



4301 Connecticut Avenue, NW  
Suite 404  
Washington, DC 20008  
202.966.5557  
info@geneticalliance.org  
<http://www.geneticalliance.org>

## **Proposal for Public Awareness and Advocacy Campaign: Educating the Public to Understand the Learning Healthcare System and What It Takes to Get Us There**

### **Background/justification**

In the upcoming months, US citizens will be faced with several opportunities to provide input into several very important rules and regulations.

- The Notice of Proposed Rulemaking for the Common Rule is due out any time. This is a critical time to engage the public and inject the process with more than the typical special interest groups' ideas. The last change in the Common Rule was 1991 – this is an opportunity that won't be available any time soon again.
- PCORnet, the National Clinical Research Network, represents the greatest single investment the nation has made in clinical research, more than \$100 million for the first 18 months. This is a 'moon shot' and should be given all of the support it can get. The public's understanding (including policy makers) of the nature of clinical research, evidence, standards of care, and the establishment of the learning healthcare system is woefully limited. This has to be bolstered in the next several months.
- The Office of Human Research Protections is currently drafting guidelines for research conducted or sponsored by the HHS that would help clarify what constitutes foreseeable and disclosable risks. This is a critical juncture – a lack of understanding about how the healthcare system learns what should be standard of care would drastically delay our capacity to improve care.
- Costs of care are astronomical for the US, as evidenced by the IOM Report, Bending the Cost Curve. How to make care more patient centric, and less costly, critical issues for the nation, an informed populace is an essential factor to the national debate.

### **Action Phase 1:**

Ten Webinars (these are the content areas, not the catchy titles) spaced two weeks apart for 20 weeks, all recorded and archived. Genetic Alliance webinars typically have a hundred real time viewers and thousands of archive viewers. Topics and order are draft only.

1. Isn't the Healthcare System already Learning?
  - a. How healthcare providers know what is best for patients
  - b. How healthcare providers know what is best to do
  - c. Gaps in both of the above
2. How we do Harm in America (can't use title – Otis Brawley's book, but we can try to get him)
  - a. A question of lack of evidence, Russian roulette
3. Where are the needs?
  - a. Life span issues

- b. Heavy burden of disease
- 4. What biomedical research can do for you?
  - a. Examples of common and rare interventions that have resulted from research
  - b. Types of research – basic, translational, clinical; behavioral, outcomes, best practices...
- 5. How is biomedical research conducted?
  - a. Hypothesis
  - b. Testing
  - c. Meaningful (statistically)
  - d. Reproducibility
  - e. Double blind placebo controlled
- 6. What are the ethics of conducting research with human participants?
  - a. Risks and benefits
  - b. Various laws and rules that govern the conduct of research
- 7. Patient Outcomes focused research
  - a. Trials that test current standard of care
  - b. Research that develops best practices
  - c. Research that focuses on what do people want – participant/patient-centric
- 8. Research on Standards of Care
  - a. When to consent
  - b. How to build awareness
  - c. How to assess risk
- 9. How to have your voice heard?
  - a. What actions can ordinary citizens take?
  - b. What actions can advocacy orgs take?
  - c. What actions can professionals take?
- 10. Building a coalition for making America stronger in biomedical research
  - a. The role of all stakeholders working together

**Action Phase 2: Technical assistance to disease advocacy organizations to respond to the OHRP draft guidance and Common Rule**

Conference calls for the coalition

Template letters to make the process simple

Campaign to get groups to send letters

Campaign to get sign on to Genetic Alliance letter

Visits by advocates/clinicians/researchers to:

- OHRP

- Secretary

- Key congressional members (Alabama senators, other impacted states)

- Other key people

Social media campaign