Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in Youth Smoking Cessation

October 16, 2002

Chicago, Illinois

Workshop Summary

This expert workshop was hosted by the Helping Young Smokers Quit (HYSQ), National Program at the Institute for Health Research and Policy, University of Illinois-Chicago with funding by The Robert Wood Johnson Foundation.

Please direct all correspondence to:

Helping Young Smokers Quit
Institute for Health Research and Policy
University of Illinois at Chicago
1747 West Roosevelt Road, Room 558
Chicago, Illinois 60608
Email: hysq@uic.edu
Fax: 312-413-4750

I. Introduction

In response to concerns voiced by researchers and practitioners in youth tobacco dependence treatment about the challenges of understanding and implementing procedures to protect human subjects, the Robert Wood Johnson Foundation (RWJF) sponsored a workshop in October 2002. The Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in Youth Smoking Cessation brought together experts representing tobacco treatment practices; major funding agencies (Centers for Disease Control and Prevention, National Cancer Institute, National Institute on Drug Abuse, RWJF); and the national association of IRB administrators and funded researchers (see Appendix A for a complete list of participants). This meeting aimed to articulate and help fill knowledge gaps between these experts in the field of youth tobacco dependence treatment and IRB and ethics experts. The group used the day to discuss common issues and challenges encountered when designing and implementing research and treatment protocols with youth smokers, and to identify specific strategies to address these challenges. In preparation for the meeting, the HYSQ project team commissioned three papers:

1. The ABC's of Human Subjects, an overview of federal and state regulations applicable to treating and conducting research on children;
2. The Institutional Review Board (IRB) perspective, a presentation of the most important factors and greatest challenges that are identified by IRB administrators while reviewing research protocols with youth involvement; and
3. Experiences from the Field, a description of the ethical and IRB challenges faced by youth smoking cessation researchers and treatment centers, along with practical strategies used to address such challenges.

The papers were presented at the workshop to provide background and stimulate discussion. Following the presentations, workshop participants worked in small groups to consider key issues and challenges, needs and solutions, and action steps for each of three potential audiences:

a) Service Delivery Professionals, those involved in the delivery of direct services to youth for tobacco use cessation;

b) IRB Professionals, those involved in ensuring protection of the rights of patients/research participants (e.g., IRB administrators and board members); and

c) Research Professionals, those involved in conducting program evaluations and randomized trials to build the evidence-base for effective treatments for tobacco use cessation.

The small groups then reconvened to summarize their discussions and to develop an action plan for presenting the issues and recommendations to the field. Common themes that emerged included:

- Improving communication among IRB administrators, researchers, and practitioners;
- Educating each audience about the relevant human subject issues encountered in youth tobacco cessation research and treatment;
- Developing resources that provide information on the issues encountered, such as successful examples of research and treatment protocols; and
- Conducting research on the implication of IRB requirements for youth tobacco research and treatment.

Finally, this collaborative forum provided an opportunity to plan for strategic dissemination of the knowledge, practices, and recommendations about conducting ethical research and treatment for youth tobacco dependence in particular, and other risky and/or illegal youth behaviors in general (see Appendix B for the full Agenda for the day). At the conclusion of the workshop, the group identified 5 important action items, which would enable the collective products from the workshop to reach a broader audience and provide additional information where knowledge gaps were identified. In 2003 and 2004, the three background papers were published as two articles in *Ethics and Behavior*, the issues and recommendations from the Workshop were summarized in poster presentations at three scientific meetings. The background papers, articles and poster presentations are available on the Helping Young Smokers Quit website (www.hysq.org).

II. Background

Researchers working in the fields of youth tobacco dependence and treatment encounter many challenges in designing and implementing treatment and research protocols. In addition to designing scientifically sound research or providing effective treatment, issues of informed consent and confidentiality must be balanced with the requirements and responsibilities of research ethics. For example, obtaining parental consent for youth to participate in either research or treatment often compromises confidentiality. In cases where other mental health issues or domestic abuse become apparent during the course of the research and/or treatment, reporting and providing referral for appropriate treatment or assistance is a legal requirement; however, such actions necessarily breach confidentiality. These challenges are not unique to youth tobacco research and treatment; indeed researchers and health care providers who work in adolescent medicine, mental health, and substance use face such issues on a regular basis.

Another layer of complication is added when researchers and treatment providers must take into account policies and requirements of the various organizations with jurisdiction over the ethical aspects of research and treatment relationships. Federal laws designate specific requirements for conducting research with youth. These federal statutes recognize varying levels of competency among children and minors, as well as varying levels of risks and benefits to research, and therefore build in substantial room for interpretation of the relevant regulations (English, 1995). In addition to the federal regulations, several states have undertaken legislation that requires additional levels of parental consent or more clearly defines who is considered a "minor," and when parental consent is required (Ford and English, 2002). Furthermore, institutional review boards (IRBs), in an effort to conform to federal and state laws or to minimize the potential for lawsuits, may implement their own interpretations of the federal or state laws, along with additional requirements or constraints regarding interactions with youth.

While many researchers and treatment providers successfully balance the ethical issues and navigate the various levels of regulations involved in working with youth, the process often involves a fair amount of trial and error. Experts in research ethics and members of IRBs often clearly understand the regulations and requirements they are designated to uphold, but may only learn of the difficulties involved with actual implementation after working with researchers or providers whose projects are compromised by adherence to the letter rather than the spirit of the regulations. This anecdotal approach to working through the complex issues involved with providing treatment for youth engaged in risky behaviors is inefficient and points to the need for an improved understanding among both IRB members and researchers of each others' professional responsibilities, requirements, and regulations.

The Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in Youth Smoking Cessation included three presentations with the goal of establishing a baseline understanding of the issues from all perspectives of the experts in attendance. The breakout session, which followed the paper presentations, fostered detailed, collaborative and productive discussions. The workshop presentations and subsequent discussions focused on three key areas:

- **Ethical and Regulatory Issues in Research:** The workshop provided an overview of the regulations for research involving youth, with particular attention to requirements for parental consent and youth assent to participate in research, the definition of minimal risk and to whom the assessment of risk applies, methods of subject recruitment and the potential for coercion, youth's rights and requirements for privacy, and the ethical distinctions between providing treatment versus conducting research. The discussions highlighted areas of the regulations and specific research contexts where such regulations were subject to interpretation. The full working paper can be obtained through the Helping Young Smokers Quit website (www.hysq.org).
- **Institutional Review Board Practices:** Prior to the workshop, a convenience-sample survey of IRB administrators was conducted, which addressed IRB experiences with "passive consent", definitions of minimal risk, the role of state-level regulations for research with youth, the use of template informed consent language, and finally solicited advice for researchers on strategies for interacting with IRBs as well as for designing ethically appropriate youth smoking cessation research projects. The manuscript from this presentation, "Human Subjects' Challenges in Youth-Focused Research: Perspectives and Practices of IRB Administrators," is published in the peer reviewed journal *Ethics &*

Behavior. The presentation and survey instrument can be obtained through the HYSQ website (http://www.hysq.org/sub-research/irb_expert_workshop.html).

- **Research and IRBs: Experiences from the field.** Prior to the workshop, a convenience sample survey of researchers with funded projects that focus on youth smoking cessation was conducted. Researchers reported on: the characteristics of their research intervention; their experiences with requirements for obtaining parental consent, and how this affected their research design and implementation; their strategies for recruitment and how their IRBs assessed and/or modified these strategies; and their recommendations for successfully working with IRBs to design both scientifically and ethically rigorous research projects. The manuscript from this presentation, "Human Subjects' Challenges in Youth Tobacco Cessation Research: Researchers' Perspectives," is published in the peer reviewed journal *Ethics & Behavior*. The presentation and survey instrument can be obtained through the HYSQ website (http://www.hysq.org/sub-research/irb_expert_workshop.html).

III. Common Themes and Consensus from Breakout Sessions

Following the three presentations, participants divided into three groups for the breakout sessions. Each group focused on identifying key issues and challenges, needs and solutions, and action steps from one of three institutional perspectives: treatment providers, IRB members, or researchers. After working for approximately an hour, the groups reconvened to share their insights and to work toward a broad consensus that would take into account the priorities and constraints of each institutional perspective (The Discussion Guide for the Small Group Sessions is provided in Appendix C.)

Overarching Theme: Communication. Each presentation and the subsequent discussions identified communication between researchers and IRBs as the critical ingredient to successfully balancing scientific and ethical principals in the design and implementation of youth smoking cessation research specifically, and with youth research in general. The following themes also emerged from the workshop's presentations and discussions:

A. Consent Issues

Passive consent: The term "passive consent" is used frequently, but does not have a common definition among researchers or IRBs. Moreover, the term "passive consent" does not exist within the federal regulatory framework that guides IRBs. Most often when researchers or IRBs use the term "passive consent" they are referring to Parental Consent Waivers.

Parental consent waivers. Both of the federal regulations--the Common Rule and Subpart B--that address research with minors define parameters for a waiver of parental consent. Under the federal regulations, a parental consent waiver is allowable if: a) the research meets the criterion of minimal risk; b) does not violate the rights of the research subject/participant or their parents; c) parental permission is not a reasonable requirement; and d) researchers can demonstrate that they have implemented an appropriate mechanism for protecting child subjects. Each of these conditions, however, is subject to interpretation by individual IRBs and is potentially superceded by state or local laws that may have more stringent or specific requirements for conducting research with minors.

Informing Parents: A potential consequence of obtaining parental consent is informing parents of their child's smoking status or other illegal activities. Several examples were provided to illustrate how the process of informing parents about research could endanger the scientific integrity of a project. For example, a research study could fail due to the inability to

enroll a sufficient number of youth subjects if parents are made aware of the youth's smoking or other behaviors. Such scenarios provide an opportunity for researchers, IRB members, and local community members to identify creative ways of informing parents and youth about the benefits and risks of the research without specifying the behaviors of individual youth. It was also suggested that the degree to which informing parents compromises the integrity of the research may be overestimated by researchers or underestimate by IRBs. Research to quantify the extent of these effects could lead to improved procedures and/or regulations.

B. Recruitment Issues

Ethics of subject payment: Several workshop participants noted the challenges of recruiting adolescents into research programs. Monetary incentives are standard practice for recruitment of both adolescents and adults into research studies, but several considerations must be weighed more carefully when using monetary incentives for youth. These include the danger of coercion and the danger that youth could use the money to purchase cigarettes or other illegal substances. Federal regulations do not specifically address the use of money for recruiting youth into research studies. Thus, individual IRBs may approach this issue differently. This is another area where communication between the researchers, IRBs, and possibly community members could provide constructive input to the process of designing research that appropriately balances scientific and ethical concerns.

C. Treatment versus Research

Different standards for treatment and research: It was noted that many research projects work with or are components of treatment programs. IRB standards for informed consent that apply to research projects do not automatically apply to the provision of clinical treatment. Indeed, written parental consent treatment is often not required for treatment because of its

potential to deter youth from receiving needed clinical services. This is another example of the importance of communication between researchers and IRBs. For youth who are already receiving treatment, it can be argued that the associated treatment evaluation would not constitute additional risk beyond that of the treatment itself; this determination, of course, would depend on the nature of the treatment. Researchers and IRBs, therefore, have an opportunity to negotiate and further consider the criterion of minimal risk that is required for parental waivers. The group suggested that researchers include service delivery professionals in study design in order to improve the relevancy of the research in a real-world treatment context. Further, the group also suggested that institutions should strive to create a feedback mechanism between providers, researchers, and IRBs to facilitate communications and improve mutual understanding of each others' goals.

D. Lack of IRB experience with adolescent research

There has been very little research on youth smoking cessation until very recently. Therefore, many IRBs or individual members of IRBs may not have experience with this issue and its ethical complexities. Moreover, many of the researchers in this field may also be inexperienced with the associated research ethics requirements. IRB inexperience with youth cessation research specifically or research on adolescents in general is exacerbated by the high turnover of IRB members. The lack of IRB and researcher experience with youth smoking cessation research points to a need for the development and dissemination of information about the ethical complexities involved with such projects. To address these issues, the group suggested that the youth cessation community work toward the structural changes within the research community:

- Require initial and continuing education of IRBs on the issues specific to adolescent research, highlighting the flexibility built into federal regulations;
- Include more researchers experienced in research with adolescents on IRBs;
- Create a pool of experts on the ethics of youth cessation research or adolescent research in general to whom IRBs and/or researchers could refer for difficult cases

E. Communication Barriers

Many researchers and IRB members approach their relationship from an unnecessarily adversarial perspective. It is therefore important that each better understand the responsibilities and requirements of the IRB and to identify when flexibility is possible. Often, researchers and IRBs do not use the same language or share a common perspective about the research being proposed. The urgency of obtaining IRB approval for timely fielding of research, coupled with the time involved with obtaining IRB consent can hinder constructive communication between researchers and IRBs. This barrier could be reduced if there were an infrastructure for regular lines of communication between the two groups. Moreover, if more researchers participated in their organization's IRBs workloads could be lessened along with the timeline for IRB review and approval.

III. Next Steps

The workshop discussions generated several suggestions, many of which centered on the theme of improving communication between researchers and IRB members. These suggestions distilled into five action steps:

1. **Develop and implement a website that will include:**
    - Case Studies of youth cessation projects and what strategies they used to work successfully with their IRBs;

- Samples of successful youth smoking cessation research protocols, which IRBs have approved;

- Frequently Asked Questions (FAQs) that IRB administrators receive from researchers, as well as questions to which youth smoking cessation researchers often must respond; and

- Consultant lists for researchers and IRBs to refer to for specific questions.

2. **Publish a literature search and synthesis of ethical/IRB issues relevant to adolescent smoking cessation research**

3. **Develop a consensus statement on regulatory/ethical issues, which would provide guidelines for IRBs that are consistent with the needs of adolescent researchers**

4. **Conduct research to test/document impact of certain IRB requirements on the treatment/evidence base**

5. **Disseminate the papers that were presented for this workshop through conference presentations and peer-reviewed publications.**

References

English, A. (1995). Guidelines for Adolescent Health Research: Legal Perspectives. *Journal of Adolescent Health* 17:277-286.

Ford, CA, English, A. (2002). Limiting Confidentiality of Adolescent Health Services: What are the risks? *JAMA* 288(6): 752-753.

National Institutes of Health. *Policy and guidelines on the inclusion of children as participants in research involving human subjects.* NIH Guide for Grants and Contracts, March 6, 1998. Retrieved November 24, 2003, from http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1977*). Report and recommendations: Research involving children* [DHEW publication no. (OS)77-0004]. Washington, DC: U.S. Department of Health, Education and Welfare.

U.S. Department of Health and Human Services; National Institutes of Health; Office for Protection from Research Risks. (2001). *Code of Federal Regulations: Title 45-Public Welfare; Part 46: Protection of Human Subjects.* Retrieved November 24, 2003, from http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

Appendix A

Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in the Area of Youth Smoking Cessation

Wednesday, October 16, 2002
Participants List

Cathy L. Backinger, MPH, PhD
Program Director, Tobacco Control Research Branch
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Boulevard - EPN 4038
Rockville, MD 20852
Email: backingc@mail.nih.gov

Dianne C. Barker, MHS
Barker Bi-Coastal Health
3556 Elm Drive
Calabasas, CA 91302
Email: dcbarker@earthlink.net

Michael Berbaum, PhD
Co-Director, Methodology Research Core
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: mberbaum@uic.edu

Richard T. Campbell, PhD
Director, Methodology Research Core
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: dcamp@uic.edu

Frank J. Chaloupka, PhD
Director, Health Policy Center
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: fjc@uic.edu

Richard R. Clayton, PhD
Center for Prevention Research
University of Kentucky
Suite B100 2365 Harrodsburg Road
Lexington, KY 40504-3381
Email: clayton@pop.uky.edu

Jeffrey A. Cooper, MD, MMM
Deputy Director
Association for the Accreditation of Human Research Protection Programs, Inc.
915 15th Street, N.W., 9th Floor
Washington, DC 20005
Email: jcooper@aahrpp.org

Susan Curry, PhD
Director, Health Research and Policy Centers
University of Illinois at Chicago
850 West Jackson Boulevard
Suite 400
Chicago, IL 60607
Email: suecurry@uic.edu

Geri Dino, PhD
Director, Prevention Research Center
West Virginia University, School of Medicine
Health Sciences Center, South 3820B
P.O. Box 9190
Morgantown, WV 26506
Email: gdino@hsc.wvu.edu

Kathleen R. Diviak, PhD
Health Research & Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: kdiviak@uic.edu

Sherry Emery, PhD
Project Director
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: slemery@uic.edu

Pebbles Fagan, PhD, MPH
Health Scientist, Tobacco Control Research Branch
Behavioral Research Program, Division of Cancer Control and Population Sciences
Nactional Cancer Institute, Executive Plaza North, Room 4042
6130 Executive Blvd., MSC 7337
Bethesda, MD 20892-7337
Email: faganp@mail.nih.gov

Jennifer Flome, MPH
RTI International
2951 Flowers Road South
Suite 119
Atlanta, GA 30341
Email: flome@rti.org

Gary Giovino, PhD
Senior Research Scientist
Roswell Park Cancer Institute
Elm and Carlton Streets
Buffalo, NY 14263
Email: gary.giovino@roswellpark.org

Debra Grossman
Division of Treatment Research and Development
National Institute on Drug Abuse
6001 Executive Boulevard
Room 4123, MSC 9551
Bethesda, MD 20892-9551
Email: dgrossma@nida.nih.gov

Timothy P. Johnson, PhD
Director, Survey Research Laboratory
University of Illinois at Chicago
Alumni Hall South, Sixth Floor
412 S. Peoria St.
Chicago, IL 60607
Email: tjohnson@srl.uic.edu

Beverly Kingsley, PhD, MPH
Epidemiologist, Office on Smoking and Health
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333
Email: bbk9@cdc.gov

Paul McDonald, PhD
Professor, Department of Health Studies and Gerontology
University of Waterloo
200 University Avenue West
Waterloo, Ontario
Canada N2L3G1
Email: pwmcdona@healthy.uwaterloo.ca

Robin J. Mermelstein, PhD
Deputy Director, Health Research and Policy Centers
University of Illinois at Chicago
850 West Jackson Boulevard
Suite 400
Chicago, IL 60607
Email: robinm@uic.edu

Micah H. Milton, MPH
Office on Smoking and Health
Centers for Disease Control and Prevention
4770 Buford Highway NE - MS K-50
Atlanta, GA 30341
Email: mmilton@cdc.gov

Paul Mowery, PhD
RTI International
2951 Flowers Road South
Suite 119
Atlanta, GA 30341
Email: pdm@rti.org

Sallie Anne Petrucci, MPH, CHES
Program Associate
Robert Wood Johnson Foundation
P.O. Box 2316
Route 1 & College Road East
Princeton, NJ 08543
Email: spetruc@rwjf.org

Ada Sue Selwitz, MA
Director, Office of Research Integrity
Adjunct Associate Professor
Behavioral Sciences
College of Medicine
University of Kentucky
303 Kinkead Hall 0057
Lexington, KY 40506
Email: selwitz@uky.edu

Joan Sieber, PhD
Professor Emeritus
Department of Psychology
California State University, Hayward
25800 Carlos Bee Boulevard
Hayward, CA 94542-3087
Email: jsieber@csuhayward.edu

Mary Simmerling, MS
University of Chicago
5835 S. Kimbark – Judd 122
Chicago, IL 60637
Email: mcs@uchicago.edu

Amy Sporer, MS
Project Coordinator
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: aksporer@uic.edu

Steve Sussman, PhD
Professor of Preventive Medicine and Psychology
Co-Director of the Transdisciplinary Drug Abuse Research Center
Institute for Health Promotion and Disease Prevention Research and Research Center for Alcoholic Liver and Pancreatic Diseases
1000 South Fremont, Unit #8
(Room 4124 in Building A-4)
Alhambra, CA 91803
Email: ssussma@hsc.usc.edu

Diane K. Wagener, PhD
RTI
6110 Executive Blvd., Suite 420
Rockville, MD 20852-3907
Email: dwagener@rti.org

Richard B. Warnecke, PhD
Director, Center for Health Service Research
Health Research and Policy Centers
University of Illinois at Chicago
850 W. Jackson Blvd., Suite 400
Chicago, IL 60607
Email: warnecke@uic.edu

Appendix B

Agenda

Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in the Area of Youth Smoking Cessation
October 16, 2002
8:30-4:00

8:30 – 9:00 Continental breakfast

9:00 – 9:30 Introductions and Overview

9:30 – 10:15 Guiding principles from federal regulations

10:15 – 11:00 Front-line practices of IRB administrators

11:00-11:15 Break

11:15 – 12:00 Front-line practices of youth tobacco researchers

12:00-1:00 Lunch

1:00-2:00 Small group discussions

- Emergent themes/issues for IRB's, Researchers, Practitioners
- Emergent needs of IRB's, Researcher, Practitioners
- Potential products/action steps

2:00 – 2:45 Report back – summaries from small group discussions

2:45 - 3:30 Action plan

3:30-3:45 Break

3:45-4:00 Wrap-up, meeting evaluation

Expert Workshop on Human Subjects and Ethical Issues Related to Treatment and Research in the Area of Youth Smoking Cessation

Discussion Guide for Small Group Session

Based on this morning's discussions and the collective expertise at this meeting, we would like each group to consider key issues/challenges, needs and solutions, and action steps for each of three potential audiences:

- **Service Delivery Professionals**, those involved in the delivery of direct services to youth for tobacco use cessation;
- **IRB Professionals**, those involved in ensuring protection of the rights of patients/research participants (e.g., IRB administrators and board members); and
- **Research Professionals**, those involved in conducting program evaluations and randomized trials to build the evidence-base for effective treatments for tobacco use cessation.

The attached tables may help group members jot down ideas to share with the rest of their group. The intention is not to limit the topics to be addressed, but to guide the group through focused discussions about the pertinent issues that were raised during our morning presentations and discussions. One person in each group should be designated as note-taker. Following the small group discussion one person (can be the same or different than the note-taker) should be prepared to report back to the larger group up to three issues/challenges, needs/solutions, and action steps for each audience.

Your discussion group location is based on the color of the star that is on the back of your nametag. To ensure balance of perspectives and expertise across the four groups, please stay with the group to which you are assigned. Below are the four room assignments that correspond to each colored star.

Red star: Northwest – the front half of the main meeting room

Blue star: TWA – the back half of the main meeting room

Green star: United A – down the hall on the left

Gold star: United B – down the hall on the left

Expert Workshop on Ethical and Human Subjects Issues Related to Treatment and Research in the Area of Youth Smoking Cessation

Discussion Guide for Small Group Session

Service Delivery Professionals

Issues/Challenges	Needs/Solutions	Recommended Action Steps for needs/solutions

Expert Workshop on Ethical and Human Subjects Issues Related to Treatment and Research in the Area of Youth Smoking Cessation

Discussion Guide for Small Group Session

IRB Professionals

Issues/Challenges	Needs/Solutions	Recommended Action Steps for needs/solutions

Expert Workshop on Ethical and Human Subjects Issues Related to Treatment and Research in the Area of Youth Smoking Cessation

Discussion Guide for Small Group Session

Research Professionals

Issues/Challenges	Needs/Solutions	Recommended Action Steps for needs/solutions