements of an IRB ruling. Because of this, protocol changes that need to be submitted for IRB review should be reviewed by the internal Review Panels prior to submittal to the IRB. For example, I am fairly confident that the scientific approaches as detailed in the protocols presented to the SRP in September of 2001 would have been approved by COMIRB and the AHS IRB. Prior review by the SRP identified additions to those protocols that should enhance the credibility of the resultant findings, and the resultant amended protocols were approved by the appropriate IRBs. IRB approval prior to submittal to the SRP would have necessitated resubmittal to the institutional review boards and unnecessary delay.

Following are some guidelines for

Ethics Review Panel

Any proposed changes in wording to informed consent documents should be submitted to the Chairman of the ERP. The Chair will determine if the change: a.) requires no action by the ERP; b.) is insignificant enough to be approved by the Chair without full Panel action; or c.) is significant enough to be considered by the entire ERP for comment. Any changes in compensation or other terms of participation by subjects should be submitted to the Chairman of the ERP for similar review. Protocol changes that alter the degree or type of interaction with study participants should also be submitted to the

ERP Chairman. Minor proposed changes such as the details of an assay or other methods related changes would not normally have ethics implications and need not be submitted.

#### Scientific Review Panel

It is the intent of the Consortium that any proposed protocol changes that have the potential to affect the scientific conduct or validity of the study should be submitted to the Chairman of the SRP. As with the ERP, the SRP Chairman will determine if the change requires no approval, the Chairman's approval, or consideration by the entire Panel. In some cases, the Chairman may refer the proposed change to a member of the SRP with specialized knowledge for input without convening the entire SRP, e.g., changing the assay for a specific endpoint from one method to another without changing the endpoint itself. Any proposed protocol change requiring action by the full SRP will be communicated to the ERP Chairman for consideration.

These procedures are not intended to hamper the conduct of the studies, and if proposed or anticipated changes are communicated in a timely manner, delays should be minimal. These procedures place a responsibility on the members of the review panels to act on submitted items as expeditiously as possible in order to avoid delaying ongoing research activities. If the Chairman of a Panel does not respond to, or acknowledge receipt of a request that is sent as an urgent matter, the vice-Chair will be contacted to keep the process moving.

Otto and Richard, I hope that the above does not cause you undue concern, but the principles underlying this clarification have been part of this project from its inception. Independent review by the Ethics and Scientific Review Panels is an integral and indispensable part of ensuring ultimate acceptance and value of the results of this research program. The consortium realizes that as principal investigators you have the ability to report protocol changes or not. However, our expectation is that the internal review procedures will be honored in the best interest of the study.

Patrick Beatty

Chairman, Technical Oversight Committee

I have attached below a document which is the official explanation of the roles and responsibilities of the committees that make up the formal structure of the Benzene Health Research Consortium. This document also lays out the roles of the Ethics Review Panel and the Scientific Review Panel as well as the expected interactions and communication channels between the Panels, the investigators and the Consortium. Although it was only finalized in December of last year, it was an oversight that we have not provided you with a copy of this earlier

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BHRC / API Roles Responsibilities  
March 2007 Review

|    | A               | B       | C                                                                                                                                                                      | D                                                                                                                              | E | F | G | H |
|----|-----------------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| 1  |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 2  |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 3  | Source Document | Section | API                                                                                                                                                                    | BHRC                                                                                                                           |   |   |   |   |
| 4  |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 5  | Contract        | 3       | Incorporation by Reference – With respect to conduct of the Program by API under Ssection 8, this Agreement incorporates by reference all API Policies and Procedures. |                                                                                                                                |   |   |   |   |
| 6  |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 7  |                 | 5b      |                                                                                                                                                                        | Oversight Committee has authority over such administrative and managerial obligations as, but not limited to,                  |   |   |   |   |
| 8  |                 |         |                                                                                                                                                                        | * accepting new mem-bers,                                                                                                      |   |   |   |   |
| 9  |                 |         |                                                                                                                                                                        | * determining the scope of the Program pursuant to Section 7 below,                                                            |   |   |   |   |
| 10 |                 |         |                                                                                                                                                                        | * the choice of investigators,                                                                                                 |   |   |   |   |
| 11 |                 |         |                                                                                                                                                                        | * approving additional expenditure of funds, and                                                                               |   |   |   |   |
| 12 |                 |         |                                                                                                                                                                        | * assuring that API performs in conformance with the Program and this Agreement.                                               |   |   |   |   |
| 13 |                 |         |                                                                                                                                                                        | * The Oversight Committee shall have the authority to form subcommittees.                                                      |   |   |   |   |
| 14 |                 | 6       |                                                                                                                                                                        | Termination – The Research Group may terminate some or all further work under this agreement upon a 2/3 vote among all members |   |   |   |   |
| 15 |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 16 |                 | 8a      | API will, among other duties, negotiate, enter into, and administer agreements for the conduct of the research program.                                                |                                                                                                                                |   |   |   |   |
| 17 |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 18 |                 | 8b      | Provide administrative oversight for the program.                                                                                                                      |                                                                                                                                |   |   |   |   |
| 19 |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 20 |                 | 8c      | Calculate, collect and disburse the financial contributions required of the Research Group under this Agreement.                                                       |                                                                                                                                |   |   |   |   |
| 21 |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |
| 22 |                 | 8d      | Communicate results to the Research Group and others as directed by the Oversight Committee.                                                                           |                                                                                                                                |   |   |   |   |
| 23 |                 |         |                                                                                                                                                                        |                                                                                                                                |   |   |   |   |

BHRC / API Roles Responsibilities  
March 2007 Review

|    | A                         | B                               | C                                                                                                                                                                                                                                   | D | E                                                                    | F | G | H |
|----|---------------------------|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----------------------------------------------------------------------|---|---|---|
| 24 |                           | 8e                              | In negotiating agreements with investigators, API agrees to use its best efforts to obtain a contractual promise and insurance coverage for negligence from the investigator(s) to fully indemnify API and participating companies. |   |                                                                      |   |   |   |
| 25 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 26 | API Policies & Procedures |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 27 |                           | Environmental & health research | includes subscription projects                                                                                                                                                                                                      |   | Relationship / Overlap w/ Special programs                           |   |   |   |
| 28 |                           |                                 | semi-annual reports                                                                                                                                                                                                                 |   |                                                                      |   |   |   |
| 29 |                           | Standard of Conduct             |                                                                                                                                                                                                                                     |   | No specific relevance                                                |   |   |   |
| 30 |                           | Delegation of "Authority        | All disbursements made only with signed authority                                                                                                                                                                                   |   |                                                                      |   |   |   |
| 31 |                           |                                 | Changes to Self-Supporting and Special Solicitation programs over 10% or \$500,000                                                                                                                                                  |   | Authorized to Approve: CFO                                           |   |   |   |
| 32 |                           |                                 |                                                                                                                                                                                                                                     |   | With approval by President and General Committee on Special Programs |   |   |   |
| 33 |                           | Commitments                     |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 34 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 35 |                           |                                 | in the case of self-supporting programs, an unbudgeted commitment may be made where                                                                                                                                                 |   |                                                                      |   |   |   |
| 36 |                           |                                 | funding has not been budgeted in the current year, provided it meets the business case and a                                                                                                                                        |   |                                                                      |   |   |   |
| 37 |                           |                                 | fund balance is available.                                                                                                                                                                                                          |   |                                                                      |   |   |   |
| 38 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 39 |                           |                                 | • Written commitments must be fully executed prior to any expenses being incurred. The onus                                                                                                                                         |   |                                                                      |   |   |   |
| 40 |                           |                                 | is on the Department Head to ensure compliance.                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 41 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 42 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 43 |                           |                                 | • In compelling, time sensitive situations, work may proceed with verbal authorization by API                                                                                                                                       |   |                                                                      |   |   |   |
| 44 |                           |                                 | staff (consistent with the Delegation Policy, Policy 361), prior to a contract being signed.                                                                                                                                        |   |                                                                      |   |   |   |
| 45 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 46 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 47 |                           |                                 | Such authorizations shall require the prior approval of the API official having signature                                                                                                                                           |   |                                                                      |   |   |   |
| 48 |                           |                                 | authority and should be disclosed as part of the background material provided when the                                                                                                                                              |   |                                                                      |   |   |   |
| 49 |                           |                                 | contract is submitted for review.                                                                                                                                                                                                   |   |                                                                      |   |   |   |
| 50 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 51 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 52 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 53 |                           | Special Programs                | Ownership of the special programs resides with API's Executive Committee and Board of                                                                                                                                               |   |                                                                      |   |   |   |
| 54 |                           |                                 | Directors.                                                                                                                                                                                                                          |   |                                                                      |   |   |   |
| 55 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |
| 56 |                           |                                 |                                                                                                                                                                                                                                     |   |                                                                      |   |   |   |

BHRC / API Roles Responsibilities  
March 2007 Review

|    | A                                      | B | C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | D                                                                                                                    | E | F | G | H |
|----|----------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| 57 |                                        |   | Revenue in excess of expenses and the recommended fund balance reserve may be used to reduce API member dues, approved annually through the program and budget planning process.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                      |   |   |   |   |
| 58 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 59 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 60 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 61 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Need assurance from API that any excess funds will be dispersed and/or refunded at the discretion of the consortium. |   |   |   |   |
| 62 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 63 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 64 |                                        |   | Special solicitation programs are generally shorter term in duration than other special programs that sell products and services. Funds remaining at the end of a special solicitation program should be disbursed as directed by those companies who participated in the program.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                      |   |   |   |   |
| 65 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 66 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 67 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 68 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 69 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 70 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 71 | BHRC Roles & Responsibilities Document |   | <p><u>Responsibilities:</u> The Business Oversight Committee shall be the ultimate administrative authority for the consortium and shall make all final decisions regarding budget, reports required to oversee financial disbursements and other agreed milestones. The Business Oversight Committee manages Consortium interactions with the study investigators and other entities, for example government officials or other interested parties. The Business Oversight Committee approves external communications. The Business Oversight Committee seeks legal advice from contracted counsel and the API legal department. The Business Oversight Committee oversees the administration of the project by API, to include oversight of contracts. The Business Oversight Committee shall have final approval over initial membership of the Ethics Review Panel and the Scientific Review Panel. The Business Oversight Committee approves membership in the Technical Committee for those other than financially contributing members of the Consortium. (See below for Panels membership and responsibilities subsequent to initial membership decisions and formation.)</p> <p>The Business Oversight Committee shall report annually to the member companies on the financial status of the Consortium. The Business Oversight Committee shall authorize collection of funding monies and all expenditures of the Consortium.</p> <p><u>Responsibilities:</u> The Technical Oversight Committee shall act as the technical consultant to the Business Oversight Committee of the consortium. This committee shall serve as the contact between the Consortium and the Principal Investigators. This committee shall facilitate project review between the Scientific and Ethics Review Panels and the Principal Investigators. This committee shall follow the progress of the research, identifying key milestones, reviewing reports from the Principal Investigators, and</p> |                                                                                                                      |   |   |   |   |
| 72 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 73 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 74 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 75 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 76 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 77 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 78 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 79 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 80 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 81 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 82 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 83 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 84 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 85 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 86 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 87 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 88 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 89 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 90 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 91 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 92 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 93 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 94 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 95 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
| 96 |                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |   |   |   |   |
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BHRC / API Roles Responsibilities  
March 2007 Review

|     | A | B | C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | D | E | F | G | H |
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| 100 |   |   | otherwise understanding the status without in any way impacting the Investigators independence or the research program as set out in the protocols. This committee will provide overviews of all manuscripts presented for publication and abstracts or presentations stemming from the consortium research. The Technical Oversight Committee comments on and provides assessments of any protocol alterations recommended by the Principal Investigators, the Scientific Review Panel or the Ethics Review Panel. The Technical Oversight Committee shall prepare abstracts of presentations and manuscripts as needed or as requested by the Business Oversight Committee for its use. |   |   |   |   |   |
| 101 |   |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |   |   |   |   |   |
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