

To: 'BenzConsort-OC@listserve.api.org' <BenzConsort-OC@api.org>; 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>
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Bcc:
Received Date: 2001-10-02 16:08:26 GMT
Subject: October 1, 2001 Conference Call Summary

Consortium Oversight and Technical Committees;

Draft Summary of call attached. Please send all comments or corrections to me via e-mail.

Thank you,

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Attachments:

ConferenceCallSummary01Oct2001.doc

**Conference Call Summary
Oversight and Technical Committees
Benzene Health Research Consortium
October 1, 2001**

Participants:

Patrick Beatty, Chevron
Patsy Clegg, Shell
Shan Tsai, Shell
Lynn Russo, ExxonMobil

Stuart Cagen, Shell
Bill Broddle, Conoco
Carol Fairbrother, ExxonMobil
Don Burnett, BP

Issues:

Documentation of SRP Protocol Review

- Needs
 - Keep the process as independent as possible
 - Maintain a good paper trail to document decisions made
 - How to deal with comments that are not relevant anymore
 - Researchers would like a final set of requested changes and a report before going to an IRB
- Types of Comments
 - Scientific/Technical – dealing with the performance of the protocols and details to be changed in the protocol (within the purview of the SRP)
 - Scope – suggestions to add other types of analyses or lines of inquiry that would necessitate additional funding. Refer these to the TC and OC.
 - Ethical Issues – questions regarding the ethics of performing certain work or gaining permission to do so (consent forms). Refer to the ERP
- Options for developing the documentation
 1. Multi-step process (Stuart Cagen's proposal):
 - a) Report of the SRP, drafted with individual written comments of members of the SRP prior to the meeting, but then formed as a committee report sometime shortly after the meeting. This would be a consensus document that should be presented from the SRP to the investigators.
 - b) Response by the investigators in the form of new protocols as per SRP comments or explanations why certain suggestions were not taken.
 - c) Final concurrence or at least understanding by the SRP.
 - d) Presentation of protocols by investigators to institutional IRBs.
 2. Meeting Summary that outlines the changes to be made to the protocols. Should include a statement: "Comments not addressed in the consensus report were agreed upon by all parties as not being relevant." Process does not follow the step-by-step process but allows some parallel work to streamline the process.
- Final Decisions
 1. Generate draft minutes and an Executive Summary of decisions on major issues.
 2. Draft minutes and Executive summary sent to researchers and SRP for review.

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3. Changes to protocols made. It was suggested that “track changes” feature be used to facilitate a review, and that this can take place concurrent to the development of the minutes.
4. Revised protocols given to SRP.
5. SRP reviews the protocols.
6. Final consensus report derived from minutes and signed by all parties.

SRP Membership and Choosing a Chair

- SRP size was expanded to a possible 13 with the approval given to ask Richard Albertini to join the permanent SRP
 - All member companies then present on the call (BP, Chevron, ExxonMobil, Shell) concurred.
- SRP Chair
 - SRP membership should vote on acceptance of nominee for chair. Nominees would be put forward by the Technical Committee
 - A vice chair should also be selected.
 - There are a number of reasons to select a chair
 - This is how NIH panels do it.
 - Avoids possible conflicts if open nominations are held
 - Streamlines the process of getting a Chair in place
 - Potential nominees (in order of preference):
 1. Jerry Rice
 2. Nancy Mueller
 3. Richard Albertini (if he agrees to serve on the SRP)
 4. Howard Rockette
 5. Robert Herrick
 - Vice Chair will be chosen using the same prioritization scheme

Action Items:

- George Woodall will contact Richard Albertini to see if he is willing to join the permanent SRP (He has been contacted and is willing to serve).
- George Woodall will send the list of SRP members via e-mail to the individual SRP members
- Patrick Beatty will assist George Woodall in developing a description of duties for the SRP Chair and Vice-Chair, which will be sent to the nominees for the position to assist them in making their decision.
- Technical Committee will review the description of the duties for the SRP Chair
- George Woodall will contact the potential nominees in order of preference to see if they would be willing to serve as the Chair.
- George Woodall will draft the minutes of the meeting of the SRP Protocol Review and the Executive Summary (with assistance from the Chair, if possible). These documents will then be distributed to the SRP and the researchers for review, hopefully by COB this Friday (October 5, 2001). The path for further documentation will follow that outlined under “Final Decisions,” above.