Minutes for Committee Members Meeting

Date: February 3, 2014
Time: 12:00 PM CDT
Means: Conference Call

Attendees: Ahmet Erdemir
Lu Tian
Joy Ku
Lealem Mulugeta
Jacob Barhak
Bill Lytton

Not Available: Jerry Myers
Gary An
Marc Garbey

1. Recap of panel discussion at IMSH 2014 - 15 min Also check http://wiki.simtk.org/cpms/IMSH_Community_Participation
2. Upcoming presentations and conferences - 15 min
   a. Panel discussion in HFES 2014
   b. Abstract submitted to ASME V&V 2014
   c. Abstract retracted from MODSIM World 2014
3. Survey - 20 min
   a. Strategy to launch the survey.
      - Filing IRB exemption request.
      - Finalizing how we will reach out to different communities.
   b. Finalization of questions.
      - Should we ask for ranking of the same rules to ensure consistency?
      - Which categories should we add to context of use question?
   c. Ideas for analysis.
      - Ranking of all rules based on their score (gross initial pass)
      - Categorical representation, for an example see http://static.wileyprojects.com/oasurvey/
4. Glossary - 5 min
   - Committee members are expected to provide (or complement) definitions for at least 2 terms before each Committee meeting. http://wiki.simtk.org/cpms/Glossary_and_Definitions
5. Other business - 5 min

New Action Items:

Data analysis group:
- Need to start working on a data analysis plan for the survey

Lealem:
- Add all publically available NASA-STD-7009 related documents and presentation available in Zotero database, and share with the Committee members

Jacob:

- Start a forum discussion for the slides we will add to the Committee summary presentation regarding what makes the committee unique from the other organizations that are focused on M&S credibility for bio/med applications.

Ahmet and Joy:

- IRB exemption application

Notes:

1. **Recap of panel discussion at IMSH 2014**
   - A small group attended the CPMS presentation session, however everyone was very engaged in the discussions and we got a lot of valuable feedback from the participants who were all very experienced in their respective fields. The session also helped us make a lot of strong contacts that will be beneficial in our work. Check http://wiki.simtk.org/cpms/IMSH_Community_Participation for synapsis of the meeting results. This is being updated on an ongoing basis, so it is best to refer to this wiki page for the latest information on the outcomes of the IMSH session.
   - David Feinstein from Harvard (anesthesiologist, and biomedical engineer with M&S background) has indicated a strong interest in engaging us as we move forward. He is an excellent resource for providing input as an outsider to the Committee and as a person who has an interest vested in the medical field and in M&S. there are several others who have the same or similar level interest with substantial amount of experience that we want to continue engaging so that we can leverage their years of experience, and possibly recruit them as future executive or advisor council members.
   - The Chair of the HSS Healthcare Systems Modeling & Simulation Affinity Group (Yue Dong) is interested in exploring how we may be able to leverage off of each other's efforts. The affinity group is a fairly new group with focus on modeling processes for designing patient care workflow rather than using M&S for therapeutics development. They are in a different domain when it comes to applying M&S for healthcare, but we similar interests in promoting M&S into the clinic to enhance patient care.
   - These people are excellent resources we need to keep engaged since they will be important ambassadors of our mission. The best way to keep them engaged is by giving them actionable items such as adding to the glossary or by providing us input on a particular document which we need further insight on above and beyond what the advisory council can give us. Most importantly, we should have them actively involved in the survey distribution process.

2. **Upcoming presentations and conferences**

   a. Panel discussion in HFES 2014
   - Ahmet is on a panel at this conference, and he is waiting on John Rice for further instructions on whether or not a presentation is needed.
   - Ahmet will engage the committee on any further input he needs in preparation for the conference.

   b. Abstract submitted to ASME V&V 2014
   - The abstract was submitted and waiting notice on acceptance status

   c. Abstract retracted from MODSIM World 2014
   - This abstract was withdrawn because we will not have sufficient data to present regarding the survey. However, many of the IMSH attendants that are in support of our work will be

3. **Survey**

- Ahmet has taken over the survey design and implementation strategy in order to ensure that everything is in compliance with government regulation
- As part of Ahmet's responsibilities as an employee of Cleveland Clinic, he needs to submit an IRB exemption request. The reason why he needs to do this is because as an employee of Cleveland Clinic, he cannot make the decision on his own and the IRB needs to determine it. However, Cleveland Clinic has a pretty quick process to do this, so this should not be much of a problem.
- Joy may need to submit an exemption request as well with Stanford.
- We will need to finalize how we are going to reach out to the various communities. But the most appropriate approach is to individually contact the various communities using a template invitation letter. We will also likely contact the community leads to help us engage the communities of interest. Going through the community leads will also help our cause gain some credibility.
- The survey questions are more or less in a final form. The only thing that remains are:
    - **i.** There are some questions that will need to be refined in terms of wording
    - **ii.** We will need to repeat a couple of rules in the survey to measure consistency of the participant's responses. Lu pointed out that his is a good idea because it will allow us to gauge how seriously the survey taker is about the survey. The general idea is that his will allow us to somehow weight each survey taker's contribution in the final interpretations based on how consistent they are in responding to the same question more than once. With that said, we cannot repeat too many questions because it may give a bad impression that we are not very organized, which could result in poor outcomes. Therefore, the recommendation is to only reword/rephrase two questions.
    - **iii.** Ahmet has included a question regarding context of use. Through general consensus within the Committee, the context of use question replaced the "interest in M&S" question.
    - **iv.** We need to decide on how to analyze the data so that something in this regard can be included as part of the IRB exemption. We also need to be cognizant of the fact that there are government people in the data analysis group, and they can only access publically available data. So we need to come up with a scheme that allows for providing the full raw data set to enable a comprehensive analysis of the data set. With this in mind, the non-government members of the data analysis group will need to go through the results of the survey to strip out all potentially identifiable information from the comment box since that is the only place that fully identifiable data may creep in to the survey. In addition, we will provide a generic data analysis plan that is more focused on our end-goal for inclusion in the IRB exemption so that we are not restricted in our end goals. The big thing is to ensure that the data is de-identified.
- Under the premise that our goal is to rank the rules, Jacob suggested using another tool that was designed for ranking of activities by dragging and dropping boxes in a form. This would allow the survey taker to drag and drop the various rules to tell us how they would rank the given set of rules. However, it was pointed out by others that trying to use this method for 30+ rules would be impractical. The drag and drop approach would be most feasible for a few rules only. Consequently, Jacob suggested using the ~10 rules the Committee has already identified based off of the internal survey. However, this was not seen as being a reasonable solution based on the following points.
    - **i.** The reason why we decided to go with surveying the broader community was because the internal survey showed that there are already differing opinions of what is important based on discipline and interests. Therefore, it was deemed important to survey the global community to get feedback on the top ten simple

rules of credible practice. If we, on the other hand, use the ~10 rules identified via the internal survey, we naturally bias the end results to the Committee's line of thinking. This may not necessarily be an accurate representation of the global perspective on the issue of credible practice of M&S in healthcare.

ii. The order of importance of the ten rules can change significantly based on the context of use. Therefore, our goal is to identify the top ten rules among the 33, and not the ranking of the ten rules since rank is based on context of use. In addition, some of the rules may have the same rank or level of importance depending on how the end results come out. So ranking of rules may not be the best approach to take.

iii. The current design was already thought through carefully for user-friendliness. Moreover, other interested parties or groups have the option of reproducing the results in the future using the drag and drop method.

iv. Surveys are generally designed in a manner that is similar to what we already have. If we attempt to change the format to something that is different to what most people are used to seeing, there is a risk that the participants may not be as inclined to participate, or give erroneous results.

Based on these points, it is best to stick with the current design we have. However, Jacob will send a link to the tool he suggested to the rest of the committee for their review. Such a tool may be useful to us for other applications.

- Jacob mentioned that if we are planning to release the data then we need reduce the potentially identifiable questions. His concern was that we don't how other people will analyze the data, and for what purpose. Therefore we need to take further precautions to ensure that the data is not put the participants at risk of being identified. Ahmet acknowledged this, and stressed that this is why we are going through the IRB exemption process. The IRB committee will review the survey content in full, and if the IRB committee deems our content to be identifiable, then we will do further work to address their concerns. If the IRB deems the content we are collecting to be de-identified data and minimal or no risk to the participants, then we are in the clear. This follows well established ethical practice, and it eliminates the risk of the investigators independently determining whether or not the data being collected puts the participant to undue risk.

4. Glossary

- No recent contributions. All committee members are encouraged to contribute two definitions before every meeting. Instructional video on how to add glossary terms and definitions is available
  i. here: https://simtk.org/websvn/wsvn/cpms/doc/multimedia/CPMS_Glossary_wiki_example.wmv
  ii. Or at the CPMS Google/YouTube Account: http://www.youtube.com/watch?v=n2c_9QEOO5c
- These videos have also been made available on the CPMS Schedule and Instructions page here: http://wiki.simtk.org/cpms/Schedule_and_Instructions

5. Other business

- It seems that there is some lack of clarity on what differentiates the Committee from other standards committee or organizations who are working in similar domains. To this end, Lealem and Ahmet outlined the following key factors that make the committee different from other organizations and committees interested in M&S practice guidelines and standards.

i. We have a very wide breadth in terms of what types of models and simulations and disciplines we are tackling. Standards groups like the V&V40 Subcommittee on Standard for Verification and Validation in Computational Methods for Medical Devices, tend to focus on narrow areas of M&S in Healthcare. In the case of V&V40 it is looking at credibility of M&S used for regulatory approval submission of biomedical devices. We are looking at M&S for medical practice and research, as well as education purposes as a tertiary area of application.
ii. Most other groups that have worked on developing guidelines or whitepapers regarding credible practice in M&S, they have done so as independently established focus groups. Unlike these groups, the CPMS was established as a direct consequence of the demand that was expressed within NIH, IMAG and MSM to establish a guideline or mechanism to help transition the substantial investment made in M&S, into clinical research and practice. In other words, we have a strong backing from the primary stakeholders.
iii. Furthermore, in order to ensure that we establish a well-balanced credible practice guideline, we have made substantial effort to recruit subject matter expert from all of the different disciplines and stakeholders. That is, we bolster a highly diverse team that is a more accurate representation of the full scope of the stakeholders in the field.
iv. Other groups tend to tackle one or two aspects or components of credibility (e.g. verification and validation), while we seek to take a more holistic approach to the problem of credibility.
v. Transparency is a key part of how we do business
vi. We are also working to address the language barriers across the different disciplines and stakeholders in order to establish a common language.

The above points need to be synthesized in a more digestible manner to be added to the committee summary presentation. Ahmet recommend using four slides that highlight Diversity, Broad Need, Transparency, and Full Scope. This will be discussed further on the forum. Jacob has offered to start a forum thread in this regard.

- Lealem was asked to post the NASA's credibility assessment method for models and simulations based off of the NASA standard 7009.