were coded in the following categories: no mention of risk; no risk; social/legal/confidentiality risks; upset or discomfort upon questioning; minimal discomfort (e.g., pain from drawing blood, discomfort from electroencephalogram [EEG]); moderate discomfort (e.g., moderate nausea or vomiting, headache, slight elevation in blood pressure, drowsiness); significant discomfort that could require medical attention (e.g., fracture of bones, developing tardive dyskinesia); potentially life-threatening condition (e.g., heart attack, stroke); and safety profile unknown, but test drug or device potentially harmful. When multiple categories of risk were indicated in a consent form or protocol, only the highest applicable level of risk, in the order indicated above, was coded.

All data extraction and coding were performed by the first author. Variables were entered into an Excel database for analysis. Consistency of statements in consent forms was determined by comparing the coding for consent forms with the coding for the associated protocols. Statistical analyses were performed using SAS release 9 (SAS Institute Inc, Cary, NC), with P < 0.05 considered statistically significant.

**Study Findings**

Of the 215 protocols eligible for inclusion in this study, 102 (47.4%) were for clinical trials, 76 (35.3%) for observational studies, 23 (10.7%) for studies involving physical interventions, and 14 (6.5%) for studies of psychosocial or behavioral interventions. These protocols represented studies involving inpatients exclusively (n = 37, 17.2%), outpatients exclusively (n = 123, 57.2%), healthy volunteers (n = 30, 14.0%), and both inpatients and outpatients (n = 25, 11.6%). Thirty-five studies (16.3%) were conducted exclusively in pediatric populations, eight studies (3.7%) involved both minors and adults, and 172 studies (80.0%) involved adults exclusively.