# Moving from Informed Consent to Informed Choice: An Ethical Imperative

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## Abstract

***Goal:* Our goal is three-fold**

**1) To provide cancer patients who are approached to enroll in a clinical trial with the needed educational materials to make an informed decision**
**2) To provide the professionals doing the consenting with training on barriers from the patient perspective.**
**3) To convey that "informed choice" is a patient's right and a doctor's responsibility to the greater research community.**

A 2001 study by Lara et al reported that the consent process with its legalistic and confusing forms is itself a barrier to patient participation with 49% of eligible patients declining enrollment.

***Strategy* : CISN principals are currently working with the following groups**

Cooperative Groups: ACRIN, CALGB and ACOSOG: Academic Medical Centers: UCSF and Mayo; Industry: Genomic Health, Genentech, Pfizer and Lilly; Nonprofit Organizations: AACR, Faster Cures, NBCC, OCNA, C-Three and PanCan

***Action Taken***

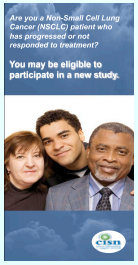
CISN is introducing the medical community to an array of issues affecting patients considering participation in clinical trials. They are also developing patient-centered, study specific, educational materials included as part of the informed consent process that may enhance patient literacy, improve patient satisfaction and advance public trust in the research enterprise, leading to responsible increased accrual and retention. Plans are being developed to move this work into template format and placed into the public domain so that all PIs and patients can benefit. A CISN principal has also been invited to serve as faculty for the annual AACR/ASCO Clinical Methods in Research Workshop, where young faculty learn how to develop study protocols and write good consent forms.

Recent work done at the Clinical Trial Summit documented that 67% of professionals consenting patients have less than 6 hours of psychosocial training. To address that issue, CISN developed a training program for those professionals who administer consent. Two PhD psychologists where brought onboard as consultants to assist in the development of the training. To date CISN has conducted two trainings at Mayo, one for ACRIN RAs at their annual meeting and one at a recent SoCRA meeting.

## Strategy

CISN's mission is to bridge the gap between stakeholders by working in a collaborative manner. We introduce the medical community to new, patient centered strategies that increase patients understanding. This leads to a more informed choice, resulting in a more ethical process.

## I. CISN / Genentech Project




CISN and Genentech have partnered to provide cancer patients with educational information about a clinical trial they may be eligible for.

**Materials Developed:**

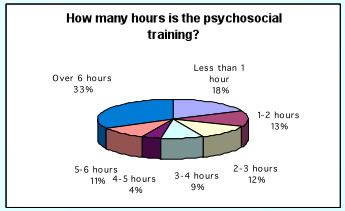
- A patient-centered educational brochure **(pictured here)**
- A study schema charting clinical visits and other study milestones that also serves as a calendar for both clinical staff & patients.

## II. Data on the Need for Staff Training

A questionnaire administered to attendees at the yearly Summit on Clinical Trials and to other CRA's across the Country, showed the gaps in training for those professionals administering consent.

**67% of all those surveyed have less than 6 hours of psychosocial training**: on how to work with people in shock, exasperated by cognitive overload.

Joining a clinical trial is a critical decision that patients may be faced with. Having well trained staff assist in the informed consent process, should be considered a component of good quality care.



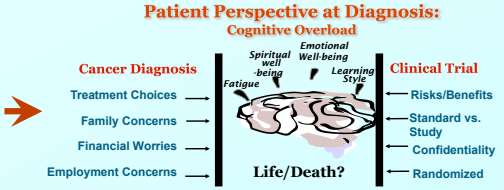

## III. Staff Training

**Barriers to clinical trial accrual from the patient perspective:**

Studies show that when people are faced with life or death decisions they enter a period of decisional conflict.

In today's fast paced clinical practice very little time is given to educating patients about clinical trials in general or the specific clinical trial they may be eligible for. Compounding this problem patients are locked in decisional conflict and suffering from emotional, physical and cognitive overload – **see example**

**This training was developed by CISN in collaboration with Jane Perlmutter, PhD and Paula Finestone, PhD**




**Slide courtesy of Jeff Belkora, PhD, UCSF in collaboration with CISN**

## IV. Other Projects

- A website to educate patients about clinical trials
- A Clinical Trial "Toolkit" that includes study templates and a staff training on DVD
- An informational brochure about clinical trials
- An advocate training for GI advocates on how to review a clinical trial protocol in collaboration with C3
- A web-cast on the barriers to clinical trials from the patient perspective that can be used for staff training, CMEs attached

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