



Subjects, Participants, Volunteers... Oh My!

What Should We Call The People Who Participate In A Clinical Trial?

If we are to deal ethically with study subjects, it is certainly appropriate to understand their motivations, concerns and situation. Unfortunately, the terminology we use to describe study subjects can limit our ability to deal with them ethically.

What should we call the people who participate in a clinical trial? Many of them are patients, but calling them "**patients**" promotes the therapeutic misconception that the study is primarily designed for their personal medical care.

They are experimental subjects, but calling them "**subjects**" communicates that they are passive recipients of the study treatments.

They are volunteers, but calling them "**volunteers**" suggests that they bear the burden for any unpleasantness that may occur. It may also flatter them into taking risks beyond what their personal welfare dictates.

We can avoid this semantic baggage by calling them "**participants**," but at the cost of offering any guidance about their role in the study. (Investigators are also participants.)

No perfect terminology exists, but all of the above terms have some merit, as well as conflict. Each provides a perspective on the people who participate in a clinical trial. However, the terms tend to reduce them to a single dimension and discount the most important perspective – that people who

participate in a clinical trial are, first and foremost, human beings.

Further, they usually are not people in isolation; they are typically part of a network of relatives, friends, healthcare providers, spiritual advisors, etc. If we ignore their personal network – their community, we see only part of the person.

Consider using the multiple terms that describe the role of a person who voluntarily agrees to participate in research as a human subject. It takes more words, but may ultimately prove more effective.

(Adapted for use by VCU from "[The Personal Side of Subject Recruitment](#)," by Norman M. Goldfarb)

OHRP—VCU 2008

Informed Consent and More: Improving Human Research Protections

Richmond, VA

Tuesday, Sept. 16, 2008

8:00 a.m.—5:15 p.m.

[http://www.research.vcu.edu/irb/
conference/index.htm](http://www.research.vcu.edu/irb/conference/index.htm)

Have questions or information/an article to share? Let us publish it here! Contact lbalance@vcu.edu. The "Bulletin" is a quarterly publication, produced and distributed electronically by the OECO. For more information, contact Monika Markowitz, Ph.D., OECO Director at 827-2157 or msmarkow@vcu.edu.

Upcoming Events

- **Tuesday, September 16, 2008: OHRP—VCU Regional Conference;** 7:00 am—5:15 pm; Sheraton Richmond West. "Informed Consent and More: Improving Human Research Protections"
- **Friday, September 26, 2008: 4th Friday for Research Coordinators;** 12:00 noon—1:00 pm; Children's Pavilion—2017. "Organizing and Keeping Track of Clinical Research: How Does Massey Do It?" **Speakers:** Martha Wellons, Assistant Director of Clinical Research, Massey Cancer Center and Patti Feldt, Regulatory Coordinator.
- **Friday, October 25, 2008: 4th Friday for Research Coordinators;** 12:00 noon—1:00 pm; Children's Pavilion—2017. TBA.
- **Thursday, October 30, 2008: 5th Thursday for Human Research Protections; 1:00 pm-2:30 pm; Ball Conference Room, Biotech I.** "Looking at Community-Based Participatory Research (CBPR) Through the Lens of the IRB: Issues and Insights" **Speaker:** Cornelia A. Ramsey, PhD, MSPH, Community Research Liaison, Center for Clinical and Translational Research.

Check events online at:

<http://www.research.vcu.edu/events/irb.htm>

Selected Recent IRB Policy Changes:

Use the hyperlinks to access the policy files directly—

[Click here](#) for a full, text-searchable, electronic set of VCU IRB written policies and procedures

WPP	Title	Effective Date
VII-2	Review Document Distribution	6-1-08
VIII-4	Continuing Review	6-1-08
XVII-10	Research Participant Inquiries / Concerns	6-1-08
Form	Initial Review Submission Form	7-15-08
Form	Continuing Review Form	7-15-08
Form	Change in Research Submission Form	7-15-08
Template	VCU Research Plan Template	7-15-08
Instructions	Submission Instructions for the Addition of Non-VCU Institutions / Sites	6-1-08
Template	Biomedical / Social-Behavioral Consent Templates	7-15-08

Recent News in Human Research

- **[Ethics of Studies in Poor Countries Lead to Call for New Regulations](#)**, New York Times, Aug 5, 2008 "Even something as apparently innocuous as health surveys can raise tricky moral questions when conducted in poor countries, researchers wrote in this month's Bulletin of the World Health Organization..." **[Demographic and health surveillance: longitudinal ethical considerations](#)**, Carrel and Rennie, Bulletin of the World Health Organization 86: 577-656, Aug 1, 2006 (full article freely available).
- **[Building and Maintaining Trust in a Community-Based Participatory Research Partnership](#)**, Christopher et al., American Journal of Public Health 98: 1398-1406, Aug 2008 (abstract freely available).
- **[The Power and the Promise: Working With Communities to Analyze Data, Interpret Findings, and Get to Outcomes](#)**, Cashman et. al., American Journal of Public Health 98: 1407-1417, Aug 2008 (abstract freely available).