Strategies for Planning and Executing a Successful Research Consortium or Complex Collaboration

Successful planning and execution of a research consortium or other complex collaborative effort (herein referred to as "consortium") requires the involvement and synchronization of numerous key players, including the Principal Investigator (PI), collaborating PIs, institutional grants and contracting offices, regulatory bodies, and key stakeholders. Lessons learned and best practices gleaned from previously funded efforts have been instrumental in the development of these strategies which should be considered when planning and executing a consortium. Note that a variety of resources are referenced throughout this document as hyperlinks. The resources provide more detailed information on some of the topics that may only be briefly discussed in this document.

I.   Planning a Successful Consortium

Collaboration is a necessity of scientific innovation, and setting up a consortium well is critical to how it will attain its overall goals. In addition to the requirements outlined in the funding opportunity announcement (FOA), the following elements should be considered when planning a consortium.

A. Consortium Structure and Collaboration

The FOA will provide guidance on how the consortium should be structured and elements PIs should implement to foster collaboration. PIs should consider the following:
- Gain a clear understanding of the needs/requirements to be addressed by the research effort and ongoing work in the area of research.
- Select partnerships/co-PIs best matched to meet the consortium goals, knowing that consortium Directors may have to cut projects, and their associated PIs, later due to performance issues.
- Be knowledgeable about other similar efforts. Specifically for clinical studies, be aware of study population dynamics and challenges to recruitment and look for ways to leverage or synergize with ongoing efforts.
- Use a combination of a coordinating center, cores, collaborating PIs/institutions, an external peer review panel, and Government advisory bodies. Previous consortium PIs have indicated that having dedicated cores (biorepository, imaging, data repository, etc.) is preferable over having the core functions distributed across institutions or imbedded within studies. This strategy reduces regulatory burden, reduces costs, and keeps the data or samples stored in and disseminated from a central location.
- Develop a well-established, regular communication plan between all key and support personnel at the proposal planning stage.
- Develop a Standard Operating Procedure (SOP) for the management of the consortium. Elements of an SOP are discussed in detail in section IIB below.

- Previous consortium PIs have indicated that it is helpful to develop a field-specific, expert panel, independent of the Government, to provide input on the scientific merit, methodology, and feasibility of proposed studies.
- Plan to incorporate the use of Common Data Elements (CDEs) into studies for fields of research for which CDEs are required.
- Plan for specific requirements regarding data collection methodology, data sharing, and long-term data storage (repository) and formalize in written plans and/or SOPs. See the [Policy on Data & Resource Sharing](#) for additional information.

B. Statement of Work (SOW) Development

The SOW is a significant component of the proposal and a tool for communicating about tasks, milestones, and timelines. When developing the SOW, take into consideration a number of issues that impact the execution timeline of the consortium:
- Development of Cooperative Research and Development Agreements (CRADAs)
- DoD human and animal regulatory requirements - When conducting multi-institutional clinical trials, PIs are advised to familiarize themselves with DoD-specific guidelines and prepare their clinical protocol(s) as soon as possible. It may be necessary to reach out to the U.S. Army Medical Research and Materiel Command (USAMRMC) Human Research Protections Office (HRPO) for initial guidance. Additional information is provided in section IIA below.
- Food and Drug Administration regulatory requirements
- DoD contracting processes
- Access to and recruitment of active duty Service members or Veterans
- Be knowledgeable about special considerations when working with intramural DoD partners (funding process/timing, regulatory approvals, limits of resource availability).

C. Budgetary and Contracting Considerations

It is important to prepare for the impact of FOA requirements on the scope, timeline, and, thus, budget, of the overall consortium. PIs should consider the following when developing the budget:
- Indicate and incorporate specified personnel categories, frequency of Government in-person meetings, regulatory requirements and timelines, level of Government oversight, and performance expectations
- When conducting clinical studies, budget for an experienced Project Coordinator to serve as the primary point of contact and a dedicated Regulatory Coordinator to oversee all Institutional Review Board (IRB)/ USAMRMC HRPO requirements.
- It may be beneficial to budget for an Administrative team dedicated to financial issues and to host a kick-off meeting for sub-award PIs, Co-PIs, and key personnel to facilitate sub-award negotiations/management.
- Plan and budget for sub-awards to project PIs/institutions and be cognizant of the time to issue sub-awards.
- It is critical that the consortium PI and Sponsored Programs Office (SPO) be aware that the process of gaining approval to add new projects or to modify existing projects

may require the approval of a Government oversight body, such as a Government Steering Committee, and always requires submission of extensive budgetary documentation to the U.S. Army Medical Research Acquisition Activity's (USAMRAA's) Grants Officer.
- Additionally, the PI should be aware of the DoD policies for invoicing, Extensions without Funds (EWOF), and overall expectations of use of funding within the period of performance.
- To streamline the administration of the consortium, academic institutions and PIs with limited experience managing large consortia could consider subcontracting aspects of consortium management to an outside organization with experience in efficient management and distribution of study funds.

D. Human and Animal Regulatory Considerations

DoD funded animal and human research requires review and oversight by the USAMRMC Office of Research Protections (ORP).
- All animal protocols must be reviewed and approved by the USAMRMC Animal Care and Use Review Office (ACURO) before animal work can be conducted.
- The DoD has specific regulatory requirements for human subjects research which must be considered and incorporated into the protocol before approval by the USAMRMC HRPO.
- The length of time required for obtaining approvals for use of animals and human subjects can be lengthy (2-3 months, or more, for human subjects) depending on the complexity of the protocol(s).
- For human subjects research, PIs should prepare the protocol and submit to their IRB as early as possible. Additionally, for multi-site studies, a master clinical protocol should be developed and approved by the USAMRMC HRPO before other sites seek IRB/ USAMRMC HRPO approval.
- The time required to obtain approvals should be anticipated and reflected in the timeline/SOW, and personnel should be budgeted for accordingly.

E. Research in a military setting, with military Service members and/or Veterans, and/or using military data

Planning for studies to be conducted in military settings, with military or Veteran populations, and/or using military data requires an understanding of military culture, the current capability gaps for the DoD or Veteran medical communities, and requirements for obtaining approvals to conduct the work.
- To better understand how to conduct research in military or Veteran settings see the VA/DoD Collaboration Guidebook for Healthcare Research – 2013 and the US Army Culture for Researchers Book for advice.
- PIs should consider the alignment of their studies with ongoing work of DoD intramural laboratories and current capability gaps and are encouraged to collaborate when possible.
- Securing access to DoD data repositories may require that PIs establish collaborations with military PIs; the funding organization does not provide direct access to such

resources. See the [Guide for DoD Researchers on Using MHS Data](#) for an overview of the military health system and the types of data available to PIs.

- PIs must demonstrate access to military populations for recruitment with a letter of support, signed by the lowest ranking person at the military institution with approval authority, for studies involving active duty military Service members, military-controlled study materials, and military databases.
- For VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must demonstrate access by including a letter of support from their clinical service chief, and non-VA PIs must demonstrate access through: (a) collaboration with a VA investigator where the VA investigator has a substantial role in the research and (b) by including a letter of support from the VA Associate Chief of Staff for Research.

II. Executing a Successful Consortium

In order to maximize the chances for success, consider the following best practices when executing research consortia or other complex collaborative efforts.

A. DoD Processes and Points of Contact

A variety of resources and guidance documents are available for understanding post-award processes and requirements. PIs should carefully review each of the following resources:

- [Congressionally Directed Medical Research Programs (CDMRP) Guide for Funded Investigators](#)
- [USAMRAA website](#)
- [USAMRMC ORP website](#)
- [HRPO Information for Investigators document](#) (for studies involving human subjects research)

Additionally, for complex, multi-institution consortia involving human subjects research, it is particularly important to reach out to USAMRMC HRPO as early as possible to receive guidance on how best to navigate the regulatory process, including development of a protocol using a centralized IRB, where possible. Throughout the duration of the period of performance, frequent communication with the USAMRAA Contract/Grant Specialist, CDMRP Science Officer/Grants Officer's Representative, and ORP Reviewer(s) is encouraged.

B. Consortium Infrastructure/ Coordinating Center

Early planning and a strong infrastructure/coordinating center are integral to consortium success. The PIs should consider the following when initially setting up a consortium:

- Develop a clear SOP early in the period of performance. The SOP outlines elements such as the objectives or mission/vision of the consortium, membership, organization (e.g., voting procedures, types of committees, cores, etc.), processes for soliciting, reviewing, and funding new studies, quality assurance and improvement, authorship, data use agreements and biospecimen sharing, management of data collection,

conflicts of interest, scientific misconduct, intellectual property rights, plan for underperforming projects, and consortium meeting requirements/format.
- Research priorities must be clearly delineated, with input from DoD points of contact, as appropriate, in order to guide consortium efforts.

Because consortium PIs often have competing demands, inclusion of an experienced Project Coordinator to serve as the primary point of contact and a dedicated Regulatory Coordinator to oversee all IRB/USAMRMC HRPO requirements are recommended, as noted in section IC above.

C. EAB/GSC Oversight

Most consortia will have a Government Steering Committee (GSC), External Advisory Board (EAB), or other oversight body.
- A Charter or SOP is created to spell out the roles and responsibilities of these oversight bodies. Obtain a copy of the Charter/SOP in order to fully understand the function of your consortium's EAB/GSC.
- Plan for regular meetings and/or teleconferences with the EAB/GSC or other oversight bodies.
- Keep in mind that, while the independent, field-specific, expert panel mentioned in section IA above advises the consortium, only the EAB/GSC can make recommendations to the Government.

D. Consortium-Funded Research Projects

Consortia are unique in that they consist of multiple individual research projects.
- When new research projects are approved and initiated, we recommend that consortia PIs hold an internal "kick-off" meeting with the project PI and key personnel. This provides an opportunity to outline expectations and processes as well as to establish a clear line of communication for the duration of the project.
- When timelines are being developed for new research projects, be sure that the project PI has planned for regulatory delays, CRADAs, and other agreements that may be needed.
- Setting clear, objective metrics and schedules with contingency plans for slow progress will clarify expectations and help to facilitate successful resolution of any future issues that may arise.

Consortia PIs have a unique responsibility to oversee all consortium-funded research projects.
- Close monitoring of funded research projects, such as conducting regularly scheduled teleconferences with project PIs, in-person progress meetings, site visits, etc., is integral in order to closely track study progress and recruitment.
- If a research project begins to struggle, early intervention by consortia PIs is encouraged. PIs should closely coordinate with CDMRP Science Officers/Grants Officer's Representatives regarding research project issues.

- Where appropriate, the consortium PI may need to discuss with the USAMRAA Contract/Grant Specialist and CDMRP Science Officer/Grants Officer's Representative the possibility of closing a failing study and reallocating the funds within the consortium.

E. Budgetary and Contracting Considerations

Managing a consortium presents numerous unique budgetary and contracting challenges.
- It is important to closely monitor the burn rate, both overall and for individual research projects.
- If delays are encountered and it is anticipated that an EWOF may be required, work with the USAMRAA Contract/Grant Specialist and CDMRP Science Officer/Grants Officer's Representative to confirm that funds will not expire prior to the completion of all tasks. It is important to note that Research Development Test and Evaluation (RDT&E) funds awarded by the DoD differ from funds awarded by other Federal funding agencies in that they expire. See Image 1 below for additional information regarding RDT&E funds.
- If new research projects are to be funded via sub-awards or if any changes requiring prior approval from the Grants Officer are necessary, the consortium PI is encouraged to submit a complete package of the required documents in order to expedite the award modification process.

Image 1.

RDT&E Funds
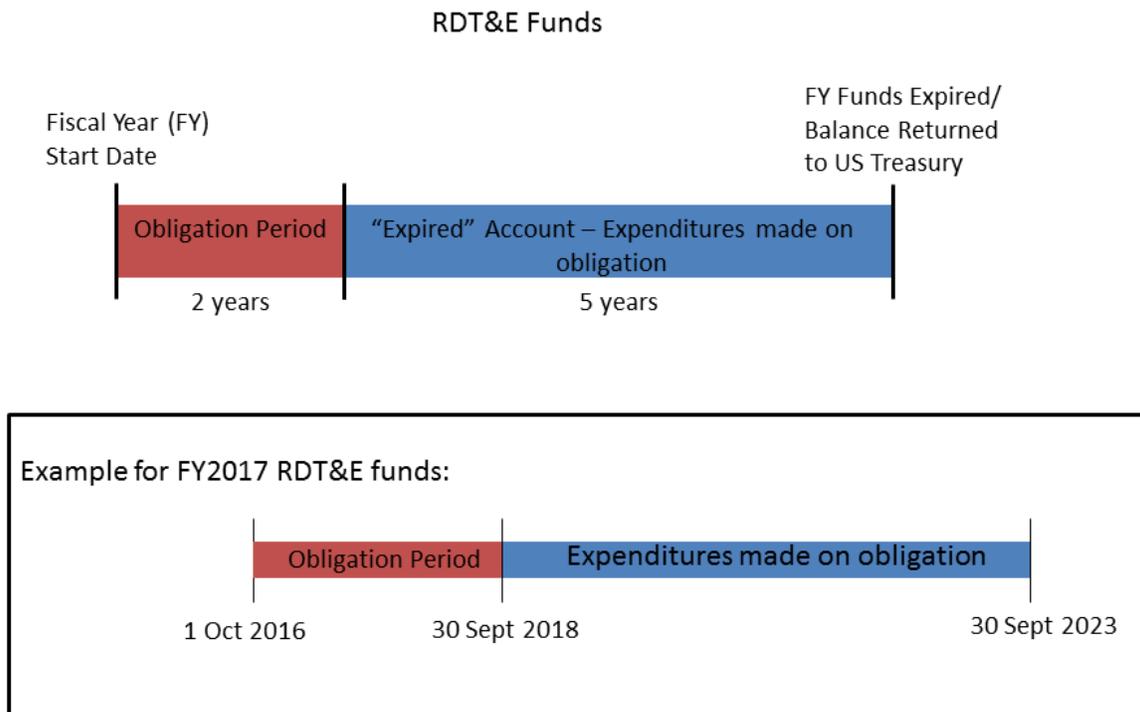
As depicted above, awards made after the obligation period can expend funds that are in an "expired account". This means that the obligation period for the funds has expired and the funds within that account cannot be

obligated or used for any purpose other than that which they were originally obligated. It is important to note that, although the obligation period is 2 years, funds are not always available to be obligated at the start of the 2 year period. Funds are available for expenditure within the timeframe of the award, not to exceed 5 years (see blue bar above). Expired funds are any funds that remain in the expired account after the 5 year expenditure period has ended. Once funds have expired, they can no longer be disbursed from the Government and must be returned to the US Treasury. Note that funds sent within the Government (via Military Interdepartmental Purchase Request, Funding Authorization Document, etc.) must be used within the fiscal year (1 Oct – 30 Sept).

Acronyms

CDMRP	Congressionally Directed Medical Research Programs
CRADA	Cooperative Research and Development Agreement
DoD	Department of Defense
EAB	External Advisory Board
EWOF	Extension without Funds
FOA	Funding Opportunity Announcement
FY	Fiscal Year
GSC	Government Steering Committee
HRPO	Human Research Protections Office
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research Development Test and Evaluation
SOP	Standard Operating Procedures
SOW	Statement of Work
SPO	Sponsored Programs Office
USAMRAA	United States Army Medical Research Acquisition Activity
USAMRMC	United States Army Medical Research and Materiel Command

If you have questions related to the content covered in this document, please contact CDMRP at usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil.