From:	Beatty, Patrick (PWBE) <PWBE@chevron.com>
Sent:	Wednesday, September 26, 2001 12:05 AM (GMT)
To:	'Cagen, Stuart Z SCC' <szcagen@Shell.Com>; 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>; 'BenzConsort-OC@listserve.api.org' <BenzConsort-OC@api.org>; Beatty, Patrick (PWBE) <PWBE@chevron.com>
Cc:	Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>; Tsai, Shan SP SHLOIL-SPS <sptsai@Shell.Com>; 'George Woodall' <Woodallg@api.org>; 'richard.irons@uchsc.edu'; 'ottowong@aol.com'
Subject:	RE: SRP meeting documentation

All
Thank you for pushing along the formalization process for the SRP protocol review. Based upon the conference call today with the US investigators and a subsequent discussion with Stuart Cagen, I would like to suggest the following manner of documenting the SRP review process and its outcome.
To have each investigator write a response to each comment from each reviewer, even if similar comments among reviewers were to be combined, could be unnecessarily onerous. This is especially true since an initial reading of the reviewers' comments suggests that many of the comments were due to confusion about the integration of the project components or some lack of definition in component descriptions. These items should be easily cleared up during the SRP meeting.
Subject to legal review:
I suggest that the report of the SRP meeting document all changes that are to be made to the protocols in response to reviewer comments. The report should ideally reflect a consensus of opinion among the reviewers and agreement by the appropriate investigator(s) as to the changes to be made.
In the event that the investigator(s) strongly disagree with the reviewers' comments on scientific or feasibility grounds, the report should reflect the position of the investigator as well as the reviewer's comment.
If the reviewer's comment is to request a change of scope of the project, the project sponsors may respond to that comment in the SRP report indicating the degree to which they are willing to expand or amend the project.
I suggest that reviewer comments which are withdrawn as a result of discussion during the SRP meeting will not be individually addressed in the SRP report
A draft report will be generated by API staff based upon notes and a transcript of the meeting. That draft will be circulated for comment and correction by the meeting participants. The final version should de accepted by consensus of the reviewers and investigators. The report should probably be reviewed by agreed upon (by the OC) legal counsel representing the consortium.
I also suggest that after the acceptance of the SRP report, the reviewer comments and meeting transcript will be destroyed. I understand that this would be similar to practice by NIH study sections when reviewing grant proposals.
I believe that the above model would be acceptable to the investigators and

to Stuart. Please respond with any comments to me. I will be back in the office on Friday.
Patrick
> -----Original Message-----
> From: Cagen, Stuart Z SCC [SMTP:szcagen@Shell.Com]
> Sent: Monday, September 24, 2001 2:01 PM
> To: 'BenzConsort-TC@listserve.api.org';
> 'BenzConsort-OC@listserve.api.org'; 'Dr. Pat Beatty'
> Cc: Clegg, Patsy M SCC-CHSE-PC; Tsai, Shan SP SHLOIL-SPS; 'George
> Woodall'
> Subject: SRP meeting
>
> Pat and all:
>
> As we approach this week's SRP meeting, here are some suggestions:
>
> First of all, I have received positive responses from my prior suggestion
> -
> sent about a month ago - regarding the need to formalize the SRP review:
>
> This can be envisioned as a multistep process:
>
> 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 week. 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.
>
>
> I would suggest that it is the responsibility of the technical committee
> to
> ensure the implementation of this process and that the technical committee
> should report to the oversight committee regarding this procedure.
>
> In order to make this happen, the SRP should appoint a chair to help run
> the
> meeting to develop and draft the SRP report. Judging from the comments
> that
> have been received, this might be easier said than done. However, there
> needs to be a single consensus report that provides scientific comment in
> a
> format that will have functional value.
>

> I am troubled by some of the comments so far received because some of the
> SRP members are confused about where the overlapping protocols overlap,
> and
> because there is only one SRP expert per discipline. Thus, Dr. Larson is
> commenting about disease diagnosis and classification and others comment
> or
> will comment on the topic concerning elements of the exposure assessment,
> etc. In the end, the SRP has to convert from a group of individual
> experts to a committee offering consensus advice. Thus the chair of the
> SRP
> would have to call upon different members of his or her committee to lead
> their discipline specific review discussion. It is along this line
> that
> the SRP might wish to recruit additional members.
>
> Along the way it is up to us (the technical committee acting on behalf of
> the sponsors) to move the process along in order to produce a functional
> interaction between the SRP and the investigators that starts on Thursday
> but continues for several years.
>
>
> Thanks
>
> Stuart
>
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