Pre-Application Technical Assistance Webinar

Precision Medicine Initiative® Cohort Program

January 14, 2016
12:00-1:30 PM Eastern Time
## PMI Cohort Program Funding Opportunities

<table>
<thead>
<tr>
<th>Title / Type</th>
<th>Year 1 $</th>
<th>Number of awards</th>
<th>Project Period</th>
<th>Application</th>
<th>Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Volunteers Pilot Studies (OT)</td>
<td>TBD</td>
<td>1</td>
<td>1 yr</td>
<td>December 22, 2015</td>
<td>February 2016</td>
</tr>
<tr>
<td>Communication Support for the Precision Medicine Initiative Research Programs (OT)</td>
<td>TBD</td>
<td>1</td>
<td>2 yrs</td>
<td>December 22, 2015</td>
<td>February 2016</td>
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<tr>
<td>PMI Cohort Program Biobank (U24)</td>
<td>$15 M</td>
<td>1</td>
<td>5 yrs</td>
<td>February 4, 2016</td>
<td>June 2016</td>
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<tr>
<td>PMI Cohort Program Coordinating Center (U2C)</td>
<td>$21 M</td>
<td>1</td>
<td>5 yrs</td>
<td>February 17, 2016</td>
<td>July 2016</td>
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<tr>
<td>PMI Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3)</td>
<td>$28 M</td>
<td>≤7</td>
<td>5 yrs</td>
<td>February 17, 2016</td>
<td>July 2016</td>
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<tr>
<td>PMI Cohort Program Participant Technologies Center (U24)</td>
<td>$8 M</td>
<td>1</td>
<td>5 yrs</td>
<td>February 17, 2016</td>
<td>July 2016</td>
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Coordinating Center (U2C)

PMI Cohort Program Coordination Center

1. Administrative Core
2. Data Core
3. Research Support Core

- HPOs (5-7 Centers)
- Biobank
- Participant Technologies
Coordinating Center: Administrative Core

- **Scientific & Administrative Leadership**
  - Ensure effective transition from pilot phase
  - Coordinate consortia-wide process for development of the baseline protocol and subsequent core protocol additions
  - Coordinate and monitor baseline protocol implementation
  - Provide consortium-wide logistical support
  - Co-chair Steering and Executive Committees
  - Monitor enrollment, retention, and tracking of data submissions from both DV and HPO participants
  - Monitor diversity across the Cohort

- **Direct Volunteer Operations**
  - Point-of-contact for direct volunteers
  - Schedule & track biospecimens and physical evaluations

- **Healthcare Provider Organization (HPO)-related Operations**
  - Ensure effective protocol implementation and consistent patient engagement strategies
Coordinating Center: Data Core

- **General Functions**
  - Develop & maintain all shared scientific and management data resources for the cohort
  - Develop and oversee implementation of a common data model
  - Establish standards and implement processes for federated data resources, such as legacy HPO health care data
  - Establish and implement standards for RUID, consent preferences, self-report, clinical & biospecimen data, return of results
  - Oversee all aspects of data security
  - Oversee all steps necessary to protect the privacy of participant data

- **Health IT Specific Operations**
  - Provide effective interfaces that facilitate integration of data from health IT records both from HPOs and from DV (Blue Button) records
Coordinating Center: Research Support Core

- Establish and oversee secure computing environment
- Define analytical capabilities for data core
- Develop software tools & algorithms for datasets
- Provide all needed researcher-focused services
- PoC for all users at all levels of sophistication to design and implement studies using the PMI Cohort Program datasets and technical issues
- Provide interface to future –omics lab services
- Oversee the development, analysis and quality assessment of cohort-wide lab analysis
Healthcare Provider Organization Enrollment Centers (UG3/UH3)

- Establish structures to enroll participants, meeting diversity targets
- Establish effective local participant engagement, monitor participant enrollment and retention
  - UG3: >10K expected enrollees
  - UH3: >35K expected enrollees/yr
- Conduct baseline physical evaluation on all enrolled participants
- Collect baseline biospecimens on all enrolled participants. Legacy biospecimens will not be used.
- Establish methods to capture complete health care information of all enrolled participants, both ongoing and when possible legacy data.
- Develop methods to transmit health care information to CC in standardized format, meeting interoperability standards across the consortium
  - Standards for EHR capture and representation of family health history
  - SNOMED CT and HL7 Version 3
Pilot enrollment through FQHCs
Enhances a focus on underserved populations
  – FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act (PHS)
  – FQHCs must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors
  – Certain tribal organizations and FQHC Look-Alikes (an organization that meets PHS Section 330 eligibility requirements, but does not receive grant funding) also may receive special Medicare and Medicaid reimbursement
- Develop, upgrade mobile applications developed in pilot phase for DV enrollment, supporting their use for entire cohort
- Provide parallel platforms for non-smartphone users (e.g., feature phones, web site)
- Provide scientific leadership and technical expertise for use of mHEALTH technologies across the cohort
  - Develop, pilot and implement use across the cohort of data acquisition from a wide array of potential participant technologies,
  - Devices should include participants own devices, novel sensors and wearable devices
- Test emerging technologies for study deployment, validate, and co-calibrate emerging technologies with existing technologies to ensure continuity of trend data over time
Biobank (U24)

- Provide biospecimen collection kits and mailers
- Receive, process, store, and distribute:
  - Phase 1: receive saliva or blood
  - Phase 2: plasma, serum, RBCs, buffy coats, urine, DNA
- Establish automation of specimen aliquoting, DNA extraction initially; Transition to automated specimen retrieval systems, when it is cost effective
- Set up information systems for sample tracking, coordinating RUIDs with CC as well as other PMI Cohort Program sites
- Establish robust QA and QC, CLIA processes
Other Transaction Authority

- Pilot Phase
- Systems & Services
- Communications & Public Relations
Direct Volunteers Pilot Studies (OT)

- Develop and test innovative methods and technologies for data collection and management, and participant engagement.
  - Website to engage potential volunteers
  - Participant interface optimized to keep participants engaged and return information
  - Data structures ensure the secure collection and sharing
  - Approaches for biospecimen collection
Support communication efforts for the PMI research programs at NIH, with particular emphasis on the PMI Cohort Program:

– Communications planning, message and visual identity development

– Collection and analysis of evaluation metrics.

– Outreach through a variety of strategies and platforms
PMI Cohort Program Information

Email address for questions related to PMI Cohort Program FOAs:

PMICPFOAIInquiries@mail.nih.gov

Link to FAQs on the PMI Cohort Program Website: