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MEMORANDUM September 7, 2011

To: Jim Corrigan and Cheryl Marks, National Cancer Institute (NCI)

From: Brent Miller and Brian Zuckerman, IDA Science and Technology Policy Institute (STPI)

CC: Sallie Keller, Director, STPI

Subject: Mouse Models of Human Cancer Consortium Feasibility Study: Final Report

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In fall 2010, the NCI Division of Cancer Biology, working with the NCI Office of Science Planning and Assessment, selected the IDA Science and Technology Policy Institute (STPI) to conduct a study to assess whether future evaluation of the third funding period of the Mouse Models of Human Cancer Consortium was feasible and warranted. The study was conducted between October 2010 and August 2011.

The attached document is the final report of our feasibility study. The study analyzed the need for evaluation of the Consortium, in a format suitable for translation, if desirable, into an application for National Institutes of Health–wide evaluation set-aside funds.

Attachment: "Mouse Models of Human Cancer Consortium Feasibility Study: Final Report"

IDA SCIENCE AND TECHNOLOGY POLICY INSTITUTE

Mouse Models of Human Cancer Consortium Feasibility Study: Final Report

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September 7, 2011

Executive Summary

The Mouse Models of Human Cancer Consortium (MMHCC or "the Consortium") was launched through Request for Applications (RFA) CA-98-013 in 1998. A second RFA, CA-04-002, was promulgated in 2002, and the third and current RFA, RFA-CA-08-018, was issued in 2008.

Given the change in program organization and goals between the first two iterations and its current form, the National Cancer Institute (NCI) Division of Cancer Biology (DCB) requested in fall 2010 that a feasibility study be conducted to prepare for a future evaluation of the current MMHCC iteration. The DCB, working with the NCI Office of Science Planning and Assessment (OSPA), selected the IDA Science and Technology Policy Institute (STPI) to conduct the feasibility study.

Methodology

The feasibility study was conducted between October 2010 and August 2011, with the bulk of data collection occurring in the first few months of 2011. The STPI study team gathered information through interviews with members of the MMHCC Leadership Team, other members of the Consortium, NCI staff, and external mouse modeling experts; observation of MMHCC Steering Committee meetings in January and June 2011; and review of programmatic documents, such as abstracts of MMHCC awards, text of the current and former RFAs, and other information provided by NCI MMHCC program staff. Team members engaged in biweekly teleconference calls with MMHCC staff, at which interim progress was discussed and evaluation measures were refined.

Evaluation Plan

The overarching finding of the feasibility study is that the Consortium is sufficiently complex that two separate evaluations would be required to properly assess it, each with its own study questions, target population, and time frame. The suggested evaluation plan reflects the need for a two-stage, integrated study of the program. The first stage of the plan would be a process evaluation, while the second stage would be an outcome evaluation. We found that each stage is both *feasible* and *warranted*. The following sections summarize findings regarding the two stages of the study.

Process Evaluation

Data obtained early in the current award period would be helpful in determining whether the change in organizational structure since the last RFA has been effective and in identifying potential improvements or mid-course corrections. We recommend NCI conduct a process evaluation in FY 2012, to identify successes to date and opportunities for mid-course correction regarding Consortium activities and organization. The process evaluation relies upon data that can be collected from an identifiable set of individuals and documents, and pilot activities conducted during this feasibility study suggest that the evaluation questions are well understood and that reliable data can be obtained.

The process evaluation relies primarily on qualitative data collected from the following sources:

- Interviews (with Consortium investigators, NCI staff involved with the Consortium, investigators external to the Consortium who are associated with it, and cancer researchers not directly associated with the Consortium but who are experts in mouse modeling)
- Review of Consortium documents (e.g., U01 cooperative agreements and leadership award applications, documentation associated with pilot projects, records of leadership calls, records of Steering Committee meetings, records from the electronic Models Information, Communication and Education, or eMICE, Internet site and other relevant websites)
- Review of Consortium publications regarding collaboration

The process evaluation will not include a comparison group, as process issues are unique to the MMHCC.

Outcome Evaluation

The MMHCC is a large and complex initiative that intends to have scientific influence through two dimensions—the direct research results of MMHCC awardees and the dissemination of MMHCC mouse models throughout the scientific community. Moreover, it represents a research activity funded by one NCI Division that is intended to influence research carried out across NCI funding programs. Given the scope and complexity of the MMHCC program, a formal evaluation is necessary to identify whether the program has achieved its objectives. STPI recommends that the outcome evaluation portion of the MMHCC evaluation plan be conducted near the end of the current award period, in advance of any subsequent MMHCC RFA, to fully capture the scientific impact of the current Consortium iteration. The outcome evaluation relies upon data that can be collected from an identifiable set of individuals and documents, and the pilot

activities conducted during this feasibility study suggest that the evaluation questions are well understood and that reliable data can be obtained.

The outcome evaluation relies on a mixture of quantitative and qualitative data collected from several sources:

- Interviews (with Consortium investigators, NCI staff involved with the Consortium, investigators external to the Consortium who are associated with it, and cancer researchers not directly associated with the Consortium but who are experts in mouse modeling)
- Review of Consortium documents (e.g., U01 cooperative agreements and leadership award annual and final reports)
- Review of Consortium publications to ascertain the overall scientific impact of the MMHCC
- Survey of users of Consortium mouse models to gather examples of model use that relate to Consortium scientific outcomes
- Expert panel assessment of the importance and significance of the outcome data collected

Including a comparison group in the outcome evaluation, while likely informative, faces a variety of challenges. Among them are:

- Lack of comparability between Consortium U01 awards and R01 research grants that generate mouse models due to the differences in award size and length and expectations imposed by the MMHCC RFA
- Difficulty of identifying downstream users and broader impacts of R01-generated mouse models research
- Additional cost and effort associated with adding a comparison group to the design

A decision on the feasibility and composition of a realistic comparison group will need to be made if the evaluation plan is implemented, but a full comparative effort is not recommended at this time.

Contents

1. Introduction

A. Background

The Mouse Models of Human Cancer Consortium (MMHCC or "the Consortium") is in its third funding period. The Consortium was launched through Request for Applications (RFA) CA-98-013 in 1998. A second RFA, CA-04-002, was promulgated in 2002, and the third and current RFA, RFA-CA-08-018, was issued in 2008.

There has been substantial change between the program in its first two iterations and in its current form. Given the change in program organization and goals, the National Institutes of Health (NIH), National Cancer Institute (NCI) Division of Cancer Biology (DCB) requested in fall 2010 that a feasibility study be conducted to prepare for future evaluation of the current MMHCC iteration. The DCB, working with the NCI Office of Science Planning and Assessment (OSPA), selected the IDA Science and Technology Policy Institute (STPI) to conduct the feasibility study.

B. Methodology

The feasibility study was conducted between October 2010 and August 2011, with the bulk of data collection occurring in the first few months of 2011. The STPI study team gathered information through three sources:

- *Interviews.* The team conducted interviews with members of the MMHCC Leadership Team (eight interviews); non-MMHCC mouse modeling experts, some of whom were involved with the review of Consortium applications (seven interviews); and NCI staff familiar with the MMHCC (three interviews). As clearance could not be obtained from the Office of Management and Budget given the task's short timeframe, all discussions were informal and results could not be tallied or analyzed statistically.
- *Participant observation.* A second source of data was team members' observation at MMHCC Steering Committee meetings. Two team members attended the January 2011 Steering Committee meeting in San Francisco, California. One team member also attended an informal meeting conducted during the June 2011 Steering Committee meeting at which issues related to evaluation and program synergies were discussed.
- *Review of documents.* Team members also reviewed programmatic documents, such as abstracts of MMHCC awards, text of the current and former RFAs, the

NCI MMHCC Progress Report and Evaluation for 2000–2007, and other information provided by NCI MMHCC program staff.

The team engaged in biweekly teleconference calls with MMHCC staff, at which interim progress was discussed and evaluation measures were refined.

2. Program Goals, Activities, and Logic Model

A. Program Goals

The ultimate purpose of the Consortium—to stimulate the integration of mouse models into cancer research—has remained consistent throughout the MMHCC's history. However, the specific role expected to be played by the MMHCC changed substantially between the second and third RFAs.

MMHCC's goals, as described in the original RFA (CA-98-013) focused on the validation of existing mouse models and the development of new models as required. The statement of goals in the original RFA reads as follows:

> …to choose which existing mouse cancer models to characterize fully for their relevance to human cancer, or which new models to derive de novo and to characterize fully when no model exists for a given malignancy, and to define the standards by which to validate the models for their relevance to human cancer biology and for testing therapy, prevention, early detection, or diagnostic imaging strategies.

The task of disseminating the results of the Consortium's efforts, as described in CA-98-013, fell to the NCI.

The second RFA (CA-04-002) maintained the original RFA's model-focused approach, while adding an infrastructure component:

> With the resources in their individual grants, the Consortium members evolve and test novel strategies to recapitulate the natural history and clinical course of human cancers in the laboratory mouse. Collectively, the MMHCC investigates the genetics and biology of the resulting strains for their ability to inform human research. They explore approaches to expand the role of mouse cancer models for translational research, using models to guide selection of, and credential, new targets for therapy, and test molecularly targeted agents, expose premalignant molecular genetic changes for early detection, disclose the genetic determinants of cancer susceptibility, test novel agents for tumor prevention and new concepts for prevention research, and incorporate imaging technologies to detect developing malignant lesions, follow their progression to invasive, metastatic tumors, and monitor response to therapy. In addition to advancing the original goals, the MMHCC is an active partner with the NCI to implement and continue to evolve the infrastructure that informs the research community about mouse cancer models and deploys them to the research community.

While this RFA, as compared with the first one, explicitly mentioned translational research uses of the Consortium-generated mouse models, the RFA specified that the Consortium itself should not be focused on the use of MMHCC models for translational purposes (CA-04-002).

> However, the routine application of mouse cancer models to translational research goals is not the intent of this RFA. Such applications are appropriate for a variety of support mechanisms, including investigator-initiated research projects and program project grants, competing supplements to existing research grants, and applications in response to other NCI special initiatives. As it was for the original RFA for the MMHCC, the intent of the NCI in this RFA is to foster research investigations, technological innovation, and extensive collaboration that cannot be pursued with traditional grant support.

The RFA describing the third and current Consortium iteration (RFA-CA-08-018) described an explicit change in emphasis.

> The principal goal of the NCI-MMHCC is research that focuses on high-risk innovations to transform how mouse models are used in human cancer research. Research projects proposed in response to this FOA should use mouse models to address crucial questions in human cancer genetics, basic discovery, translational, prevention, and clinical cancer research. Projects that propose only the development and validation of new mouse models, which were the original scientific goals of the NCI–MMHCC in 2000, will not be supported.

This RFA added an explicit "science leadership" goal, whose objectives were specified as follows:

> (a) coordinate intra-NCI-MMHCC projects in specific research clusters;
>
> (b) foster collaborations throughout the NCI-MMHCC and with other NCI networks and consortia; and (c) enhance the existing NCI cancer models bioinformatics infrastructure and integrate it with relevant human bioinformatics systems in collaboration with the NCI Center for Biomedical Informatics and Information Technology, NCI CBIIT.

B. Activities Supported

The initial RFA identified that the predominant activities would be research-focused; it assumed six research groups would be funded through U01 awards and two intramural research groups would join the Consortium (CA-98-013). The second iteration assumed up to eighteen U01 awards would be supported and up to four intramural groups would participate; all programmatic activities, including the infrastructure (workshops and symposia, providing information to databases such as electronic Models Information,

Communication and Education, or eMICE, and the Cancer Models database) would be supported through these U01 awards.

In the third RFA, however, the program's structure shifted. NCI still solicited research-focused U01 awards, but also added a second category of science leadership U01 awards. Consortium principal investigators (PIs) could apply for these awards, which would serve as the locus for fostering collaboration within the Consortium, reaching out to other NCI-supported networks and consortia (e.g., the Specialized Program of Research Excellence, or SPORE, program), and coordinating efforts around bioinformatics and database development. NCI funded four such leadership awards under RFA-CA-08-018.

C. Program Logic Model

The STPI study team used information from the comparison of stated program goals and activities, coupled with the results of the interviews with Consortium members and discussions with NCI program staff, to produce a logic model that describes the MMHCC in its current state. Several features of this logic model, depicted in Figure 1, are worth highlighting:

- The set of programmatic activities (the "activities" portion of the logic model) is more explicit and detailed than the language in RFA-CA-08-018. This enhanced understanding of the MMHCC activities—especially the leadership award activities—was an important finding of the feasibility study.
- The set of scientific outcomes (the "advances in cancer research" box in the "outcomes and impacts" portion) is also more explicit and detailed than the RFA language. The RFA specifies that the use of mouse models is the current Consortium's primary goal but does not exclude the refinement or creation of new models to support that goal. It is important to note that *some* interviewees perceived the language of the RFA as prohibitive to the development of new genetically engineered mouse (GEM) models and modeling techniques. Those interviewees stated it is often necessary to refine existing models, or develop new models or techniques, to solve emerging research challenges. As a result, a modeling-related goal was included in the logic model, even though it was not identified as a primary goal in the RFA.
- Consortium members also stated that the broader impacts of the MMHCC had the potential to extend beyond research, and suggested adding a broader impact with respect to economic spillovers such as the formation of new companies that were founded based on use of or results from a Consortium-developed model.

- Finally, the interviews clarified that Consortium outcomes can be reached through two logical paths. The first path flows directly from the research of the Consortium U01 holders when their research leads to a set of advances in cancer research. The second path flows indirectly, as investigators outside of the MMHCC use Consortium-derived models to conduct research that leads to advances. These new users of mouse models may derive from a range of Consortium activities—whether through traditional scientific dissemination such as publications, Consortium outreach activities, collaborations with Consortium investigators, or the enhanced MMHCC bioinformatics infrastructure. Given the complexity of the logical chain by which outcomes were achieved, more detailed theory-of-action logic models were created for the U01 holders and for other investigators. These models are shown in Appendix A.

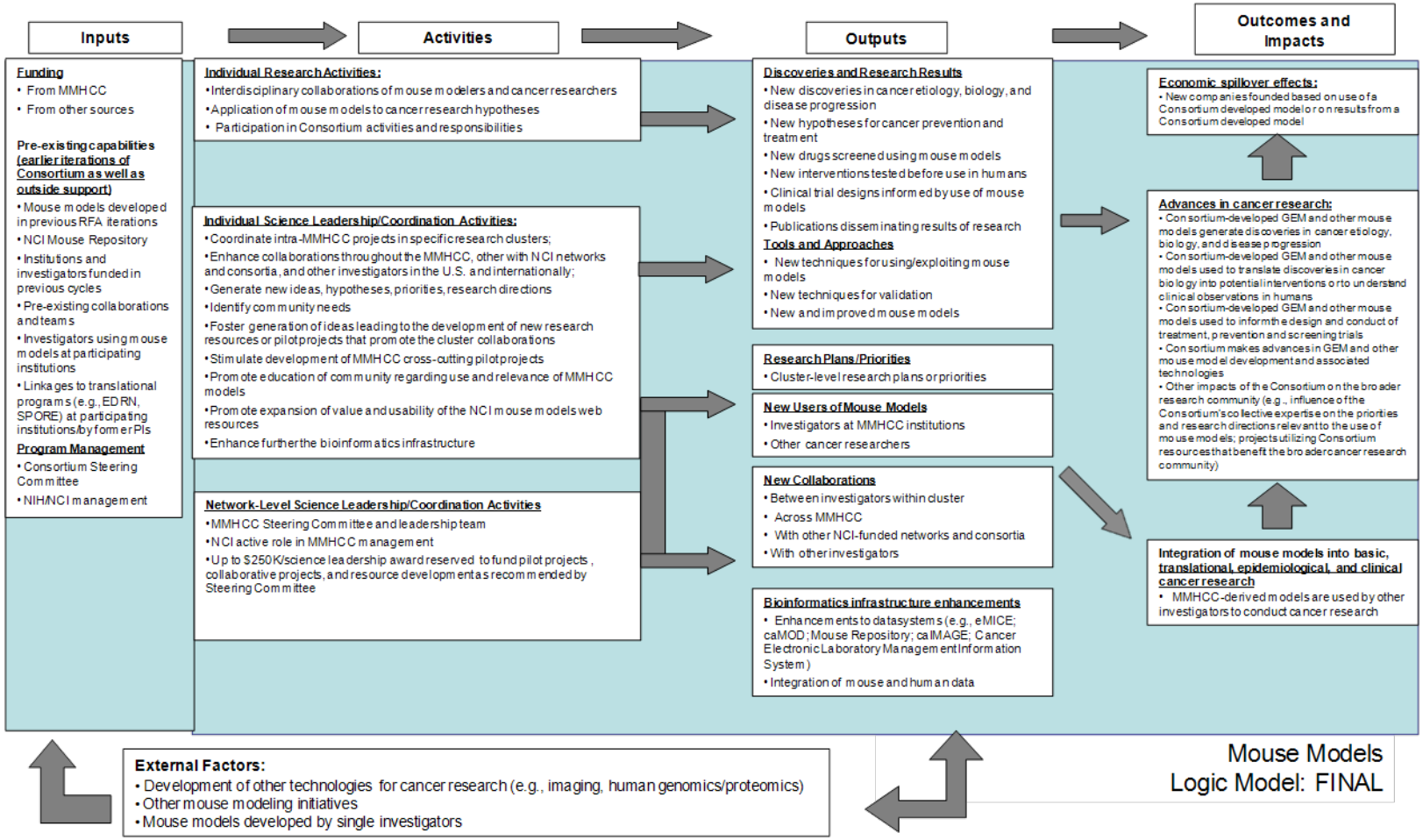

Figure 1. Program Logic Model

3. Evaluation Plan

A. Overall Evaluation Plan

Following the team's discussion with MMHCC program staff of the results of the interviews, it was evident that two separate evaluation studies would be required to properly assess the MMHCC, each with its own set of study questions, target population, and time frame. The evaluation plan laid out in the balance of this document therefore reflects the need for a two-stage, integrated study.

1. Process Evaluation

The first recommended activity is a process evaluation that should be conducted quickly, preferably in fiscal year 2012. The goal of the process evaluation would be to identify successes to date and opportunities for mid-course correction regarding Consortium activities and organization. It would focus heavily on the Consortium's activities and management processes, though some information regarding outputs and outcomes to date would certainly be sought and collected. Moreover, the process evaluation is focused on the MMHCC awardees themselves, rather than on downstream users of MMHCC models or the broader NCI cancer research community.

The process evaluation described here is *warranted*. The MMHCC reorganized as a result of the most recent RFA, so it would be valuable to obtain data early in the current award period to identify whether the change in organizational structure and program intent has been effective and to suggest potential improvements or mid-course corrections. Another rationale for conducting a process evaluation is that the Consortium's structure and activities have evolved since NCI's description of the desired program and its results in the 2008 RFA. A process evaluation would capture the current state of the program in detail and in a fashion that would allow for identification as to whether improvements or mid-course corrections—whether they result from the evaluation itself or from the MMHCC's internal process—have been successful.

The process evaluation, as described below, is *feasible* as well. Given the need for a study to be conducted as soon as possible, any such study should rely on easily collectable data, using a well-understood set of evaluation questions. The described study meets these criteria. It relies upon data that can be collected from an identifiable set of individuals and documents, and the pilot activities conducted during the feasibility study suggest that the evaluation questions are well understood and that reliable data can be obtained.

Finally, the team recommends that the process evaluation, or some aspects thereof, be repeated near the end of the current award period along with the outcome evaluation. The intent would be to identify whether any mid-course process changes have been successful. The exact form of that process evaluation would depend both on the results of the currently recommended process evaluation and on any changes to Consortium structure, management, and other processes that have occurred since the spring of 2011 when the data collection for this feasibility study was completed.

2. Outcome Evaluation

The second facet of the proposed evaluation plan is for an outcome evaluation, to be conducted near the end of the current award period, in advance of any subsequent MMHCC RFA, to fully capture the scientific impact of the current Consortium iteration.

Current NCI policies require evaluation of all programs funded through RFAs as a requirement for renewal and re-competition. But even beyond this NCI-mandated evaluation requirement, an outcome evaluation of the MMHCC would be *warranted*. The MMHCC is a large and complex initiative of the Division of Cancer Biology that intends to have scientific influence through two dimensions—the direct research results of the U01/leadership awardees and the dissemination of MMHCC mouse models throughout the scientific community. Moreover, it represents a research activity funded by one NCI Division that is intended to influence research carried out across NCI funding programs. Given the scope and complexity of the MMHCC program, evaluation is necessary to identify whether the program has achieved its objectives.

Unlike the process evaluation component of the evaluation plan, whose feasibility is evident by the limited nature and scope of the study population, the outcome evaluation will need to be designed carefully for it to be feasible. One question related to feasibility concerns the breadth of inquiry regarding the study population, especially with respect to the degree to which NCI researchers who are not identified users of Consortium models and tools are included. A second question related to feasibility concerns the inclusion of a comparison group in the design.

Given the complexity of the MMHCC and the challenges associated with comprehensively identifying the results and impact of the Consortium, STPI concluded that the most feasible design would be a conservative one. As will be described below, the target population for the outcome evaluation includes the U01 holders themselves and identified users of Consortium models—and excludes the broader universe of NCI cancer researchers who are not users of MMHCC models. A broader study might be of value in assessing the reasons why researchers do not use the Consortium models and the Consortium's effectiveness in communicating the value of the models. However, several challenges make such an approach difficult if not impossible to implement, including:

(1) the difficulty of identifying the universe of NCI researchers who could potentially be using Consortium models in their research but are not doing so and (2) the difficulty of identifying a representative sample of those researchers, given the diversity of the research programs covered and the complex nature of the decision by which investigators choose one animal model over another or choose not to use animal models of any kind.

Similarly, including a comparison group in the outcome evaluation, while likely informative, faces a variety of challenges, including (1) the lack of comparability between Consortium U01 awards and R01s that generate mouse models to answer specific research questions due to the differences in award size and length and expectations imposed by the MMHCC RFA; (2) the difficulty of identifying downstream users and broader impacts of R01-generated mouse models research; and (3) the additional cost and effort associated with adding a comparison group to the design. A decision on the feasibility and composition of a realistic comparison group will need to be made if the evaluation plan is implemented, but at this time a full comparative effort is not recommended.

As a result, the recommended design is likely to miss two things. The first is the reasons why cancer researchers have not used MMHCC models and the second is whether the MMHCC models have had a greater impact on cancer research than models developed through R01s, dollar for dollar. However, the evaluation would provide a reasonable measure of the outcomes and impacts of the Consortium and could be conducted at a reasonable level of effort and cost.

B. Process Evaluation: Study Questions, Target Population, and Data Sources

This section outlines the design of the process evaluation, including the high-level evaluation study questions, the target population, and data sources. A more detailed design is presented in Appendix B, and draft interview guides for the process evaluation are in Appendix C.

1. High-Level Evaluation Questions

Based on our analysis of the data collected during the feasibility study, six fundamental process-related parameters were identified as the subjects of inquiry for the process evaluation:

1. Communication within the Consortium
2. Collaborative nature of the Consortium
3. Communication between the Consortium and the external cancer research community (both academia and industry)

4. Impact of Consortium clusters
5. Investigator participation in the Consortium
6. NCI role in the Consortium

These six fundamental parameters reflect the potential synergies and value added that were part of the design of the Consortium. They translate into the guiding study questions for the process evaluation:

1. To what extent has the Consortium's processes led to enhanced communication among Consortium members that has facilitated the generation of new ideas, hypotheses, enabling resources and research directions, and to what extent has this enhanced communication impacted the MMHCC's future activities, direction, and structure?
2. To what extent has the Consortium's processes led to the development of research collaborations among MMHCC investigators and between MMHCC investigators and other researchers?
3. To what extent has the Consortium's processes led to communication between MMHCC members and the external cancer research community regarding community needs, education on the use and relevance of GEM and other mouse models, and the nature and availability of Consortium resources?
4. What has been the impact to date of the Consortium's research clusters on the conduct of research and on Consortium operations?
5. What has been the effect of participation in the MMHCC on Consortium investigators?
6. What has been the NCI's role in and impact on the Consortium's operations and processes?

2. Target Population

The primary target population for the evaluation would be the Consortium investigators who constitute the MMHCC itself—the 4 leadership awardees and the 21 PIs of the MMHCC awards, plus co-investigators—and NCI staff involved with the MMHCC. Secondary populations would be Consortium collaborators and researchers using MMHCC resources as well as non-MMHCC mouse modeling experts.

3. Data Sources

Due to the complex nature of the Consortium, the process evaluation relies primarily on qualitative information to understand the issues in depth, supported by quantitative data whenever possible.

The process evaluation will collect primary data from individual interviews, as the interactivity of the interview process allows for deeper exploration of topics. Proposed interviewees include:

- Consortium investigators (U01 holders, leadership group/steering committee members)
- NCI staff involved with the Consortium
- Investigators external to the Consortium who are associated with it as collaborators, users of resources, and the like.
- Cancer researchers not directly associated with the Consortium but who are experts in mouse modeling (e.g., MMHCC reviewers and others identified by NCI staff)

Approximately 50 interviews would be required to collect the data for the process evaluation. As there are study populations where more than nine interviews will be required (e.g., Consortium investigators, external collaborators and cancer researchers not involved with the Consortium), clearance from the Office of Management and Budget would be required.

Interviews will be supplemented by review of Consortium documents including:

- U01 and leadership award applications to identify initial plans/proposed approaches
- Documentation associated with pilot projects
- Records of leadership calls
- Records of Steering Committee meetings
- Records from the eMICE Internet site and other Consortium-relevant websites
- Other documents (e.g., lists of cluster participants)

Consortium publications will be collected and analyzed to serve as data sources regarding collaboration.

C. Outcome Evaluation: Study Questions, Target Population, and Data Sources

This section outlines the design of the outcome evaluation, including the high-level evaluation study questions, the target population, and data sources. A more detailed design is presented in Appendix D. As the Consortium is expected to evolve between the time of this feasibility study and the outcome evaluation, it was considered impractical to create detailed interview guides or draft survey instruments, since they would in any event need to be modified substantially at the point the outcome evaluation is conducted.

1. High-Level Evaluation Questions

Based on STPI's analysis of the data collected during the feasibility study, five fundamental study questions were identified, corresponding to the outcome statements shown in the logic model:

1. What has been the use of Consortium-developed GEM and other mouse models to generate discoveries in cancer etiology, biology, and disease progression?
2. What has been the use of Consortium-developed GEM and other mouse models to translate discoveries in cancer biology into potential interventions or to understand clinical observations in humans?
3. What has been the use of Consortium-developed GEM and other mouse models to inform the design and conduct of treatment, prevention, and screening trials?
4. What have been the Consortium's advances in GEM and other mouse model development and associated technologies?
5. What has been the impact of the Consortium on the broader cancer research community?

2. Target Population

As shown in the theory-of-action logic models in Appendix A, there are two paths of consortium influence, each with a corresponding target population. The population for the direct route of influence—the Consortium investigators themselves—is identical to the primary target population for the process evaluation: the leadership awardees and the investigators on the 21 U01 awards of the Consortium plus NCI involved with the MMHCC. The population for the indirect route of influence—those investigators who make use of Consortium mouse models—will evolve with the success of the Consortium's activities. The number and identity of MMHCC model users is known to the Consortium and this universe of users should be involved if possible in the outcome evaluation.

3. Data Sources

Due to the complex nature of the Consortium, the outcome evaluation relies on a mix of quantitative and qualitative sources.

The outcome evaluation will collect primary data from individual interviews, as the interactivity of the interview process allows for deeper exploration of topics. Proposed interviewees include:

- Consortium investigators (U01 holders and leadership group/steering committee members)
- NCI staff involved with the Consortium
- Investigators external to the Consortium who are involved with it as collaborators, users of resources, and the like.
- Cancer researchers not directly associated with the Consortium but who are experts in mouse modeling (e.g., MMHCC reviewers and others identified by NCI staff)

Additional primary data will be collected through a survey of users of Consortium mouse models to gather examples of model use that relate to Consortium scientific outcomes.

Primary data collection will be supplemented by review of Consortium U01 and leadership award progress reports to identify results of research. Consortium publications will serve as a data source regarding the overall scientific impact of the MMHCC.

Finally, the team recommends an expert panel be convened as part of the outcome evaluation to assess the importance and significance of the outcome data collected.

Both the interviews and the survey will require clearance from the Office of Management and Budget.

D. Products of the Evaluation and Use of Results

1. Process Evaluation

The process evaluation is intended to serve as a means for reflecting on the Consortium's organization, management, and structure; for identifying strengths and weaknesses; and for recommending opportunities for internal improvement. Therefore, the results of the process evaluation likely will be of interest predominantly to program staff (potentially including Division leadership) and Consortium members themselves. The final report would thus be intended for an internal audience, and may never be formally disseminated.

2. Outcome Evaluation

The outcome evaluation, on the other hand, likely will be of value to a broader set of stakeholders. In addition to the internal stakeholders served by the process evaluation, the outcome evaluation might be used by a range of groups, including:

- NCI senior leadership (as part of a determination as to whether and how the program might continue)
- Division of Cancer Biology leadership (to identify how to assess other DCB programs)
- NCI science policy and evaluation staff (to assess how best to evaluate complex programs of this type)
- Funders of mouse modeling research at the NCI and elsewhere
- The cancer biology/cancer research community

As a result, the report from the outcome evaluation might be a public document or at least disseminated widely within NCI and NIH. Given the varied stakeholders, summary material in briefing or executive summary form would be useful for disseminating information to NCI senior leadership. A peer-reviewed journal article or presentation at a relevant scientific society meeting may be the best means for disseminating the results to the investigator community.

E. Limitations

There are limitations, both methodological and resource-based, that constrain any potential evaluation design. The following sections describe the primary limitations of the MMHCC process and outcome evaluations and recommended approaches to mitigating those limitations.

1. Process Evaluation

Because the MMHCC is an evolving, learning organization, the primary limitation of the process evaluation is that Consortium processes continue to change over time. One strategy for mitigating this limitation is to conduct the initial evaluation as soon as possible after its design in early 2011. If the process evaluation is delayed too long, then key variables and organizational processes may have changed and results based on the original design may not be meaningful. Moreover, because the Consortium is likely to continue to change subsequent to the initial evaluation, repeating at least some elements of the process evaluation near the end of the award period will also be important. This will allow for conduct of a pre-post analysis with respect to Consortium processes and will allow the evaluator to ascertain the effect of implementing any recommended changes derived from the initial process evaluation.

A second mitigation strategy is that the process evaluation was designed not simply based on the original RFA but also on interviews with Consortium members. This ensures that the design is grounded in current practice, which may not be identical to that described in the RFA. A third mitigation strategy is the reliance on interviews rather than a survey for primary data collection. Using interviews instead of a survey allows for interactivity during the data collection process, which is of value given the continuing evolution of the Consortium.

2. Outcome Evaluation

One primary limitation of the outcome evaluation is that it is a non-experimental design. It considers the cumulative effect of this five years' worth of MMHCC funding on the use of Consortium mouse models rather than incorporating a comparison group or other quasi-experimental design strategy. It is therefore not possible to explore the critical evaluation question, "What might have happened in the absence of the MMHCC?"

While this is a fundamental limitation of the recommended study, it is not clear there are meaningful methods for overcoming it. First, there is no comparable NCI-funded mouse modeling program, and other programs (e.g., Knockout Mouse Project or International Mouse Phenotyping Consortium) are sufficiently different in scope and aims that they cannot be directly compared with the MMHCC. Second, while other NCI-funded research is relevant to mouse models, two features of Consortium research make a comparison with individual R01-type awards difficult:

- MMHCC U01s support large, multidisciplinary teams with most awards between $750,000 and $835,000 per year in direct costs, which is nearly twice the size of the standard NCI R01.[1]
- Two of the five outcome evaluation study questions address the dissemination of Consortium mouse models and other impacts on the cancer research community. These outcomes are expected to stem from the leadership awards, which were created specifically to carry out activities that are not expected to occur under a standard R01.

Finally, adding a comparison group would substantially increase the cost and complexity of the study.

Another limitation is that the non-Consortium investigators involved in the evaluation are limited to known users of Consortium mouse models. This has the potential to underestimate the benefits to the wider cancer research community of results

[1] NIH Data Book, slide "Research Grants R01-Equivalent grants: Average size," http://report nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=158&catId=2. The average R01-equivalent award size in 2010 dollars was $403,691.

generated using Consortium models. However, the study as designed does address two important pathways of influence—outcomes from research conducted by non-MMHCC members using Consortium models as well as research conducted by Consortium investigators.

Appendix A. Theory-of-Action Logic Models

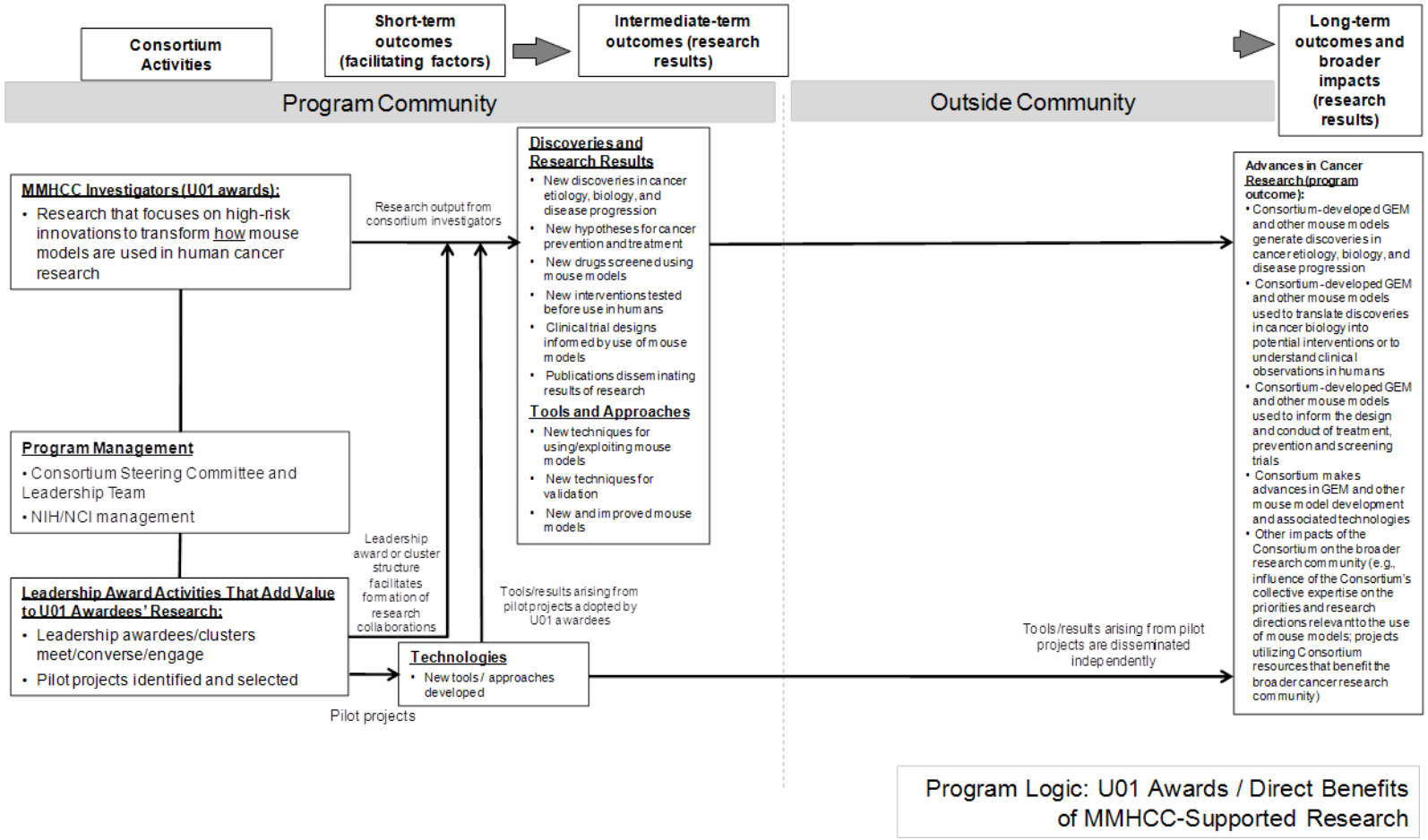

Figure A-1. Theory-of-Action Logic Model: U01 Awardees

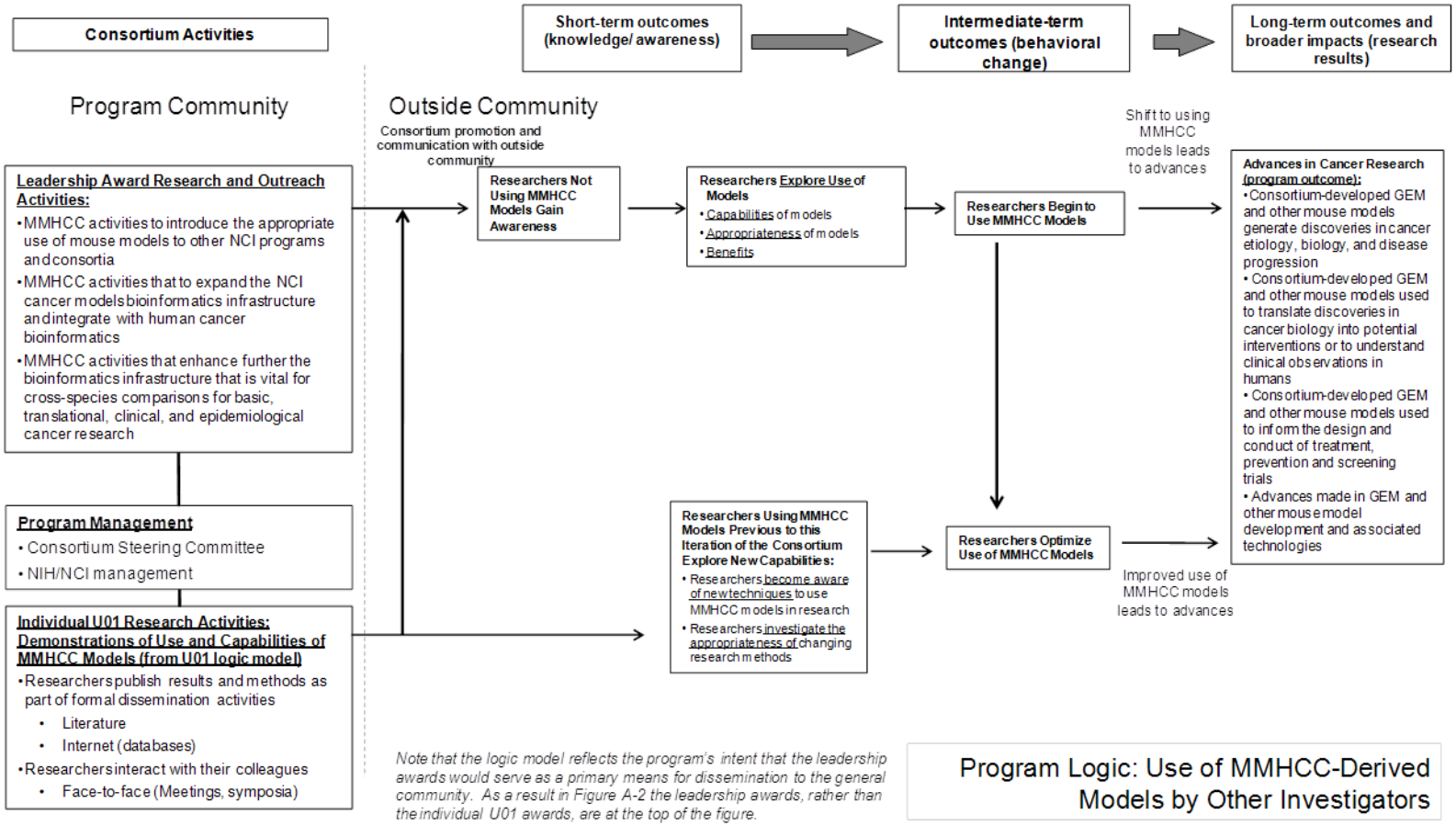

Figure A-2. Theory-of-Action Logic Model: Other Investigators

Appendix B. Process Evaluation Detailed Design

The Process Evaluation will address the six process parameters listed below. For each parameter, a set of measures are proposed for evaluating MMHCC performance with regard to that parameter as well as the data collection approaches to be used for each measure. Collection activities for each parameter, by measure, are then summarized in a table. If this conceptual plan is approved, preparation of detailed interview guides and document analysis methodologies will be part of the project to conduct the evaluation. For most of the process measures, the intent is to probe differences between the current iteration of the Consortium and previous iterations.

Process Parameter 1: Communication within the Consortium

Measure 1a. Impact on generation of new ideas, hypotheses, priorities and research directions

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning the impact of Consortium communication on generating research ideas, hypotheses, priorities and research directions
- **Analysis of leadership applications:** Identify strategies for promoting communication with the goal of generating for new research ideas, hypotheses, priorities, directions
- **Analysis of leadership call and Steering Committee meeting notes:** Identify new research ideas, hypotheses, priorities and directions that were initially discussed or further developed in these venues

Measure 1b. Impact on development of enabling resources, research approaches, etc.

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning the impact of Consortium communication on the development of enabling resources (e.g., model systems, bioinformatics tools) or research approaches
- **Analysis of leadership applications:** Identify strategies for promoting communication with the goal of developing enabling resources (e.g., model systems, bioinformatics tools) or research approaches
- **Analysis of leadership call and Steering Committee meeting notes:** Identify enabling resources (e.g., model systems, bioinformatics tools) or research approaches that were initially discussed or further developed in these venues

Measure 1c. Impact on the activities, direction and structure of the overall Consortium

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning the impact of Consortium communication on the activities, direction and structure of the overall Consortium
- **Analysis of leadership applications:** Identify strategies for promoting communication with the goal of influencing the activities, direction, and structure of the overall Consortium
- **Analysis of leadership call and Steering Committee meeting notes:** Identify major changes to the activities, direction and structure of the overall Consortium that were initially discussed or further developed in these venues

Measure 1d. Value of meetings, workshops, clusters in promoting communication

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning the value of meetings, workshops, clusters in promoting communication

Measure 1e. Consortium leadership contributions to promoting communication

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning the contributions of Consortium leadership in promoting communication
- **Analysis of leadership applications:** Identify plans for promoting communication by Consortium leadership

Measure 1f. Degree to which communication channels and opportunities would have developed among investigators in the absence of the Consortium

- **Interviews with Consortium investigators:** Gather perceptions on the extent to which the communication channels and opportunities described above would have occurred in the absence of the Consortium

Process Parameter 2: Collaborative nature of the Consortium

Measure 2a. Collaborations established among Consortium investigators

- **Interviews with Consortium investigators and NCI staff:** Gather information on new collaborations formed among Consortium members during the award period including the Consortium investigators involved and how the collaboration originated
- **Analysis of leadership applications:** Identify plans for promoting collaborations among Consortium members
- **Analysis of pilot project documentation:** Characterize participants in pilot or other Consortium-level projects to determine:

1) Number and percentage of projects involving collaborators from different MMHCC U01 awards
2) Number and percentage of projects involving collaborators associated with different clusters
3) Number and percentage of projects involving collaborations identified as being "new" from the interviews

- **Bibliometric analysis:** Analyze Consortium publications to identify:
  1) Number and percentage of publications associated with pilot projects versus U01 projects
  2) Number and percentage of publications involving collaborators from different MMHCC U01 awards
  3) Number and percentage of publications involving collaborators associated with different clusters
  4) Number and percentage of publications involving collaborations identified as being "new" from the interviews

Measure 2b. Collaborations established with non-Consortium investigators (domestic and international), other NCI components and industry

- **Interviews with Consortium investigators and NCI staff:** Gather information on new collaborations formed with non-Consortium investigators during the award period including the investigators involved and how the collaboration originated
- **Analysis of leadership applications:** Identify plans for promoting collaborations external to the Consortium
- **Bibliometric analysis:** Analyze Consortium publications to identify:
  1) Number and percentage of publications involving non-Consortium collaborators
  2) Number and percentage of publications involving non-Consortium collaborations identified as being "new" from the interviews

Measure 2c. Non-Consortium investigators' perception of the willingness of Consortium members to collaborate

- **Interviews with identified collaborators**: Gather perceptions concerning the ease or difficulty of establishing collaborations with Consortium members and what barriers, if any, were encountered in establishing and nurturing the collaborations

- **Interviews with investigators not collaborating with the Consortium:**[2] Gather perceptions concerning the willingness of Consortium members to collaborate and what barriers, if any, exist to establishing collaborations

Measure 2d. Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators

- **Interviews with Consortium investigators and NCI staff:** Gather examples of Consortium-developed resources (e.g., models, data, experimental approaches) provided to non-Consortium investigators including which resources and to whom
- **Interviews with investigators provided resources:** Gather perceptions concerning the ease or difficulty of gaining access to resources and what barriers, if any, were encountered in receiving access
- **Interviews with investigators not using Consortium resources:**[1] Gather perceptions concerning the ease or difficulty of gaining access to resources
- **Analysis of leadership applications:** Identify approaches for making resources available outside the consortium

Process Parameter 3: Communication between the Consortium and the external cancer research community (both academia and industry)

Measure 3a. Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)

- **Interviews with Consortium investigators and NCI staff:** Gather information on procedures used by the Consortium or its members to identify community needs and how the Consortium responded to identified needs
- **Interviews with identified collaborators and investigators provided Consortium resources**: Gather information on the most important community needs and perceptions as to whether the Consortium reached out to the investigator community to identify those needs and responded to identified needs

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[2] Gathering perceptions from members of the cancer research community that are not currently involved with the Consortium on this measure would be highly desirable. However, given the size and diversity of that community, selecting a representative sample will be challenging. One approach would be to draw the sample from investigators that have requested mice from the repository but did not collaborate with the Consortium in any other way. This might be a biased set in that they are clearly interested in the use of mouse models. However, to draw from a broader group would risk interviewing investigators whose research would never reasonably be expected to benefit from mouse models. Deciding whether interviewing such an external group of investigators is essential to the evaluation and determining how best to choose a relevant group will need to be made by NCI and the evaluation team when the evaluation is conducted. Making such a decision is beyond the scope of the current project.

- **Interviews with investigators not involved with the Consortium:**[1] Gather information on the most important community needs and perceptions as to whether the Consortium reached out to the investigator community to identify those needs and responded to identified needs
- **Analysis of leadership applications:** Identify plans for identifying and responding to community needs

Measure 3b. Education on the use and relevance of GEM and other mouse models (e.g., publications, conferences, web resources)

- **Interviews with Consortium investigators and NCI staff:** Gather information on activities undertaken by the Consortium or its members to educate the investigator community
- **Interviews with identified collaborators and investigators provided Consortium resources**: Gather information on use of or participation in any Consortium-sponsored educational activities and whether these activities were valuable
- **Interviews with investigators not involved with the Consortium:**[1] Gather information on use of or participation in any Consortium-sponsored educational activities and whether these activities were valuable
- **Analysis of leadership applications:** Identify plans for education on the use and relevance of GEM and other mouse models

Measure 3c. Value and usability of web resources developed through the Consortium (e.g., eMICE, caMOD, Mouse Repository, caIMAGE, Cancer Electronic Laboratory Management Information System)[3] and extent of use by non-Consortium investigators

- **Interviews with Consortium investigators and NCI staff:** Gather information on activities undertaken by the Consortium or its members to develop web-based resources for disseminating the use of GEM and other mouse models
- **Interviews with identified collaborators and investigators provided Consortium resources**: Gather information on use of the web-based resources and, if used, whether the resources were valuable and easy to navigate and use
- **Interviews with investigators not involved with the Consortium:**[1] Gather information on use of the web-based resources and, if used, whether the resources were valuable and easy to navigate and use
- **Web resources analysis:** Determine the number of "hits" and information downloads for the web-based resources; analyze web traffic statistics (e.g., location of originating computers, registration information for users) if available[4]

[3] The Consortium's contribution to each of these resources will need to be defined.

[4] Analysis stratified by Consortium and non-Consortium information.

- **Analysis of leadership applications:** Identify plans for enhancing the utility and value of web-based resources

Measure 3d. Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning whether and by what means new advances and/or biological research approaches have been or are being introduced into the Consortium's research activities
- **Interviews with MMHCC reviewers/expert panel members:**[5] Gather information concerning new advances and/or biological research approaches that should be brought into the Consortium's research activities and whether they have been incorporated appropriately

Process Parameter 4: Impact of Consortium clusters[6]

Measure 4a. Rationale for cluster designations

- **Analysis of leadership applications:** Identify rationale for proposing particular clusters
- **Interviews with Consortium investigators and NCI staff:** Gather perceptions on the process for identifying the need for a cluster and how selected clusters were developed
- **Analysis of leadership call and Steering Committee meeting notes:** Identify any discussions of the rationale for the current cluster designations or for the formation of new clusters

Measure 4b. Articulation of cluster goals and success in achieving them

- **Analysis of leadership applications:** Identify particular cluster goals and success measures.
- **Interviews with Consortium investigators and NCI staff:** Gather perceptions on the process by which cluster goals and measures of success are developed and refined over time and whether the goals and success measures are clear

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[5] MMHCC reviewers and the expert panel convened to validate the importance and significance of the examples and perceptions collected as part of the Outcomes Evaluation are recommended as appropriate non-Consortium investigators to interview for this measure.

[6] Will require access to information on cluster participants and leadership and any change over time.

- **Interviews with MMHCC reviewers/expert panel members:**[2] Gather perceptions as to whether the cluster goals are clear and measurable and if they are likely to be achieved during the award period

Measure 4c. Strength of member/cluster affiliations

- **Interviews with Consortium investigators and NCI staff:** Gather perceptions on the meaning of cluster "affiliation", how strongly Consortium members affiliate with one or more clusters and why and how members might change cluster affiliation

Measure 4d. Impact on format/structure/content of meetings

- **Analysis of Steering Committee meeting notes:** Identify extent to which meetings (or parts of meetings) are cluster-specific
- **Interviews with Consortium investigators and NCI staff:** Gather information on the extent, content and value of cluster specific meetings, whether held during Steering Committee meetings or in separate venues

Measure 4e. Impact on collaboration, communication and outreach

- **Interviews with Consortium investigators and NCI staff:** Gather perceptions concerning the effect of the cluster structure on collaboration among Consortium members as well as external communication and outreach efforts
- **Analysis of leadership applications:** Identify the extent to which planned collaboration, communication and outreach activities are cluster-specific as opposed to Consortium-wide
- **Analysis of leadership call and Steering Committee meeting notes:** Identify discussions of collaboration, communication and outreach activities that are cluster-specific

Measure 4f. Cluster dependent output—publications, pilot projects etc.

- **Analysis of pilot project documentation:** Characterize pilot projects as cluster-specific or Consortium-wide
- **Bibliometric analysis:** Characterize Consortium publications as cluster-specific, U01-specific or Consortium-wide

Process Parameter 5: Investigator participation in the Consortium

Measure 5a. Impact on investigators of Consortium activities and responsibilities that are above and beyond those for typical grants

- **Analysis of U01 applications:** Identify proposed activities that are above and beyond those for typical grants and the support requested for those activities
- **Interviews with Consortium investigators:** Gather examples and perceptions concerning Consortium activities and responsibilities above and beyond those of typical grants and the time required

Measure 5b. Value of the additional activities and responsibilities

- **Interviews with Consortium investigators:** Gather perceptions concerning the value of the additional activities and responsibilities to the Consortium and to the investigator's research

Measure 5c. Degree to which additional activities and responsibilities are shared equally by Consortium investigators

- **Interviews with Consortium investigators and NCI staff:** Gather perceptions concerning whether the additional activities and responsibilities are shared equally among Consortium investigators

Measure 5d. Additional responsibilities of Consortium leadership and if those are adequately funded

- **Analysis of leadership applications:** Identify proposed leadership award activities and requested funding
- **Interviews with Consortium leadership:** Gather perceptions concerning the additional responsibilities of Consortium leadership, the time required, and if the leadership award is sufficient to support these activities
- **Interviews with NCI staff:** Determine original assumptions concerning leadership responsibilities (character and required effort), whether those assumptions have borne out in practice, and suggested changes

Process Parameter 6: NCI role in the Consortium

Measure 6a. NCI activities that facilitate Consortium activities (e.g., resolving intellectual property issues with industry, flexibility in use of award funds, funding for outreach)

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning activities undertaken by NCI that facilitate Consortium activities and their relative importance

Measure 6b. NCI activities that impede Consortium activities (e.g., inadequate funding for the high cost of animal use)

- **Interviews with Consortium investigators and NCI staff:** Gather examples and perceptions concerning negative effects of NCI activities on Consortium activities and their relative importance

Measure 6c. Impact of new 2008 RFA Guidelines on Consortium activities, goals, productivity

- **Interviews with Consortium investigators[7] and NCI staff:** Gather examples and perceptions concerning differences between the Consortium's activities, goals, and productivity under the current RFA and previous iterations and which changes have been most influential

[7] Limited to investigators involved with the Consortium in at least one prior award period.

Summary of Process Evaluation

COMMUNICATION WITHIN THE CONSORTIUM				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
Impact on generation of new ideas, hypotheses, priorities and research directions	Yes	Yes	No	Leadership applications, Leadership call/Steering Committee Meeting notes
Impact on development of enabling resources, research approaches, etc.	Yes	Yes	No	Leadership applications, Leadership call/Steering Committee Meeting notes
Impact on the activities, direction and structure of the overall Consortium	Yes	Yes	No	Leadership applications, Leadership call/Steering Committee Meeting notes
Value of meetings, workshops, clusters in promoting communication	Yes	Yes	No	None
Consortium leadership contributions to promoting communication	Yes	Yes	No	Leadership applications
Degree to which communication channels and opportunities would have developed among investigators in the absence of the Consortium	Yes	No	No	None

COLLABORATIVE NATURE OF THE CONSORTIUM				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
Collaborations established among Consortium investigators	Yes	Yes	No	Leadership applications, Pilot project documents, Publications
Collaborations established with non-Consortium investigators (domestic and international), other NCI components and industry	Yes	Yes	No	Leadership applications, Publications
Non-Consortium investigators' perception of the willingness of Consortium members to collaborate	No	No	Yes	None
Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators	Yes	Yes	Yes	Leadership applications

COMMUNICATION BETWEEN THE CONSORTIUM AND THE EXTERNAL CANCER RESEARCH COMMUNITY (BOTH ACADEMIA AND INDUSTRY)				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)	Yes	Yes	Yes	Leadership applications
Education on the use and relevance of GEM and other mouse models (e.g., publications, conferences, web resources)	Yes	Yes	Yes	Leadership applications
Value and usability of web resources developed through the Consortium (e.g., eMICE, caMOD, Mouse Repository, caIMAGE, Cancer Electronic Laboratory Management Information System)[a] and extent of use by non-Consortium investigators	Yes	Yes	Yes	Web resources, Leadership applications
Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research	Yes	Yes	MMHCC reviewers, Expert panel members	None

[a] The Consortium's contribution to each of these resources will need to be defined.

IMPACT OF CONSORTIUM CLUSTERS				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
Rationale for cluster designations	Yes	Yes	No	Leadership applications, Leadership call/Steering Committee meeting notes
Articulation of cluster goals and success in achieving them	Yes	Yes	MMHCC reviewers, Expert panel members	Leadership applications
Strength of member/cluster affiliations	Yes	Yes	No	None
Impact on format/structure/content of meetings	Yes	Yes	No	Steering Committee meeting notes
Impact on collaboration, communication and outreach	Yes	Yes	No	Leadership applications, Leadership call/Steering Committee Meeting notes
Cluster dependent output—publications, pilot projects etc**.**	No	No	No	Pilot project documents, Publications

INVESTIGATOR PARTICIPATION IN THE CONSORTIUM				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
Impact on investigators of Consortium activities and responsibilities that are above and beyond those for typical grants	Yes	No	No	U10 applications
Value of the additional activities and responsibilities	Yes	No	No	None
Degree to which additional activities and responsibilities are shared equally by Consortium investigators	Yes	Yes	No	None
Additional responsibilities of Consortium leadership and if those are adequately funded	Yes	Yes	No	Leadership applications

NCI ROLE IN THE CONSORTIUM				
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**
NCI activities that facilitate of Consortium activities (e.g., resolving intellectual property issues with industry, flexibility in use of award funds, funding for outreach)	Yes	Yes	No	None
NCI activities that impede Consortium activities (e.g., inadequate funding for the high cost of animal use)	Yes	Yes	No	None
Impact of new 2008 RFA Guidelines on Consortium activities, goals, productivity	Yes	Yes	No	None

Appendix C. Draft Process Evaluation Interview Guides

Consortium Leadership

Process Parameter 1: Communication within the Consortium

Measure 1a. Impact on generation of new ideas, hypotheses, priorities and research directions

1. What are your perceptions of the quality of communication within the Consortium?
2. Has communication within the Consortium fostered the generation of new research ideas, hypotheses and research directions?
    a. No, why not?
3. Please describe examples where Consortium communication led to the generation of:
    a. Research ideas
    b. New hypotheses
    c. New research directions
4. What activities have been most influential in promoting communication for generating new research ideas, hypotheses, priorities and directions?
5. Beyond the current activities of the Consortium, what strategies or activities can you identify that could promote communication?

Measure 1b. Impact on development of enabling resources, research approaches, etc.

1. Has communication within the Consortium fostered the generation of enabling resources (e.g., model systems, bioinformatics tools) or research approaches?
    a. No, why not?
2. With respect to the Consortium, please describe examples where Consortium communication led to the development of:
    a. Enabling resources
    b. Research approaches
3. What activities have been most influential in promoting communication for generating enabling resources and new research approaches?

Measure 1c. Impact on activities, direction and structure of the overall Consortium

1. Has communication within the Consortium influenced the activities, direction or structure of the Consortium?
    a. No, why not?
2. Please describe examples where Consortium communication has influenced the activities, direction or structure of the Consortium?
3. What is your impression of the quality of Consortium communication directed toward the activities, direction or structure of the overall Consortium?

Measure 1d. Value of meetings, workshops, clusters in promoting communication

1. What are your perceptions of the quality of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
2. What are your perceptions of the value of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
3. Are there specific examples that support the high quality or value of the Steering Committee meetings?
4. Are there specific instances where the Steering Committee, as a mechanism of communication, should have been used but was not?
    a. Please explain.
5. What are your perceptions of the quality of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
6. What are your perceptions of the value of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
7. Are there specific examples that support the high quality or value of the workshops?
8. Are there specific instances where workshops, as a mechanism of communication, should have been used but were not?
    a. Please explain.

9. What are your perceptions of the quality of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
10. What are your perceptions of the value of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
11. Are there specific examples that support the high quality or value of the clusters as a communication mechanism?

Measure 1e. Consortium leadership contributions to promoting communication

1. As a Consortium leader, what is your role with respect to promoting communication?
    a. Please provide examples of activities or actions that led to productive communication.
2. As a consortium leader, what barriers have you encountered in promoting communication?

Measure 1f. Degree to which communication channels and opportunities would have developed among investigators in the absence of the Consortium

1. Do you believe the Consortium provides unique communication channels or opportunities that are NOT possible without the Consortium?
    a. No, why not?
    b. Yes, please provide examples of communication channels or opportunities that would NOT have occurred without the Consortium.
2. Are there examples where the collective knowledge, resources, or influence of the Consortium have proved beneficial (e.g., in negotiations with industry or funders)?

Process Parameter 2: Collaborative nature of the Consortium

Measure 2a. Collaborations established among Consortium investigators

1. Within the Consortium, who have you collaborated with and what was the nature of those collaborations?
    a. Would the stated collaborations exist in the absence of the Consortium?
2. What Consortium created mechanisms to foster intra-Consortium collaborations have your used? (Workshops, Steering Committee Meetings, etc.)

    a. What other mechanisms to establish intra-consortium collaborations would you suggest?
3. Overall, what are your perceptions of the collaborative nature of the Consortium?
    a. How would you describe the structure of intra-consortium collaborations?
    b. How would you describe the character of intra-consortium collaborations?
4. What value do you place on intra-Consortium collaboration?
    a. Has your view of this changed from previous iterations of the Consortium?
5. Is the motivation for collaborating within the consortium significantly different from previous iterations of the Consortium?
    a. Why?
6. Is the success of intra-Consortium collaborations significantly different from previous iterations of the Consortium?
    a. Why?

Measure 2b. Collaborations established with non-Consortium investigators (domestic and international), other NCI components and industry

1. With respect to your Consortium research, whom have you collaborated with and what was the nature of those collaborations?
    a. Domestic (academic, industry, consortia)
    b. International (academic, industry, consortia)
2. With respect to your Consortium research, which NCI components have you collaborated with and what was the nature of those collaborations?
3. What was the mechanism (workshops, meetings, personal communication) by which these collaborations were established?
    a. What other mechanisms to establish external collaborations would you suggest for use by the Consortium?
4. What are your perceptions about the collaborative nature of the Consortium with the external community?
    a. Has there been a supportive atmosphere for establishing external collaborations?
        i. From within the Consortium?
        ii. From NCI?
    b. What are the barriers for establishing external collaborations?
        i. Are they different for domestic vs. international?
5. What do you think are the perceptions of the non-consortium investigator with respect to collaborating with Consortium members?
6. What value do you place on external collaborations?
    a. Has this changed over the life of the Consortium?

Measure 2d. Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators

1. Provide examples of Consortium-developed resources (models, data, and experimental approaches) that you are aware of.
    a. Provide examples that you have used in your own research?
    b. Was access to these resources easy or difficult?
        i. What mechanism did you use to gain access?
        ii. What were the barriers?
2. Provide examples of resources that you believe the Consortium is in a position to provide for the external community, but has not?
3. How might the Consortium better serve the external community with respect to knowledge, research guidance, infrastructure, etc.?

Process Parameter 3: Communication between the Consortium and the external cancer research community (both academia and industry)

Measure 3a. Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)

1. What mechanisms have the Consortium used to identify community needs?
2. What mechanisms would you suggest that could increase the communication between the external community and the Consortium?
3. What were the most important community needs identified by the Consortium?
4. Please provide examples in which the Consortium identified a community need and acted on that need.
    a. What value do you place on the example(s)?
5. What are your perceptions of the Consortiums outreach activities to identify and support community needs?
6. Are there examples where the Consortium could have been used to the advantage of the external community?
7. Is the motivation for communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?
8. Is the success of communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?

Measure 3b. Education on the use and relevance of GEMM and other mouse models (e.g., publications, conferences, web resources)

1. What activities/mechanisms has the Consortium used to educate the external community about the use and relevance of GEMM and other mouse models?
    a. Publications

b. Conferences/workshops (Quantity/Quality)
c. Web resources (Quantity/Quality)

2. Beyond the typical dissemination of results (e.g., publication, conferences), what are your perceptions of the Consortium's efforts to educate the external community on the use/relevance of GEMM and other mouse models?
3. Please suggest alternative strategies/mechanisms to educate the external community on the use and relevance of GEMM and other mouse Models.
4. Are the activities/mechanisms used for education of the external community significantly different from previous iterations of the Consortium?

Measure 3c. Value and usability of web resources developed through the Consortium (e.g., eMICE, caMOD, Mouse Repository, caIMAGE, Cancer Electronic Laboratory Management Information System)[8] and extent of use by non-Consortium investigators

1. Have the Consortium developed web resource(s) been valuable to your research?
   a. Why/why not, please explain
   b. What is your impression of the usability of the web resources?
2. With respect to Consortium generated information, please suggest web resources that would be valuable to your research.

Measure 3d. Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research

1. Please identify examples where outside advances (e.g., technologies, methods etc.) or research approaches (e.g., systems biology) have been identified by the Consortium and integrated into the Consortium's repertoire of approaches.
2. Please describe the mechanism by which these advances or research approaches were identified and taken up by the Consortium.

Process Parameter 4: Impact of Consortium clusters[9]

Measure 4a. Rationale for cluster designations

1. What is the rational for the use of clusters as an organizing principle?
2. What was the mechanism/basis for selecting the extant clusters?
3. What process/concept was established for the development of the clusters?

Measure 4b. Articulation of cluster goals and success in achieving them

1. Within your specific cluster, what are the goals and success measures?

[8] The Consortium's contribution to each of these resources will need to be defined.

[9] Will require access to information on cluster participants and leadership and any change over time.

2. What was the process for developing the goals and success measures?
3. What is your position on the clarity, reality, and measurability of the goals and success measures?
4. What is your impression of how well the goals and success measures were communicated within the cluster?

Measure 4c. Strength of member/cluster affiliations

1. What is your impression of affiliation (strength of association) within your cluster?
2. What is your impression of how strongly Consortium members affiliate with one or more clusters?
3. Is there a mechanism for changing clusters?
    a. If so, what is the process?

Measure 4d. Impact on format/structure/content of meetings

1. How have clusters impacted the format/structure/content of Steering Committee meetings or workshops?
    a. Are portions of the events cluster-specific?
2. Does your cluster(s) meet (physically or virtually) on a regular basis?
    a. How often do you meet?
    b. What is the structure of the meetings?
    c. What is the nature of the meetings (strategy/planning, result reporting, etc.)?
3. What is your impression of the value of those meetings?
4. What is the product of the meetings?

Measure 4e. Impact on collaboration, communication and outreach

1. Does being part of a cluster improve your level of collaboration and communication with others in the cluster?
    a. Would the cluster relationships have existed in the absence of the Consortium?
2. Does your cluster promote collaboration, communication, and/or outreach activities?
    a. Intra-Consortium and/or externally?
3. What effect do the cluster activities have on your collaborations within the Consortium?
4. What effect do the cluster activities have on your collaborations outside the Consortium?

5. What effect do the cluster activities have on your ability to communicate with other Consortium members?
6. What effect do the cluster activities have on your ability to communicate with the external community?
7. Compared to previous iterations of the Consortium, what is the relative effect of the clusters on collaboration and communication?

Measure 4f. Cluster dependent output—publications, pilot projects etc.

1. Please provide examples of cluster dependent outputs (e.g., pilot projects or workshops).

Process Parameter 5: Investigator participation in the Consortium

Measure 5a. Impact on investigators of Consortium activities and responsibilities that are above and beyond those for typical grants

1. Please provide examples of Consortium activities/responsibilities that you perceive are "above and beyond" what is typically required for traditional NIH research support (i.e., RO1).
2. What is your opinion of the support (financial and business) given for the activities that are "above and beyond"?
    a. Please provide support in the form of examples.

Measure 5b. Value of the additional activities and responsibilities

1. What is your perception of the value of the activities and responsibilities you've deemed "above and beyond"?
    a. Please provide support in the form of examples.
2. Has the value of these activities and responsibilities changed over the lifetime of the Consortium?
    a. Why?

Measure 5c. Degree to which additional activities and responsibilities are shared equally by Consortium investigators

1. What are your perceptions of the distribution of labor relative to the additional activities and responsibilities required by Consortium membership?
2. By what process are activities and responsibilities divided among members of the Consortium?

Measure 5d. Additional responsibilities of Consortium leadership and if those are adequately funded

1. As a Consortium leader, what additional activities and responsibilities are required of you?
    a. What are the general time requirements to fulfill these obligations?
2. What is your impression of the support (financial and business) given through the leadership awards?

Process Parameter 6: NCI role in the Consortium

Measure 6a. NCI activities that facilitate Consortium activities (e.g., Resolving intellectual property issues with industry, flexibility in use of award funds, funding for outreach)

1. Provide examples in which the NCI has actively helped the Consortium overcome an obstacle or achieve a goal (e.g., limited access to material, intellectual property issues, issues requiring flexibility of funding, or increasing outreach).
2. What is your impression of the support (financial and business) given by the NCI for these examples?
    a. With what ease was the support obtained?
    b. What suggestions do you have for improvement?
3. What is your perception of the relative importance/value of these activities?
    a. To the Consortium?
    b. To the NCI?
4. As a Consortium Leader, what has been your role in working with NCI to facilitate Consortium activities?

Measure 6b. NCI activities that impede Consortium activities (e.g., inadequate funding for the high cost of animal use)

1. Please provide examples where NCI actions or decisions had a negative effect on Consortium activities or goals.
    a. With respect to the examples, what is your impression of the impact of those actions or decisions on the Consortium?

Measure 6c. Impact of new 2008 RFA Guidelines on Consortium activities, goals, productivity

1. Have the Consortium's activities, its goals or productivity been in line with most recent (2008) RFA Guidelines?
    a. Provide examples or reasoning to support why or why not.
2. Relative to previous iterations of the Consortium, is the current Consortium as productive?
    a. Provide examples or reasoning to support why or why not.

3. What changes to the most recent RFA have been most influential, both positively and negatively?
    a. Provide examples or reasoning to support your choice

Other Consortium Investigators

Process Parameter 1: Communication within the Consortium

Measure 1a. Impact on generation of new ideas, hypotheses, priorities and research directions

1. What are your perceptions of the quality of communication within the Consortium?
2. Has communication within the Consortium fostered the generation of new research ideas, hypotheses and research directions?
    a. No, why not?
3. As a Consortium member, please describe examples where Consortium communication led to the generation of:
    a. Research ideas
    b. New hypotheses
    c. New research directions
4. What activities have been most influential in promoting communication for generating new research ideas, hypotheses, priorities and directions?
5. Beyond the current activities of the Consortium, what strategies or activities can you identify that could promote communication?

Measure 1b. Impact on development of enabling resources, research approaches, etc.

1. Has communication within the Consortium fostered the generation of enabling resources (e.g., model systems, bioinformatics tools) or research approaches?
    a. No, why not?
2. With respect to the Consortium, please describe examples where Consortium communication led to the development of:
    a. Enabling resources
    b. Research approaches
3. What activities have been most influential in promoting communication for generating enabling resources and new research approaches?

Measure 1c. Impact on activities, direction and structure of the overall Consortium

1. Has communication within the Consortium influenced the activities, direction or structure of the Consortium?
    a. No, why not?

2. Please describe examples where Consortium communication has influenced the activities, direction or structure of the Consortium?
3. What is your impression of the quality of Consortium communication directed toward the activities, direction or structure of the overall Consortium?

Measure 1d. Value of meetings, workshops, clusters in promoting communication

1. What are your perceptions of the quality of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
2. What are your perceptions of the value of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
3. Are there specific examples that support the high quality or value of the Steering Committee meetings?
4. Are there specific instances where the Steering Committee, as a mechanism of communication, should have been used but was not?
    a. Please explain.
5. What are your perceptions of the quality of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
6. What are your perceptions of the value of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
7. Are there specific examples that support the high quality or value of the workshops?
8. Are there specific instances where workshops, as a mechanism of communication, should have been used but were not?
    a. Please explain.
9. What are your perceptions of the quality of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities

    c. Outreach to external investigators
10. What are your perceptions of the value of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
11. Are there specific examples that support the high quality or value of the clusters as a communication mechanism?

Measure 1e. Consortium leadership contributions to promoting communication

1. What is your perception of the Consortium leadership with respect to promoting communication?
2. Please provide examples of when the Consortium's leaders' activities led to productive communication.

Measure 1f. Degree to which communication channels and opportunities would have developed among investigators in the absence of the Consortium

1. Do you believe the Consortium provides unique communication channels or opportunities that are NOT possible without the Consortium?
    a. No, why not?
    b. Yes, please provide examples of communication channels or opportunities that would NOT have occurred without the Consortium.
2. Are there examples where the collective knowledge, resources, or influence of the Consortium have proved beneficial (e.g., in negotiations with industry or funders)?

Process Parameter 2: Collaborative nature of the Consortium

Measure 2a. Collaborations established among Consortium investigators

1. Within the Consortium, who have you collaborated with and what was the nature of those collaborations?
    a. Would the stated collaborations exist in the absence of the Consortium?
2. What Consortium created mechanisms to foster intra-Consortium collaborations have your used? (Workshops, Steering Committee Meetings, etc.)
    a. What other mechanisms to establish intra-consortium collaborations would you suggest?
3. Overall, what are your perceptions of the collaborative nature of the Consortium?
    a. How would you describe the structure of intra-consortium collaborations?
    b. How would you describe the character of intra-consortium collaborations?
4. What value do you place on intra-Consortium collaboration?

    a. Has your view of this changed from previous iterations of the Consortium?
5. Is the motivation for collaborating within the consortium significantly different from previous iterations of the Consortium?
    a. Why?
6. Is the success of intra-Consortium collaborations significantly different from previous iterations of the Consortium?
    a. Why?

Measure 2b. Collaborations established with non-Consortium investigators (domestic and international), other NCI components and industry

1. With respect to your Consortium research, whom have you collaborated with and what was the nature of those collaborations?
    a. Domestic (academic, industry, consortia)
    b. International (academic, industry, consortia)
2. With respect to your Consortium research, which NCI components have you collaborated with and what was the nature of those collaborations?
3. What was the mechanism (workshops, meetings, personal communication) by which these collaborations were established?
    a. What other mechanisms to establish external collaborations would you suggest for use by the Consortium?
4. What are your perceptions about the collaborative nature of the Consortium with the external community?
    a. Has there been a supportive atmosphere for establishing external collaborations?
        i. From within the Consortium?
        ii. From NCI?
    b. What are the barriers for establishing external collaborations?
        i. Are they different for domestic vs. international?
5. What do you think are the perceptions of the non-consortium investigator with respect to collaborating with Consortium members?
6. What value do you place on external collaborations?
    a. Has this changed over the life of the Consortium?

Measure 2d. Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators

1. Provide examples of Consortium-developed resources (models, data, and experimental approaches) that you are aware of.
    a. Provide examples that you have used in your own research?
    b. Was access to these resources easy or difficult?

        i. What mechanism did you use to gain access?
        ii. What were the barriers?
2. Provide examples of resources that you believe the Consortium is in a position to provide for the external community, but has not?
3. How might the Consortium better serve the external community with respect to knowledge, research guidance, infrastructure, etc.?

Process Parameter 3: Communication between the Consortium and the external cancer research community (both academia and industry)

Measure 3a. Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)

1. What mechanisms have the Consortium used to identify community needs?
2. What mechanisms would you suggest that could increase the communication between the external community and the Consortium?
3. What were the most important community needs identified by the Consortium?
4. Please provide examples in which the Consortium identified a community need and acted on that need.
    a. What value do you place on the example(s)?
5. What are your perceptions of the Consortiums outreach activities to identify and support community needs?
6. Are there examples where the Consortium could have been used to the advantage of the external community?
7. Is the motivation for communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?
8. Is the success of communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?

Measure 3b. Education on the use and relevance of GEMM and other mouse models (e.g., publications, conferences, web resources)

1. What activities/mechanisms has the Consortium used to educate the external community about the use and relevance of GEMM and other mouse models?
    a. Publications
    b. Conferences/workshops (Quantity/Quality)
    c. Web resources (Quantity/Quality)
2. Beyond the typical dissemination of results (e.g., publication, conferences), what are your perceptions of the Consortium's efforts to educate the external community on the use/relevance of GEMM and other mouse models?

3. Please suggest alternative strategies/mechanisms to educate the external community on the use and relevance of GEMM and other mouse Models.
4. Are the activities/mechanisms used for education of the external community significantly different from previous iterations of the Consortium?

Measure 3c. Value and usability of web resources developed through the Consortium (e.g., eMICE, caMOD, Mouse Repository, caIMAGE, Cancer Electronic Laboratory Management Information System)[10] and extent of use by non-Consortium investigators

1. Have the Consortium developed web resource(s) been valuable to your research?
    a. Why/why not, please explain
    b. What is your impression of the usability of the web resources?
2. With respect to Consortium generated information, please suggest web resources that would be valuable to your research.

Measure 3d. Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research

1. Please identify examples where outside advances (e.g., technologies, methods etc.) or research approaches (e.g., systems biology) have been identified by the Consortium and integrated into the Consortium's repertoire of approaches.
2. Please describe the mechanism by which these advances or research approaches were identified and taken up by the Consortium.
3. Please describe outside advances or research approaches that <u>should have been adopted</u> by the Consortium.

Process Parameter 4: Impact of Consortium clusters[11]

Measure 4a. Rationale for cluster designations

1. What is the rational for the use of clusters as an organizing principle?
2. What was the mechanism/basis for selecting the extant clusters?
3. What process/concept was established for the development of the clusters?

Measure 4b. Articulation of cluster goals and success in achieving them

1. Within your specific cluster, what are the goals and success measures?
2. What was the process for developing the goals and success measures?
3. What is your position on the clarity, reality, and measurability of the goals and success measures?
4. What is your impression of how well the goals and success measures were communicated within the cluster?

[10] The Consortium's contribution to each of these resources will need to be defined.

[11] Will require access to information on cluster participants and leadership and any change over time.

Measure 4c. Strength of member/cluster affiliations

1. What is your impression of affiliation (strength of association) within your cluster?
2. What is your impression of how strongly Consortium members affiliate with one or more clusters?
3. Is there a mechanism/process for changing clusters?
    a. If so, what is the process?

Measure 4d. Impact on format/structure/content of meetings

1. How have clusters impacted the format/structure/content of Steering Committee meetings or workshops?
    a. Are portions of the events cluster-specific?
2. Does your cluster(s) meet (physically or virtually) on a regular basis?
    a. How often do you meet?
    b. What is the structure of the meetings?
    c. What is the nature of the meetings (strategy/planning, result reporting, etc.)?
3. What is your impression of the value of those meetings?
4. What is the product of the meetings?

Measure 4e. Impact on collaboration, communication and outreach

1. Does being part of a cluster improve your level of collaboration and communication with others in the cluster?
    a. Would the cluster relationships have existed in the absence of the Consortium?
2. Does your cluster promote collaboration, communication, and/or outreach activities?
    a. Intra-Consortium and/or externally?
3. What effect do the cluster activities have on your collaborations within the Consortium?
4. What effect do the cluster activities have on your collaborations outside the Consortium?
5. What effect do the cluster activities have on your ability to communicate with other Consortium members?
6. What effect do the cluster activities have on your ability to communicate with the external community?
7. Compared to previous iterations of the Consortium, what is the relative effect of the clusters on collaboration and communication?

Measure 4f. Cluster dependent output—publications, pilot projects etc.

1. Please provide examples of cluster dependent outputs (e.g., pilot projects or workshops).

Process Parameter 5: Investigator participation in the Consortium

Measure 5a. Impact on investigators of Consortium activities and responsibilities that are above and beyond those for typical grants

1. Please provide examples of Consortium activities/responsibilities that you perceive are "above and beyond" what is typically required for traditional NIH research support (i.e., RO1).
2. What is your opinion of the support (financial and business) given for the activities that are "above and beyond"?
    a. Please provide support in the form of examples.

Measure 5b. Value of the additional activities and responsibilities

1. What is your perception of the value of the activities and responsibilities you've deemed "above and beyond"?
    a. Please provide support in the form of examples.
2. Has the value of these activities and responsibilities changed over the lifetime of the Consortium?
    a. Why?

Measure 5c. Degree to which additional activities and responsibilities are shared equally by Consortium investigators

1. What are your perceptions of the distribution of labor relative to the additional activities and responsibilities required by Consortium membership?
2. By what process are activities and responsibilities divided among members of the Consortium?

Process Parameter 6: NCI role in the Consortium

Measure 6a. NCI activities that facilitate Consortium activities (e.g., Resolving intellectual property issues with industry, flexibility in use of award funds, funding for outreach)

1. Provide examples in which the NCI has actively helped the Consortium overcome an obstacle or achieve a goal (e.g., limited access to material, intellectual property issues, issues requiring flexibility of funding, or increasing outreach).
2. What is your impression of the support (financial and business) given by the NCI for these examples?

    a. With what ease was the support obtained?
    b. What suggestions do you have for improvement?
3. What is your perception of the relative importance/value of these activities?
    a. To the Consortium?
    b. To the NCI?

Measure 6b. NCI activities that impede Consortium activities (e.g., inadequate funding for the high cost of animal use)

1. Please provide examples where NCI actions or decisions had a negative effect on Consortium activities or goals.
    a. With respect to the examples, what is your impression of the impact of those actions or decisions on the Consortium?

Measure 6c. Impact of new 2008 RFA Guidelines on Consortium activities, goals, productivity

1. Have the Consortium's activities, its goals or productivity been in line with most recent (2008) RFA Guidelines?
    a. Provide examples or reasoning to support why or why not.
2. Relative to previous iterations of the Consortium, is the current Consortium as productive?
    a. Provide examples or reasoning to support why or why not.
3. What changes to the most recent RFA have been most influential, both positively and negatively?
    a. Provide examples or reasoning to support your choice.

NCI Program Staff

Process Parameter 1: Communication within the Consortium

Measure 1a. Impact on generation of new ideas, hypotheses, priorities and research directions

1. What are your perceptions of the quality of communication within the Consortium?
2. Has communication within the Consortium fostered the generation of new research ideas, hypotheses and research directions?
    a. No, why not?
3. What activities have been most influential in promoting communication for generating new research ideas, hypotheses, priorities and directions?

Measure 1b. Impact on development of enabling resources, research approaches, etc.

1. Has communication within the Consortium fostered the generation of enabling resources (e.g., model systems, bioinformatics tools) or research approaches?
    a. No, why not?
2. With respect to the Consortium, please describe examples where Consortium communication led to the development of:
    a. Enabling resources
    b. Research approaches
3. What activities have been most influential in promoting communication for generating enabling resources and new research approaches?

Measure 1c. Impact on activities, direction and structure of the overall Consortium

1. Has communication within the Consortium influenced the activities, direction or structure of the Consortium?
    a. No, why not?
2. Please describe examples where Consortium communication has influenced the activities, direction or structure of the Consortium?
3. What is your impression of the quality of Consortium communication directed toward the activities, direction or structure of the overall Consortium?

Measure 1d. Value of meetings, workshops, clusters in promoting communication

1. What are your perceptions of the quality of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
2. What are your perceptions of the value of past Steering Committee meetings for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
3. Are there specific examples that support the high quality or value of the Steering Committee meetings?
4. Are there specific instances where the Steering Committee, as a mechanism of communication, should have been used but was not?
    a. Please explain.
5. What are your perceptions of the quality of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators

6. What are your perceptions of the value of workshops for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
7. Are there specific examples that support the high quality or value of the workshops?
8. Are there specific instances where workshops, as a mechanism of communication, should have been used but were not?
    a. Please explain.
9. What are your perceptions of the quality of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
10. What are your perceptions of the value of the clusters for communicating or promoting:
    a. Research results
    b. Consortium activities
    c. Outreach to external investigators
11. Are there specific examples that support the high quality or value of the clusters as a communication mechanism?

Measure 1e. Consortium leadership contributions to promoting communication

1. What is your perception of the Consortium leadership with respect to promoting communication?
2. Please provide examples of when the Consortium's leaders' activities led to productive communication.

Measure 1f. Degree to which communication channels and opportunities would have developed among investigators in the absence of the Consortium

1. Do you believe the Consortium provides unique communication channels or opportunities that are NOT possible without the Consortium?
    a. No, why not?
    b. Yes, please provide examples of communication channels or opportunities that would NOT have occurred without the Consortium.
2. Are there examples where the collective knowledge, resources, or influence of the Consortium have proved beneficial (e.g., in negotiations with industry or funders)?

Process Parameter 2: Collaborative nature of the Consortium

Measure 2a. Collaborations established among Consortium investigators

1. Overall, what are your perceptions of the collaborative nature of the Consortium?
    a. How would you describe the structure of intra-consortium collaborations?
    b. How would you describe the character of intra-consortium collaborations?
2. What value do you place on intra-Consortium collaboration?
    a. Has your view of this changed from previous iterations of the Consortium?
3. Is the motivation for collaborating within the consortium significantly different from previous iterations of the Consortium?
    a. Why?
4. Is the success of intra-Consortium collaborations significantly different from previous iterations of the Consortium?
    a. Why?

Measure 2b. Collaborations established with non-Consortium investigators (domestic and international), other NCI components and industry

1. What are your perceptions about the collaborative nature of the Consortium with the external community?
    a. Has there been a supportive atmosphere for establishing external collaborations?
        i. From within the Consortium?
        ii. From NCI?
    b. What are the barriers for establishing external collaborations?
        i. Are they different for domestic vs. international?
2. What do you think are the perceptions of the non-consortium investigator with respect to collaborating with Consortium members?
3. What value do you place on external collaborations?
    a. Has this changed over the life of the Consortium?

Measure 2d. Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators

1. Provide examples of Consortium-developed resources (models, data, and experimental approaches) that you are aware of.
    a. Provide examples that you have used in your own research?
    b. Was access to these resources easy or difficult?
        i. What mechanism did you use to gain access?
        ii. What were the barriers?

2. Provide examples of resources that you believe the Consortium is in a position to provide for the external community, but has not?
3. How might the Consortium better serve the external community with respect to knowledge, research guidance, infrastructure, etc.?

Process Parameter 3: Communication between the Consortium and the external cancer research community (both academia and industry)

Measure 3a. Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)

1. What mechanisms have the Consortium used to identify community needs?
2. What were the most important community needs identified by the Consortium?
3. Please provide examples in which the Consortium identified a community need and acted on that need.
    a. What value do you place on the example(s)?
4. What are your perceptions of the Consortiums outreach activities to identify and support community needs?
5. Are there examples where the Consortium could have been used to the advantage of the external community?
6. Is the motivation for communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?
7. Is the success of communicating with the external community significantly different from previous iterations of the Consortium?
    a. Why?

Measure 3b. Education on the use and relevance of GEMM and other mouse models (e.g., publications, conferences, web resources)

1. What activities/mechanisms has the Consortium used to educate the external community about the use and relevance of GEMM and other mouse models?
    a. Publications
    b. Conferences/workshops (Quantity/Quality)
    c. Web resources (Quantity/Quality)
2. Beyond the typical dissemination of results (e.g., publication, conferences), what are your perceptions of the Consortium's efforts to educate the external community on the use/relevance of GEMM and other mouse models?
3. Are the activities/mechanisms used for education of the external community significantly different from previous iterations of the Consortium?

Measure 3d. Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research

1. Please identify examples where outside advances (e.g., technologies, methods etc.) or research approaches (e.g., systems biology) have been identified by the Consortium and integrated into the Consortium's repertoire of approaches.
2. Please describe the mechanism by which these advances or research approaches were identified and taken up by the Consortium.

Process Parameter 4: Impact of Consortium clusters[12]

Measure 4a. Rationale for cluster designations

1. What is the rational for the use of clusters as an organizing principle?
2. What was the mechanism/basis for selecting the extant clusters?
3. What process/concept was established for the development of the clusters?

Measure 4b. Articulation of cluster goals and success in achieving them

1. Do clusters articulate goals and success measures?
2. What was the process for developing the goals and success measures?
3. What is your position on the clarity, reality, and measurability of the goals and success measures?

Measure 4c. Strength of member/cluster affiliations

1. What is your impression of affiliation (strength of association) within clusters?
2. What is your impression of how strongly Consortium members affiliate with one or more clusters?
3. Is there a mechanism/process for changing clusters?
    a. If so, what is the process?

Measure 4d. Impact on format/structure/content of meetings

1. How have clusters impacted the format/structure/content of Steering Committee meetings or workshops?
    a. Are portions of the events cluster-specific?
2. What is your impression of the value of cluster meetings?

Measure 4e. Impact on collaboration, communication and outreach

1. Compared to previous iterations of the Consortium, what is the relative effect of the clusters on collaboration and communication?

Process Parameter 5: Investigator participation in the Consortium

[12] Will require access to information on cluster participants and leadership and any change over time

Measure 5a. Impact on investigators of Consortium activities and responsibilities that are above and beyond those for typical grants

1. Please provide examples of Consortium activities/responsibilities that you perceive are "above and beyond" what is typically required for traditional NIH research support (i.e., RO1).
2. What is your opinion of the support (financial and business) given for the activities that are "above and beyond"?
    a. Please provide support in the form of examples.

Measure 5b. Value of the additional activities and responsibilities

1. What is your perception of the value of the activities and responsibilities you've deemed "above and beyond"?
    a. Please provide support in the form of examples.
2. Has the value of these activities and responsibilities changed over the lifetime of the Consortium?
    a. Why?

Measure 5c. Degree to which additional activities and responsibilities are shared equally by Consortium investigators

1. What are your perceptions of the distribution of labor relative to the additional activities and responsibilities required by Consortium membership?

Measure 5d. Additional responsibilities of Consortium leadership and if those are adequately funded

1. What additional activities and responsibilities are required from the Consortium leadership?
    a. What is your perception of the general time requirements to fulfill these obligations?
2. What is your impression of the support (financial and business) given through the leadership awards?

Process Parameter 6: NCI role in the Consortium

Measure 6a. NCI activities that facilitate Consortium activities (e.g., Resolving intellectual property issues with industry, flexibility in use of award funds, funding for outreach)

1. Provide examples in which the NCI has actively helped the Consortium overcome an obstacle or achieve a goal (e.g., limited access to material, intellectual property issues, issues requiring flexibility of funding, or increasing outreach).

2. What is your impression of the support (financial and business) given by the NCI for these examples?
    a. With what ease was the support obtained?
    b. What suggestions do you have for improvement?
3. What is your perception of the relative importance/value of these activities?
    a. To the Consortium?
    b. To the NCI?

Measure 6b. NCI activities that impede Consortium activities (e.g., inadequate funding for the high cost of animal use)

1. Please provide examples where NCI actions or decisions had a negative effect on Consortium activities or goals.
    a. With respect to the examples, what is your impression of the impact of those actions or decisions on the Consortium?

Measure 6c. Impact of new 2008 RFA Guidelines on Consortium activities, goals, productivity

1. Have the Consortium's activities, its goals or productivity been in line with most recent (2008) RFA Guidelines?
    a. Provide examples or reasoning to support why or why not.
2. Relative to previous iterations of the Consortium, is the current Consortium as productive?
    a. Provide examples or reasoning to support why or why not.
3. What changes to the most recent RFA have been most influential, both positively and negatively?
    a. Provide examples or reasoning to support your choice.

Other Investigators

Process Parameter 2: Collaborative nature of the Consortium

Measure 2c. Non-Consortium investigators' perception of the willingness of Consortium members to collaborate

1. What are your perceptions about the collaborative nature of the Consortium?
2. Has there been a supportive atmosphere for establishing collaborations?
    a. From within the Consortium?
    b. From NCI?
3. What are the barriers for establishing collaborations?
4. What mechanisms would you suggest to improve the quantity/quality of collaborations with the Consortium?
5. Which Consortium members have you collaborated with?

a. What is the nature of those collaborations?
b. Were these collaborations dependent on the existence of the Consortium?

6. What value do you place on collaborating with the Consortium?
    a. What does collaboration with the Consortium offer that is unique? (Knowledge, infrastructure, etc.)

Measure 2d. Value and accessibility of Consortium resources (e.g., models, data, experimental approaches) for use by non-Consortium investigators

1. Provide examples of Consortium-developed resources (models, data, and experimental approaches) that you are aware of.
    a. Provide examples that you have used in your own research?
    b. Was access to these resources easy or difficult?
        i. What mechanism did you use to gain access?
        ii. What were the barriers?
2. Provide examples of resources that you believe the Consortium is in a position to provide for the external community, but has not?
3. How might the Consortium better serve the external community with respect to knowledge, research guidance, infrastructure, etc.?

Process Parameter 3: Communication between the Consortium and the external cancer research community (both academia and industry)

Measure 3a. Identification and response to community needs (e.g., new research approaches/methodologies, model validations, setting of research priorities)

1. What mechanisms would you suggest that could increase the communication between the external community and the Consortium?
2. What were the most important community needs identified by the Consortium?
3. What are your perceptions of the Consortiums outreach activities to identify and support community needs?
4. Are there examples where the Consortium could have been used to the advantage of the external community?

Measure 3b. Education on the use and relevance of GEMM and other mouse models (e.g., publications, conferences, web resources)

1. Beyond the typical dissemination of results (e.g., publication, conferences), what are your perceptions of the Consortium's efforts to educate the external community on the use/relevance of GEMM and other mouse models?
2. Please suggest alternative strategies/mechanisms to educate the external community on the use and relevance of GEMM and other mouse Models.
3. Which Consortium-sponsored educational activities have you participated in?
    a. What value do you assign to those activities?

b. Did those activities significantly impact your research?
    i. Adoption of a GEMM or other mouse model
    ii. Change the approach of your research
c. Would these changes to your research have occurred in the absence of the Consortium? Is the value ascribed to the activities of Consortium only attributable to the Consortium?

Measure 3c. Value and usability of web resources developed through the Consortium (e.g., eMICE, caMOD, Mouse Repository, caIMAGE, Cancer Electronic Laboratory Management Information System)[13] and extent of use by non-Consortium investigators

1. Have the Consortium developed web resource(s) been valuable to your research?
    a. Why/why not, please explain
    b. What is your impression of the usability of the web resources?
2. With respect to Consortium generated information, please suggest web resources that would be valuable to your research.

Measure 3d. Integration of outside advances and/or biological research approaches (e.g., systems biology) into Consortium research

1. Please describe outside advances or research approaches that should have been adopted by the Consortium.

[13] The Consortium's contribution to each of these resources will need to be defined.

Appendix D.
Outcome Evaluation Detailed Design

The Outcome Evaluation will address the five outcomes listed below. For each outcome, a set of measures is proposed for evaluating MMHCC performance with regard to that outcome as well as the data collection approaches to be used for each measure. Collection activities for each parameter, by measure, are then summarized in a table. The basic design for the majority of the outcome evaluation is to identify examples relevant to each measure from MMHCC progress reports and then conduct interviews with MMHCC participants to clarify the identified examples, perhaps gather additional examples, and determine the role of Consortium interactions with regard to the examples (i.e., was there synergy). The outcome evaluation also involves surveys of Consortium model users for additional examples. If the conceptual plan is approved, preparation of detailed interview guides, survey instruments and document analysis methodologies will be part of the project to conduct the evaluation.

Outcome 1: Use of Consortium-developed GEM and other mouse models to generate discoveries in cancer etiology, biology, and disease progression

Measure 1a. Advances in understanding biological pathways relevant to cancer susceptibility, resistance, initiation and progression (e.g., tumorigenesis, metastasis, interaction with cellular environment)

- **Analysis of U01 progress reports:** Gather examples of advances made
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development
- **Survey of users:**[14] Gather examples of advances made using Consortium-derived models

Measure 1b. New hypotheses for cancer prevention and treatment

- **Analysis of U01 progress reports:** Gather examples of new hypotheses generated **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development

[14] Users of Consortium models obtained from the records of the various repositories from which Consortium models are available.

- **Survey of users:**[1] Gather examples of new hypotheses generated using Consor**r**tium-derived models

Measure 1c. New biomarkers of cancer response, toxicity, prognosis, etc.

- **Analysis of U01 progress reports:** Gather examples of newly identified biomarkers
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development
- **Survey of users:**[1] Gather examples of new biomarkers identified using Consortium-derived models

Outcome 2: Use of Consortium-developed GEM and other mouse models to translate discoveries in cancer biology into potential interventions or to understand clinical observations in humans.[15]

Measure 2a. Testing and refining options for interventions before use in humans (e.g., combination therapies, correlation of genetic markers with response, toxicity, effect of genetic background on response)

- **Analysis of U01 progress reports:** Gather examples of using Consortium models to test and refine intervention options before use in humans
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the research; for all examples determine whether Consortium interactions contributed to their development; identify non-Consortium investigators who have used Consortium-derived models for this purpose
- **Interviews with identified investigators:** Gather information concerning their use of Consortium models to test and refine intervention options before use in humans
- **Survey of users:**[1] Gather examples of using Consortium models to test and refine intervention options before use in humans

Measure 2b. Answering human cancer questions which can only be addressed using a mouse model (e.g., early tumor progression, prostate cancer, pancreatic cancer)

- **Analysis of U01 progress reports:** Gather examples of using Consortium models to answer human cancer questions which can only be addressed using a mouse model

[15] This outcome will be determined for both academic research and pharmaceutical company research.

- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the research; identify non-Consortium investigators who have used Consortium-derived models for this purpose
- **Interviews with identified investigators:** Gather information concerning their use of Consortium models to answer human cancer questions which can only be addressed using a mouse model
- **Survey of users:**[1] Gather examples of using Consortium models to answer human cancer questions which can only be addressed using a mouse model

Measure 2c. Drug screening

- **Analysis of U01 progress reports:** Gather examples of drug screening using Consortium models
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the research; identify non-Consortium investigators who have used Consortium-derived models for this purpose
- **Interviews with identified investigators:** Gather information concerning their use of Consortium models for drug screening
- **Survey of users:**[1]Gather examples of using Consortium models for drug screening

Measure 2d. Enhanced understanding of observations in humans (e.g., deficiencies in response to standard of care, interpreting and/or validating human cancer research results)

- **Analysis of U01 progress reports:** Gather examples of using Consortium models to enhance understanding of observations in humans
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the research; identify non-Consortium investigators who have used Consortium-derived models for this purpose
- **Interviews with identified investigators:** Gather information concerning use of Consortium models to enhance understanding of observations in humans
- **Survey of users:**[1] Gather examples of using Consortium models to enhance understanding of observations in humans

Outcome 3: Use of Consortium-developed GEM and other mouse models to inform the design and conduct of treatment, prevention and screening trials.2

Measure 3a. Clinical trial designs (e.g., patient stratification, drug treatment regimens, and combination therapies) based on mouse preclinical "trials"

- **Analysis of U01 progress reports:** Gather examples of clinical trial designs based on mouse preclinical "trials" using Consortium models
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the preclinical "trials" conducted; identify investigators who have based clinical trial designs on preclinical "trials" using Consortium-derived models
- **Survey of users:**[1] Gather examples of clinical trial designs based on mouse preclinical "trials" using Consortium models; identify investigators who have based clinical trial designs on preclinical "trials" using Consortium-derived models
- **Interviews with identified investigators:** Gather information concerning their clinical trial designs which are based on mouse preclinical "trials" using Consortium models

Measure 3b. "Co-preclinical trials" in mouse models which provided results that changed the treatment course for subjects in a parallel clinical trial

- **Analysis of U01 progress reports:** Gather examples of "co-preclinical trials" using Consortium models that changed clinical trial treatment course
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the preclinical "trials" conducted; identify investigators who have conducted clinical trials "paired" with preclinical "trials" using Consortium-derived models
- **Survey of users:**[1] Gather examples of "co-preclinical trials" using Consortium models that changed clinical trial treatment course; identify investigators who have conducted clinical trials "paired" with preclinical "trials" using Consortium-derived models
- **Interviews with identified investigators:** Gather information concerning their clinical trials which have been "paired" with preclinical "trials" using Consortium-derived models

Measure 3c. Preclinical mouse trials that replaced a proof of concept clinical trial and led directly to a confirmatory late phase clinical trial

- **Analysis of U01 progress reports:** Gather examples of preclinical mouse "trials" using Consortium models that replaced a proof of concept clinical trial and led directly to a confirmatory late phase trial

- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the preclinical "trials" conducted; identify investigators who have designed late phase trials based on such preclinical "trials"
- **Survey of users:**[1] Gather examples of preclinical mouse "trials" using Consortium models that replaced a proof of concept clinical trial and led directly to a confirmatory late phase trial; identify investigators who have designed late phase trials based on such preclinical "trials"
- **Interviews with identified investigators:** Gather examples of confirmatory late phase trials based on proof of concept preclinical mouse "trials"

Measure 3d. Mouse mimetic intervention technologies that provided the basis for developing new human interventions

- **Analysis of U01 progress reports:** Gather examples of mouse mimetic intervention technologies developed using Consortium models that provided the basis for developing new human interventions
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the mimetic intervention technologies developed; identify investigators who have developed human interventions based on mouse mimetic technologies
- **Survey of users:**[1] Gather examples of mouse mimetic intervention technologies developed using Consortium models that provided the basis for developing new human interventions; identify investigators who have developed human interventions based on mouse mimetic technologies
- **Interviews with identified investigators:** Gather examples of human interventions based on mouse mimetic technologies

Outcome 4: Consortium advances in GEM and other mouse model development and associated technologies.

Measure 4a. New and improved mouse models that address scientific/clinical questions for which current models do not exist or are inadequate

- **Analysis of U01 award progress reports:** Gather examples of new and improved mouse models developed
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development

Measure 4b. New and improved mouse models that recapitulate characteristics of human cancers (e.g., initiation, progression, response) for which current models do not exist or are inadequate

- **Analysis of U01 award progress reports:** Gather examples of new and improved mouse models developed
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development

Measure 4c. New and improved mouse models for human cancers for which current models do not exist or are inadequate.

- **Analysis of U01 award progress reports:** Gather examples of new and improved mouse models developed
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development

Measure 4d. More extensive integration of mouse and human data

- **Analysis of U01 and leadership award progress reports:** Gather examples of datasets that integrate of mouse and human data
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the integration achieved
- **Identified dataset analysis:** Verify integration of mouse and human data in identified datasets

Measure 4e. More extensive integration of Consortium mouse data with mouse data from non-Consortium investigators

- **Analysis of U01 and leadership award progress reports:** Gather examples of datasets that integrate of Consortium mouse data and non-Consortium mouse data
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to the integration achieved
- **Identified dataset analysis:** Verify integration of Consortium mouse data and mouse data from non-Consortium investigators in identified datasets

Measure 4f. New mouse mimetic intervention technologies based on interventions used in human studies

- **Analysis of U01 award progress reports:** Gather examples of new mouse mimetic intervention technologies developed
- **Interviews with Consortium investigators and NCI staff:** Clarify identified examples and potentially gather additional examples; for all examples determine whether Consortium interactions contributed to their development

Outcome 5: Impact of the Consortium on the broader cancer research community.

Measure 5a. Use of Consortium developed models by non-Consortium investigators

- **User data analysis**: Tabulate the number of investigators requesting each of the Consortium-developed mouse models; data would be stratified (e.g., by disease area, by MMHCC investigator who developed the model) for further analysis

Measure 5b. Influence of the Consortium's collective expertise on the priorities and research directions relevant to the use of mouse models

- **Interviews with Consortium investigators and NCI staff:** Gather examples of the influence of Consortium expertise on priorities and research directions for the use of mouse models outside the Consortium

Measure 5c. Projects utilizing Consortium resources that benefit the broader community (e.g., TCGA)

- **Interviews with Consortium investigators and NCI staff:** Gather examples of projects utilizing Consortium resources that benefit the broader community
- **Interviews with identified project leaders:** Gather perceptions regarding the Consortium's contributions to the project

Measure 5d. New companies founded based on use of a Consortium developed model or on results from a Consortium developed model

- **Interviews with Consortium investigators and NCI staff:** Gather examples of new companies founded
- **Survey of users:**[1] Gather examples of new companies founded
- **Interviews with identified company founders:** Gather perceptions as to the importance of the Consortium developed model(s) or the results from Consortium developed model(s) to the founding of the company

Measure 5e. Impact of Consortium publications[16]

- **Publications:** Count of publications attributed to the MMHCC (via IMPAC II and progress reports)
- **Impact factors and citations to publications:** Impact of MMHCC publications, as measured through impact factors and citations

[16] Impact of publications is an area whereby a comparison group would be feasible and straightforward to conduct. The evaluator, working with NCI, would identify a set of R01 (or equivalent) awards whereby the investigators developed and then used mouse models in basic research or preclinical development of new interventions; those awards would need to be of a cohort similar to the MMHCC U01s to allow for a fair comparison. Analysis would then compare both total publications and measures of efficiency (e.g., publications per M$ in NIH direct costs) to identify whether there were statistically significant differences in publication quantity and quality between the two groups.

Summary of Outcome Evaluation

USE OF CONSORTIUM-DEVELOPED GEM AND OTHER MOUSE MODELS TO GENERATE DISCOVERIES IN CANCER ETIOLOGY, BIOLOGY, AND DISEASE PROGRESSION					
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**	**User Survey**
Advances in understanding biological pathways relevant to cancer susceptibility, resistance, initiation and progression (e.g., tumorigenesis, metastasis, interaction with cellular environment)	Yes	Yes	No	U01 progress reports	Yes
New hypotheses for cancer prevention and treatment	Yes	Yes	No	U01 progress reports	Yes
New biomarkers of cancer response, **t**oxicity, prognosis, etc.	Yes	Yes	No	U01 progress reports	Yes

USE OF CONSORTIUM-DEVELOPED GEM AND OTHER MOUSE MODELS TO TRANSLATE DISCOVERIES IN CANCER BIOLOGY INTO POTENTIAL INTERVENTIONS OR TO UNDERSTAND CLINICAL OBSERVATIONS IN HUMANS					
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**	**User Survey**
Testing and refining options for interventions before use in humans (e.g., combination therapies, correlation of genetic markers with response, toxicity, effect of genetic background on response)	Yes	Yes	Yes	U01 progress reports	Yes
Answering human cancer questions which can only be addressed using a mouse model (e.g., early tumor progression, prostate cancer, pancreatic cancer)	Yes	Yes	Yes	U01 progress reports	Yes
Drug screening	Yes	Yes	Yes	U01 progress reports	Yes
Enhanced understanding of observations in humans (e.g., deficiencies in response to standard of care, interpreting and/or validating human cancer research results)	Yes	Yes	Yes	U01 progress reports	Yes

USE OF CONSORTIUM-DEVELOPED GEM AND OTHER MOUSE MODELS TO INFORM THE DESIGN AND CONDUCT OF TREATMENT, PREVENTION AND SCREENING TRIALS					
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**	**User Survey**
Clinical trial designs (e.g., patient stratification, drug treatment regimens, and combination therapies) based on mouse preclinical "trials"	Yes	Yes	Yes	U01 progress reports	Yes
"Co-preclinical trials" in mouse models which provided results that changed the treatment course for subjects in a parallel clinical trial	Yes	Yes	Yes	U01 progress reports	Yes
Preclinical mouse trials that replaced a proof of concept clinical trial and led directly to a confirmatory late phase clinical trial	Yes	Yes	Yes	U01 progress reports	Yes
Mouse mimetic intervention technologies that provided the basis for developing new human interventions	Yes	Yes	Yes	U01 progress reports	Yes

CONSORTIUM ADVANCES IN GEM AND OTHER MOUSE MODEL DEVELOPMENT AND ASSOCIATED TECHNOLOGIES					
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**	**User Survey**
New and improved mouse models that address scientific/clinical questions for which current models do not exist or are inadequate	Yes	Yes	No	U01 award progress reports	No
New and improved mouse models that recapitulate characteristics of human cancers (e.g., initiation, progression, response) for which current models do not exist or are inadequate	Yes	Yes	No	U01 award progress reports	No
New and improved mouse models for human cancers for which current models do not exist or are inadequate	Yes	Yes	No	U01 award progress reports	No
More extensive integration of mouse and human data	Yes	Yes	No	U01 and Leadership award progress reports, Dataset analysis	No
More extensive integration of Consortium mouse data with mouse data from non-Consortium investigators	Yes	Yes	No	U01 and Leadership award progress reports, Dataset analysis	No
New mouse mimetic intervention technologies based on interventions used in human studies	Yes	Yes	No	U01 progress reports	No

IMPACT OF THE CONSORTIUM ON THE BROADER CANCER RESEARCH COMMUNITY					
Evaluation Measure	**Consortium Investigator Interviews**	**NCI Staff Interviews**	**Non-Consortium Investigator Interviews**	**Document Analysis**	**User Survey**
Use of Consortium developed models by non-Consortium investigators	No	No	No	User data analysis	No
Influence of the Consortium's collective expertise on the priorities and research directions relevant to the use of mouse models	Yes	Yes	No	None	No
Projects utilizing Consortium resources that benefit the broader community (e.g., TCGA)	Yes	Yes	Project leaders	None	No
New companies founded based on use of a Consortium developed model or on results from a Consortium developed model	Yes	Yes	Company founders	None	Yes
Impact of Consortium publications	No	No	No	Publications, Impact factors and citations to publications	No