The proposed study will test the effectiveness of a nationally distributed decision aid developed by CDC, and extend the existing literature on informed decision making. No past trials of prostate cancer screening decision aids have evaluated the role of primary care provider practice style. The proposed study results may inform the national discussion about informed decision-making and prostate cancer screening, and influence the clinical guidelines and primary care provider practices on prostate cancer screening. Moreover, the data may inform revisions to the current line of prostate cancer screening educational materials and influence the development of new materials.

The randomized control trial (RCT) will recruit 400 men between the ages of 50–70 years reporting for health maintenance exams with primary care providers. The intervention being tested in this project will be the decision aid entitled, *Prostate Cancer Screening: A Decision Guide,* used to assess the main and interactive effects of primary care provider practice style and exposure to the decision aid on prostate cancer screening.

In 2005, CDC conducted a replicated measures validation study (OMB# 0920–0651); Expiration date: 11/30/07, in which measures were validated with the target audiences to both versions of the decision aid: (1) men eligible for screening in the general population (N=200) and (2) African American men eligible for screening (N=200). The estimate of burden for the instrument is based on results from this study.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 210.

Estimated Annualized Burden

Types of responses or kinds of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Men, all races aged 50–70 years	240	1	60
Men, all races aged 50–70 years (intervention group)	100	1	100
Men, all races aged 50–70 years (control group)	100	1	50

Dated: March 14, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–06–0556]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 371–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a–1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention—(1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under this act.

The Centers for Disease Control and Prevention (CDC) is seeking a 3 year Office of Management and Budget (OMB) approval for a revision of a reporting system for the Assisted Reproductive Technology (ART) Program. This reporting system has been designed by Westat for CDC to comply with the requirements of the FCSRCA. The reporting system includes all ART cycles initiated by any of the approximately 400 ART programs in the United States, and covers the pregnancy outcome of each cycle, as well as a number of data items deemed important to explain variability in success rates across ART programs and across individuals. (An ART cycle is considered to begin when a woman begins taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of having embryos transferred. The data file is organized with one record per cycle.) Data is to be collected through Web-based data collection system developed by Westat in consultation with CDC.

In developing the definition of pregnancy success rates and the list of data items to be reported, CDC has consulted with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine, and RESOLVE, the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field.

Approximately 400 ART programs reported data in 2002. The average number of ART cycles (responses) per ART program was 288. Using these numbers as a baseline, approximately 10% of the ART programs will be selected for data validation. An average of 50 ART cycles per ART program will be selected for full validation. In addition, an average of 33 ART cycles per selected ART program that resulted in a live birth will be selected for an abbreviated validation.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 72,313.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ART Programs (data entry)	400	288	37/60
ART Programs (10% selected for data validation-full validation)	40	50	23/60
ART Programs (10% selected for data validation-abbreviated validation on live births)	40	33	23/60

Dated: April 12, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–06–05CY]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Survey of Illness and Injury Among Backcountry Users in Yellowstone National Park—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

There are few data on the risk factors for illness and injury among persons who travel into the backcountry in the United States. The backcountry encompasses primitive or wilderness areas that lack most facilities and services and that are reached primarily by hiking, boating, or horseback. In general, backcountry users must bring in their own supplies (such as shelter, food, water, or water treatment supplies). As many as 68% to 82% of long-distance hikers and backpackers have reported experiencing illnesses or injuries during their time in the backcountry. For example, 4% to 56% have reported gastrointestinal illness and 41% to 62% have reported musculoskeletal injuries.

Such a high burden of disease has significant medical and economic implications given the increasing popularity of backcountry use. In 1994–95, almost 8% of Americans age 16 years and older (about 15 million persons) went backpacking in the previous 12 months, which involved camping for one or more nights along a trail and carrying food, shelter, and utensils with them. In the same period of time, about 14% (or 28 million persons) camped in primitive settings that usually lacked restrooms, hookups, and most facilities and services. In fact, camping in backcountry areas grew by about 72% from 1982–83 to 1994–95. While people can travel in the backcountry in many locations and on both private and public lands, many travelers hike, backpack, and camp in the backcountry in national parks. In 2003, there were over 266 million recreational visits to national parks with over 1.8 million overnight stays in the backcountry. Yellowstone National Park alone had almost 19,690 persons visit the backcountry in 2003, accounting for over 46,000 overnight stays.

Because little is known about the health outcomes for visitors who use the backcountry areas of our nation's parks, advice to park managers and the public is currently general in nature, based only on standard disease prevention principles. Furthermore, some outdoor use groups have recently questioned some of this standard advice, such as the universal need for careful filtration and disinfection of backcountry drinking water. This study will investigate behavioral and environmental risk factors that may be associated with illness and injury among persons who require park permits to travel into backcountry areas in Yellowstone National Park during the backcountry season from May 1–Oct. 31, 2006. The data collected will be used to provide an estimate of the burden of illness and injury among backcountry users and will also provide information about a variety of risk factors for illness and injury in the backcountry, including the risks associated with drinking untreated water from lakes and streams. With this information, the National Park Service (NPS) will be able to address many of the questions raised by outdoor users and public health officials, and improve and strengthen evidence-based NPS guidelines for backcountry health and sanitation practices. To gather this information, consent to contact after the conclusion of the backcountry trip will be requested from an estimated 12,906 backcountry users when they present to the Yellowstone National Park's permit offices prior to entering the backcountry. Approximately 10,325 of these backcountry users will be adults who are eligible to participate in the survey. A questionnaire (in either Internet-based or paper-based format) will then be offered to an estimated 5,276 adult backcountry users who consent to be contacted. Participants will be asked about their health (before, during and after backcountry travel), water consumption, water preparation habits, food consumption, food preparation habits, sanitation practices, recreational water use, animal exposure, and demographics.

This study is the beginning of what will be an on-going effort to improve the science-basis of the NPS recommendations and policies related to protecting human health in the backcountry. This effort seeks to begin to identify disease transmission pathways and assess disease and injury risks associated with specific activities, choices, and behaviors of backcountry visitors, such as water purification, sanitation practices, and hygiene. Thoroughly understanding transmission pathways and the interactions of agent, environment, and host will enable the NPS to effectively and efficiently improve visitor protection efforts. There will be no cost to respondents. Participation is voluntary and will not affect the application process for the backcountry use permit. The total estimated annualized hours requested are 1,803.