Title of proposed program: Allowing Every Individual to Become a Research Subject

Submitting Source: Strategic Planning Meetings

What is the major obstacle/challenge/opportunity that the Common Fund should address?

Identifying, enrolling and maintaining human subjects in health research studies present unique challenges. Despite the vast number of patients currently served by health care systems in the U.S., health data collected by these systems are rarely accessible to outside investigators. No widely accepted policies and approaches currently exist to allow individual health care patients to enroll freely in research studies. Yet the contribution of these data to the research enterprise could have an enormous impact on advancing clinical discoveries and improving patient care by establishing a positive feedback loop to provide patients with timely health information. Barriers to allowing "every patient can become a research subject" include ethical, legal, and social impediments, uncertainty about which types of data to capture, difficulty in linking disparate patient data sources, and measurement of impact on patient health.

What would the goals of the program be?

This program would have 4 goals:

- Address ethical, legal, social implications of enabling every patient to become a research subject
- Define ideal data sources and sets for capture
- Integrate datasets via visually intuitive formats
- Measure impact of program on improving human health and well being

Why is a trans-NIH strategy needed to achieve these goals?

Incorporation of all patients into a collective pool of research subjects is too massive an enterprise for any one IC, although the program would be of potential benefit to all ICs.

What initiatives might form the strategic plan for this topic?

- Address ethical, legal, social implications of this type of research model
    - Address privacy/policy/ethical issues/anthropology
    - Develop procedures for every patient to give informed consent
    - Develop procedures to share results with subjects
    - Develop educational tools for the public
    - Incentivize patient participation
- Define optimal sources of data for capture
    - Develop standards for consistent data collection
    - Expand and systematize patient outcomes in a way that increases benefits
- Integrate datasets
    - Create links to Knowledge Network
    - Develop storage and sharing methods
    - Provide training to ensure input of quality data

- o   Develop ontologies
  - o   Systemize outcomes
- Measure impact of program
  - o   Develop tools, methods, and analytical procedures to measure impact

If a Common Fund program on this topic achieved its objectives, what would be the impact?
A successful program would create a new model for clinical research, potentially change the culture regarding ownership of clinical data, and lead to development of pragmatic and sensitive approaches to privacy, ultimately improving human health.