Massachusetts AI & Technology Center

for Connected Care in Aging & Alzheimer's Disease

Required Documents for MassAITC Supplemental Awardees

Please see https://massaitc.org/pilot-resources/ for annotated templates and samples. *Please do not submit without having reviewed samples and all comments in the annotated templates. Revise any previously submitted documents as needed to conform with these instructions.*

How to submit these files

Please create **a single zipped folder** containing final versions of all required documents and email to jmolony@umass.edu. All submitted documentation should be saved as "GY2_*PI Last Name*" followed by the document detail. PDF is the preferred document format.

Document	Notes
NIH PHS 398 – Principal Investigators, Summary & Relevance, Personnel	List PIs and CO-PIs for all sites. Please note that these will be made public via NIH Reporter.
NIH PHS 398 - Detailed Budget, Checklist and Budget Justification	Complete all pages. Budget total must match amount in proposal unless otherwise instructed. Pilots with multiple sites must complete separate sets for each site. Subcontracting costs should not be included on either, UMass Amherst will contract directly with sites. Budget justification should be on separate page. Please note that PHS 398 face page is not required. Click here for NIH budget guidelines.
Research Strategy	Please include a 3-page research strategy document and a 1-page specific aims document. Reference these instructions. Include contact PI name in header. Do not include phrases and/or terms that may be construed as clinical trial activity, such as: • "Clinical trial" • "Intervention" • "Efficacy" • "Human subjects trial" • "Randomized Controlled Trial" or "RCT"
NIH Biosketch	Limit five pages. Required for all PIs. Only NIH formatting is acceptable.
Study Record: PHS Human Subjects and Clinical Trials Information Form	Complete if your study has human subjects. Use this decision tool to help make determination. How to open the form. MassAITC does not fund clinical trials.

	Reference these instructions and complete all *required* attachments per guidelines.
UMass Subrecipient Commitment Form	Federal Demonstration Partnership Member Institutions must complete the FDP subrecipient commitment forms, other must complete the non-FDP form. Separate Subrecipient Commitment Form required for each site for multi-site awards. For industry awardees, if your organization does not have a compliant audit report, please submit two years of tax returns for your organization. Once we confirm that your documents and budget can be finalized, please have this document signed by a University Sponsored Research Office or other authorized official. Not required for UMass PIs. Budget numbers included must match NIH PHS 398 budget forms.
Statement of Work	Typically no longer than one page. Separate statement of work required for each site for multi-site awards. Include contact PI name in header. Detailed enough to legally define the site's role and responsibilities in the research. Provide sufficient details and specify criteria for measuring success and related rationale. Specify the timeline for each milestone.
F&A rate Agreement	If available, otherwise use De Minimus indirect rate of 10%.
Data and Resource Sharing Agreement	Complete and sign.
Funding Overlap Policy Compliance	Complete and sign.
Letters of Support	1-3 optional letters of support may be included.

Determining overlap with SBIR Funding

For industry applicants, the NIA has given strong guidelines that they will not fund any applications that overlap any current or past SBIRs awarded to an applicant. If you have a current or past SBIR, please compare aims and the technology you will be developing in each application in anticipation of a careful review for any overlap between projects.

To be eligible for MassAITC pilot project funding, pilot project teams must also agree to participate in the following activities:

- **Data sharing:** NIA requires a cohesive Data Sharing Plan across all participating AITCs. The specific details of this plan are still in progress but will be shared with you as soon as possible. Please note that you will be asked to share non-proprietary data through a Collective-controlled

data commons of de-identified clinical and biomedical source data (not algorithms) for AI inference.

- **IRB:** Every study staff member included on the Institutional Review Board (IRB) is required to fulfill CITI Training Requirements. Current CITI Training certificates should be kept in the study's local regulatory files and submitted to the Executive Director.

  Prior to initiating any human subjects research, you are required to obtain IRB approval either your local IRB (if applicable) and by the UMass Amherst IRB. The following documents may be required for submission depending on specific details of your pilot project:

  - Detailed Protocol
  - Data to be collected
  - Patient/Subject-facing materials
  - Consent document(s)
  - Case Report Forms (CRFs), surveys, and interview guides
  - Reliance agreement

  You will also need to follow all IRB regulations for reporting things such as protocol deviations, adverse events, regulatory record-keeping and continuing review. Please make sure you are aware of your local or UMass Amherst IRB requirements.
- **Announcement of pilot project award:** We would like to publicize your award on our website and newsletter. The announcement will include basic information about their pilot project including their project title and abstract, and the names and affiliations of the lead investigators. We may also request a short video, and descriptive graphic.
- **Participation in quarterly progress meetings.** Pilot project teams are required to meet at least once a quarter with representatives of MassAITC to discuss the status of their pilot project. We will ask you to submit a progress update prior to the quarterly meeting.
- **Participation in webinar series.** MassAITC hosts monthly webinars aimed at fostering collaboration and growing a multidisciplinary network of researchers and practitioners. Pilot PI(s) are encouraged to attend these monthly webinars. Additionally, Pilot PI(s) will be required to present their project during one of the monthly webinars.
- **Attendance at annual meeting.** At least one pilot project lead investigator must attend the AITC annual symposium in Philadelphia during the award period. Funds to attend the annual meeting must be included in the pilot project budget(typically about $3,000).
- **Resource sharing:** Where possible, pilot projects should plan to share resources derived from this funding with the research community.