From:	Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>
Sent:	Wednesday, September 26, 2001 6:27 PM (GMT)
To:	'BenzConsort-OC@listserve.api.org' <BenzConsort-OC@api.org>; 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>
Subject:	SRP Meeting Documentation - Resend

Stuart is having technical difficulty working from home today, so he asked me to forward this message.
Patsy
Pat and all:
Pat: Thanks for taking the time to review the proposed process and your alternative proposal.
It looks as though the version you are proposing is different than mine and it is even different than the one I thought we agreed to propose yesterday in our discussion. The main difference is that you are suggesting a one step process where the meeting minutes capture both the SRP comments and the response and the earlier version that you and I agreed to on the phone (and one more like the NIH study section process) was a two step process where the SRP provides a peer review report and the investigators provide their official response (which can agree or disagree with SRP suggestions). Regardless, the investigators would only have to deal with the consensus SRP report and would not have to wade through individual comments.
As we are nearing the actual SRP meeting (tomorrow !!) it looks as though it is too late to resolve this in a timely manner. I would recommend, however, that we move this forward as soon as possible and I think the best next step is to ask the oversight committee to help us design the dimensions of the peer review process - for both the current protocol reviews as well as subsequent peer review.
Meanwhile I would recommend that the SRP should be informed of our situation and to not give them specific follow-up actions until we reach consensus as to what the consortia wants. As you mentioned, this process needs further legal (and perhaps ethics committee) review.
Finally, it is important at this stage to NOT DESTROY ANY DOCUMENTS. My guess is that in the end we will have a study file that contains rough draft type comments and meeting transcripts, etc.
Thanks
Stuart
Stuart Cagen, Ph.D., Staff Toxicology Advisor
Shell Chemical Company, P.O. Box 4320, Houston, Texas 77210
tel: 713-241-1407; fax: 713-241-3325; email: szcagen@shellus.com
mobile: 832-309-1984
> -----Original Message-----
> From: Beatty, Patrick (PWBE) [SMTP:PWBE@chevron.com]
> Sent: Tuesday, September 25, 2001 7:05 PM
> To: 'Cagen, Stuart Z SCC'; 'BenzConsort-TC@listserve.api.org';
> 'BenzConsort-OC@listserve.api.org'; Beatty, Patrick (PWBE)
> Cc: Clegg, Patsy M SCC-CHSE-PC; Tsai, Shan SP SHLOIL-SPS; 'George
> Woodall'; '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
> >
> > Stuart Cagen, Ph.D., Staff Toxicology Advisor

> > Shell Chemical Company, P.O. Box 4320, Houston, Texas 77210
> > tel: 713-241-1407; fax: 713-241-3325; email: szcagen@shellus.com
> > mobile: 832-309-1984
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