Making Your Organizations Registry and or Biobank a Reality

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http://www.resourcerepository.org/documents/2030/makingyourorganizationsregistryandorbiobankareality/
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**Mission:** To make CFS widely understood, diagnosable, curable and preventable.

**Research Strategy:** To build, support and link a critical mass of innovative and credible researchers focused on early detection, objective diagnosis and effective treatment and to create, identify and leverage new private and federal funding sources and opportunities for CFS investigators.
What do we know about CFS?

- Diagnosis – characteristic symptom pattern, exclude other causes – no single test
- 7-8 different definitions used for research
- At least one million Americans affected; millions worldwide
- Less than 20 percent diagnosed
- 25 percent of CFS patients completely disabled; by definition CFS is disabling
- 4 times more common in women
- Different levels of severity, remitting-relapsing pattern
- Most frequently diagnosed in ages 40-50, but all ages (including teens) can get it
- Occurs in all ethnic & racial groups, all income & education levels
- Occurs in families (mother-daughter), suggesting genetic link or common exposures
CFS is a mixture

Classify based biomarkers

Molecular subtyping

Pharmacogenomic interventions

CFS in clinic populations vs. community samples

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Classify based biomarkers

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CFS

prolonged fatigue

comorbid
CFS is challenging to study
CFS Research Network

Some common instruments
Some common samples collected
Hard to standardize
IRB, hypothesis-driven barriers
Biobank is a solution

To bridge the gap

Bench Bedside
Biorepository helps address these research challenges

- Drawing participants across geographic boundaries
- Consistent entry criteria for subject selection
- Consistent data collection
- Follow participants over time, multiple sample points
- Greatest cost for studies is enrollment of well-characterized subjects
- Customize sample collection for different hypotheses
- Cross-study validation of promising research
- Provides a common platform for:
  - Institutional Review Board approval – necessary for protection of people (human subjects) involved in research (significant hurdles in academia)
  - Informed Consent – crucial to help participants make the right decision about participating in research (clinical info vs. research info)
Biorepository helps ACCELERATE RESEARCH
The SolveCFS BioBank is unique in CFS research field

- Scalable – rare or common, different comorbidities/overlaps
- Operational infrastructure includes:
  - Institutional Review Board – necessary for protection of people (human subjects) involved in research
  - Informed Consent – to help you make the right decision about participating in research
  - Web-based collection of standardized clinical information
  - Blood/tissue sample collection, processing according to standard procedures
  - Inventory and tracking of samples
  - Data management
  - Data and sample query tools
  - Strong security & access control
  - Knowledge base & expertise of others (Genetic Alliance – huge resource!)
- Customizable for different studies
Timeline for Initiation of SolveCFS BioBank

- Conceptual: Pre-2007 interest in biorepository & registry
- Research network: Established early 2009
- Awareness of Genetic Alliance BioBank: September 2009
- Expedited due diligence: September-November 2009
- Board Approval: December 2009
- Application to Genetic Alliance: January 2010
- IRB approval: March 8, 2010
- Announcement to community: March 29, 2010 (targeted enrollment)
- First sample collected: April 2010
- Begin first study collaboration: May 2010
- General enrollment announcement: June 8, 2010
- Total enrollment as of Aug. 1:
The SolveCFS Biobank is a Catalyst for Translational Research

- **The SolveCFS Biobank is a cost-effective resource for research**
  - Engages all stakeholders (e.g., researchers, advocates, patients, pharma, etc)

- **Creates opportunities for cooperative research**

- **Asset as a hub for quality biologic samples and standardized clinical information**

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