RTRN™

RCMI TRANSLATIONAL RESEARCH NETWORK

RTRN Steering Committee Meeting Biorepositories Working Group

Chair: Luisel Ricks-Santi

Sept. 20, 2016

Goals, Mission and Vision

Mission and Vision

- To improve the quality and availability of biospecimens from ***ethnically diverse populations*** by increasing access to technical assistance, addressing ethical, social, and cultural issues, improving informed consent processes and dissemination strategies for participants and researchers, and ultimately ensuring that biospecimens and associated data are used in effective and ethically sound studies designed to reduce health disparities in the communities served by RCMI grantee institutions.

Goals

- To identify and leverage biospecimen resources within the RCMI community and share best practices.

BWG Members

Luisel Ricks-Santi, Ph.D., Hampton University
Nathan Bowen, Ph.D., Clark Atlanta University
Muneer Abbas, Ph.D., Howard University
Josh Astern, Ph.D., University of Hawaii
Billy R. Ballard, M.D., D.D.S., Meharry College of Medicine
Gene D'Amour, PhD, Xavier university
Timothy Dye, Ph.D., University of Rochester
(formerly University of Hawaii- RMATRIX)
Idhaliz Flores, Ph.D., Ponce School of Medicine and Health Sciences
Solomon Garner, PhD, Jackson State University
Rob Kirken, PhD, UTEP
Edna Mora-Pinero, MD, UPR
Sidd Pratap, Ph.D., Meharry Medical College
Jeremy Ross, PhD, UTEP
William Seffens, Ph.D., Morehouse School of Medicine
Natalia Silvestrov, M.S., Morehouse School of Medicine
Stephen Sodeke, PhD, Tuskegee
Winston Thompson, PhD, Morehouse School of Medicine
Bradford Wilson, Ph.D., Howard University

BWG Active Members: Oct. 13th 2015 "Head Count"

"Can you please update me on your status with the Biorepositories Working Group? I need a quick head count of active members.

Please indicate, if you're available to participate in

- Conference calls
- Surveys
- Grant writing
- Technology/software development
- Abstract development
- Conference presentations
- Other (please specify)_____"

- 7/22 responses*

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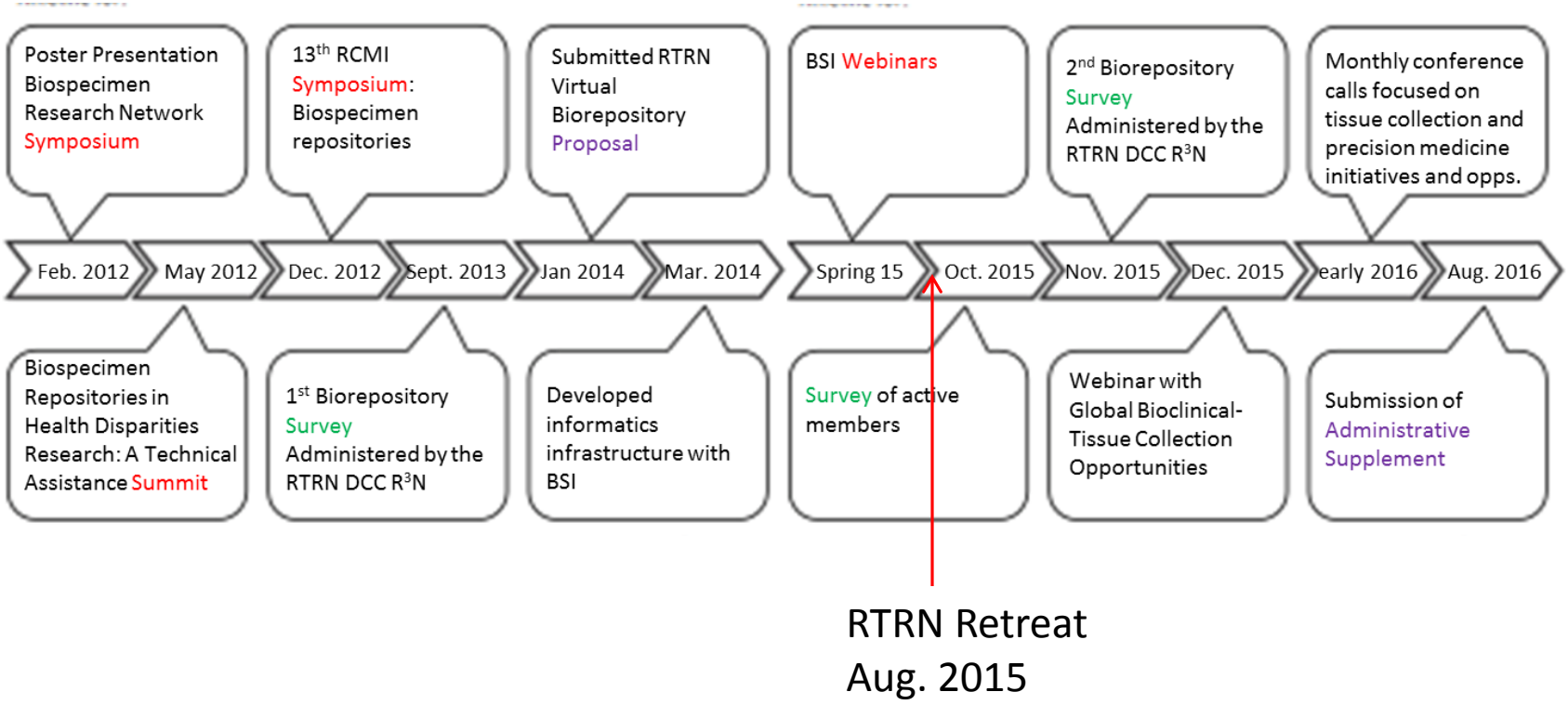
Stephen Sodeke, PhD, Tuskegee
Bradford Wilson, Ph.D., Howard University

Red- responded to head count request
Green- active but did not respond

Timeline of BWG Activities



Survey Results for Biorepository

	Yes	No	
• Centralized Tissue Repository	26.1%	73.1%	
• Non-Centralized Tissue Repository	38.8%	61.2%	
• Collect bio samples for research	45.6%	54.4%	
• Store bio samples for research	42.6%	57.4%	
• Can RTRN contact you if yes	48.4%	51.6%	
• Clinical Partner	22.2%	77.8%	
• Biorepository linked to a database	18.2%	81.8%	
• Informed consent all for “storage and future use”	41.9%	58.1%	
• Additional consent for “storage and future use”	18.8%	46.9%	both 34.4%

- **Sample tracking, inventory, process LIMS (Laboratory Information Management System)** (11, 19.3%), MS Excel (14, 24.6%), MS Access (5, 8.8%), CaBig (CaTissue, CaLIMS etc.) (0, 0%), Physical lab notebook (14, 24.6%), None (26, 45.6%)
- **Type of samples** - DNA (21, 45.7%), Plasmids (12, 26.1%), Antibodies (11, 23.9%), Malignant tissue (8, 17.4%), Benign tissue (8, 17.4%), Diseased tissue (4, 8.7%), Normal tissue (14, 30.4%), Biofluids (urine, serum, plasma, buffy coat) (14, 30.4%), Blood (16, 34.8%), Placenta (3, 6.5%), Breast, Uterus & Ovary (4, 8.7%), Colon, Stomach, and Esophagus (4, 8.7%), Kidney, Bladder & Prostate (1, 2.2%), Liver, Pancreas, & Spleen (2, 4.3%), Lung, Pharynx, & Oral Cavity (1, 2.2%), Brain, Spinal Cord, & Peripheral Nerves (2, 4.3%), Muscle, Skin & Soft Tissue (4, 8.7%), Primary cells from tissue (6, 13%), Cell lines (28, 60.9%)
- **Type of data for specimens Demographic** (Race, ethnicity, gender, DOB, etc) (21, 53.8%), Height (11, 28.2%), Weight (12, 30.8%), BMI (12, 30.8%), Clinical (Patient Vitals, Pathology/Radiology Reports etc.) (18, 46.2%), Non-clinical (Medical & Family Medical History) (8, 20.5%), Other (19, 48.7%)
- **Purpose of biorepository** All biospecimens (i.e pathology samples and blood collections) collected at our institution are automatically stored in the biorepository (4, 8.9%), Specimens were collected specifically for biorepository purposes (10, 22.2%), Specimens were collected as part of an old or existing study, then were deposited and stored in a biorepository (15, 33.3%), Specimens were collected as part of an old or existing study, then were kept in our freezers or other storage for long-term storage (17, 37.8%), I am not sure that I have a biorepository (14, 31.1%), Other (4, 8.9%)
- **Location of repository Off-site** (3, 7%), In our hospital (1, 2.3%), In a lab (24, 55.8%), In a designated storage facility at our institution(15, 34.9%), Other (6, 14%)
- **Shared or separate from Institution** Shared (11, 29.7%), Separate (23, 62.2%), Both (3, 8.1%)
- **Interest in a RCMI biorepository** Not Sure (19, 45.2%), Yes (16, 38.1%), Yes, but only if others were doing the same kind of research I was doing (2, 4.8%), Yes, but only to other RCMI investigators (2, 4.8%), Yes, but only for Health disparities Research (1, 2.4%), No (5, 11.9%), Other reason (0, 0%)

RTRN Administrative Supplements: Specific Aims

Specific Aim 1: Discover and manage existing research biorepository resources within the RCMI Consortium by building a scalable, secure and compatible infrastructure to facilitate the standardization of data- and biospecimen-sharing across all RCMI institutions.

a) Continue identification and accrual of biospecimens at collaborating RCMI institutions.

b) Gather available clinical and demographic data and characterize biospecimens at collaborating institutions.

c) Leverage an existing laboratory information management system (LIMS), such as BSI, to annotate and store biospecimen location and biomarker data

Specific Aim 2: To **launch and implement the RTRN "Virtual Biorepository", a clinically annotated and catalogued database of biospecimens stored across collaborating RCMI institutions by providing online and on-site training on the newly developed RTRN LIMS.**

a) To establish the virtual biorepository, the RTRN will deploy and implement a laboratory information management system (LIMS) as part of a larger enterprise biospecimen management system rollout.

b) To facilitate the utilization of the RTRN V-Bio by providing online and on-site training

Opportunities and Challenges

Opportunities

- To provide PIs with resources for tissue annotation and biorepository infrastructure
- To provide technical assistance and tissue procurement protocol harmonization
- To share ideas
- To increase research collaborations between institutions
- To improve grant proposal success rates due to increased collaborations

Challenges

- Biorepositories at different stages of organization (i.e retrospective vs. prospective)
- Decentralized biobanks (~75% of RTRN biobanks)
- Biorepositories result from studies- sometimes afterthought
- Time consuming effort that requires personnel, resources, and infrastructure
- Sharing tissues not feasible for different reasons (i.e IRB, “precious”, not well annotated, etc.)

Recommendations

- Send out invitation for new and engaged members
- Help provide infrastructure
  - Software for biobanking
  - Personnel and time for tissue annotation
- Incentivize biobanking
  - If you're part of network, informatics, personnel may be provided for a limited time
- Focus on institutional preparation for PMI studies

https://grants.nih.gov/grants/guide/notice-files/NOT-PM-16-006.html

Notice of Intent to Publish a Reissue of Funding Opportunity Announcement for the Precision Medicine Initiative® Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3)

Notice Number: NOT-PM-16-006

Key Dates

Release Date: June 27, 2016

Estimated Publication Date of Announcement: Early Spring 2017
First Estimated Application Due Date: Late Spring 2017
Earliest Estimated Award Date: September 2017
Earliest Estimated Start Date: September 2017

Related Announcements

NOT-PM-16-007
RFA-PM-16-002

Issued by

National Institutes of Health (NIH)

Purpose

The NIH Precision Medicine Initiative® (PMI) Cohort Program intends to issue a second funding opportunity announcement (FOA) to solicit applications proposing to provide support for centers to enroll participants from U.S. healthcare provider organizations (HPOs) into the PMI Cohort Program. The goal of the PMI Cohort Program is to build a research cohort of one million or more U.S. volunteers who are engaged as partners in a longitudinal, long-term effort to transform the understanding of factors contributing to individual health and disease.

This FOA will be a second issuance to expand the catchment areas and participant populations being recruited by HPOs in the PMI Cohort Program. Awards from the first issuance of RFA-PM-16-002 will be announced on the PMI Cohort Program Funding website when they are made.

This Notice is being provided to allow potential applicants sufficient time to develop responsive projects.

The FOA is expected to be published in early Spring 2017 with an expected application due date in late Spring 2017.

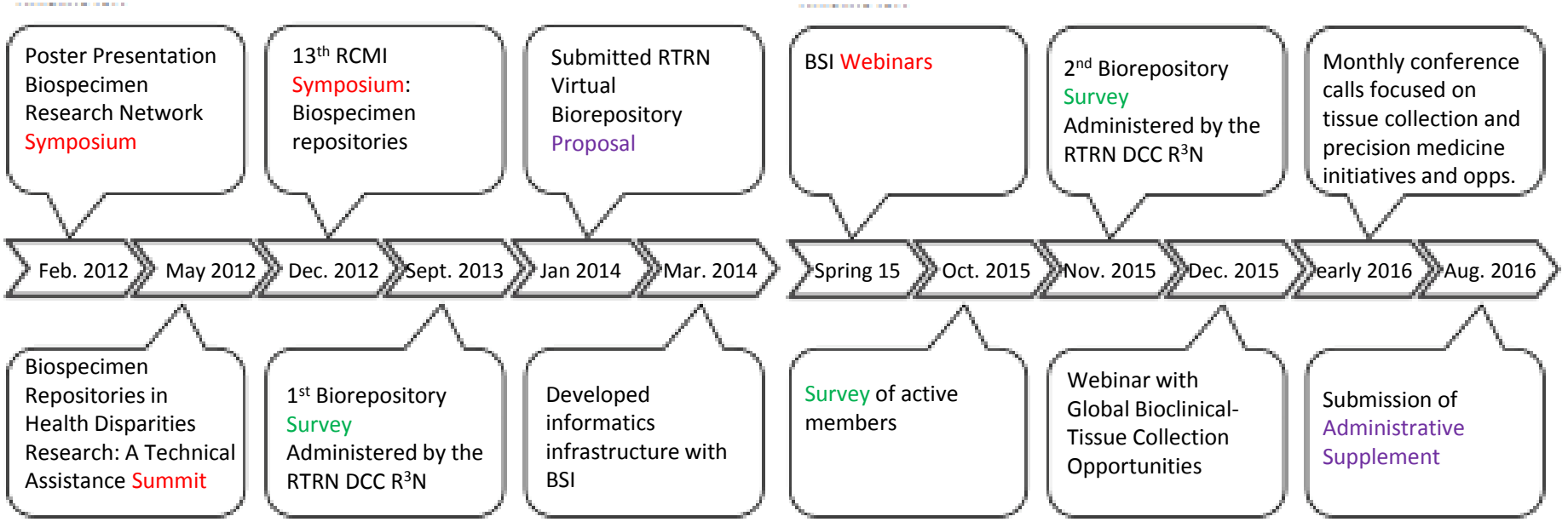
This FOA will utilize the UG3/UH3 activity code. Details of the planned FOA are provided below.

Research Initiative Details

The goal of this initiative is to solicit HPOs that expand the catchment areas and participant populations for the PMI cohort program. HPOs awarded from this FOA will join a network of HPOs awarded through RFA-PM-16-002, and are expected to compliment and collaborate with activities being done by those HPOs, as well as by the Data and Research Support Center, Biobank and Participant Technologies Center. HPOs are key partners in the PMI Cohort. HPOs will be responsible for collaborating on engagement and enrollment, communication, biospecimen collection, healthcare data collection, and participant retention for the participants enrolled through their efforts. These data will be made available as a rich research resource for addressing precision medicine research questions. Awards made through this FOA will initially support a 1-year, milestone-driven development phase (UG3), with possible rapid transition to a full implementation phase (UH3). UH3s will be awarded after administrative review of eligible UG3s that have met the scientific milestone and feasibility requirements. The UG3/UH3 application must be submitted as a single application, and applicants should note specific instructions for each phase in this FOA.

Joni L. Rutter, PhD
Director, Division of Programs & Strategic Implementation
Precision Medicine Initiative® Cohort Program

Timeline of activities



*Email list for Oct. 2015 survey

'Gene D'Amour' <gdamour@xula.edu>; 'wseffens@msm.edu'; 'Wilson, Bradford D.' <bradford.wilson@howard.edu>; 'solomon.t.garner@jsums.edu'; 'brballard@mmc.edu'; 'IFLORES@psm.edu'; 'Ross, Jeremy' <jross@utep.edu>; 'bowen@cau.edu'; 'astokes@hawaii.edu'; 'snekhai@howard.edu'; 'juan.salomonandonie@howard.edu'; 'nerurkar@hawaii.edu'; 'nbrowner@msm.edu'; 'tim_dye@urmc.rochester.edu'; 'Karen.martinez4@upr.edu'; 'dsarpong@xula.edu'; 'xieh@TSU.EDU' <xieh@tsu.edu>; 'Kaumudi.Joshipura@upr.edu'; 'eddy.rios@uccaribe.edu'; 'cyates@mytu.tuskegee.edu'; 'rnoel@psm.edu'; 'sodeke@mytu.tuskegee.edu'; mabbas@howard.edu; Osafo, Nana Y. (nosafo@Howard.edu); spratap@mmc.edu; WHITE KRISTA <KRISTA.WHITE@HAMPTONU.EDU>; 'm.edwina.barnett@rtrn.net'; 'mforeman@msm.edu'; 'ncrowell@msm.edu'; 'traci.hayes@rtrn.net'; 'cajackson@msm.edu'; cyates@mytu.tuskegee.edu; 'sodeke@mytu.tuskegee.edu'; Taylor, Robert E. (rtaylor@Howard.edu); Gerald Porter (gwporter2@gmail.com)