

# Recruitment and retention in the Wake Forest University CCOP Research Base.

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Abstract:

**Background:** Clinical trials can lead to important advances in treatment, prevention, and symptom management. Unfortunately, study participation is low, especially for minorities, the elderly, the poor, and those in rural areas. Participation is needed in all populations to ensure generalizable results. Retention in a clinical trial is also crucial. Dropout lowers study power and can result in biased estimates of treatment effect. We reviewed the accrual and retention of participants in clinical trials offered through the CCCWFU Research Base (CCCWFU-RB), which is comprised of CCOPS from a broad geographic base. **Methods:** The CCCWFU-RB is a Cancer Control Research Base which emphasizes symptom management trials. Accrual and retention estimates were pooled over all CCCWFU-RB cancer control studies. Actual minority accrual was compared to expected accrual based on incidence, prevalence, and population estimates in our recruitment area. **Results:** Between 2001 and 2009, 1388 patients were accrued to 12 cancer control protocols. Accrual rates ranged from < 1 per month to almost 5 per day; actual accrual typically lagged behind expected accrual. Participants were 19-91 years (median 57), with 31% 65+ years. The race/ethnic distribution was 87% white, 10% black, and 2% Hispanic. Based on our geographic recruitment area, 17% black and 4% Hispanic participation would have been expected. Retention on studies ranged from 50% to 92% with an average of 73% across our 6 largest trials. Drop-outs have resulted from unclear protocols and definitions, as well as patient refusal. Underrepresented participants were no more likely to dropout than any other participant groups. **Conclusions:** Recruitment of under-represented populations has been lower than expected, and retention of all study participants has been problematic. Steps have been taken to increase accrual of under-represented populations and improve retention, including education, clearer protocols and race-specific objectives. (Supported by NCI grant 3

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