

1.1 Protocol Synopsis

Objectives:

The BACH Survey is designed to provide population-based prevalence data on urological conditions and concomitant risk factors in Hispanic, African American, and Caucasian men and women aged 30 to 79 years. Specifically, the objectives of BACH are to:

- Estimate prevalence of symptoms associated with urological disorders, overall and by age and gender
- Assess risk factors for these symptoms
- Assess impact of symptoms on quality of life
- Collect and archive blood specimens so that future biomarkers and their relation to urological disorders can be assessed
- Determine longitudinal course of symptoms with aging (in future panels of this survey)

The urological conditions of interest are:

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| <ul style="list-style-type: none">• Chronic pelvic pain of the bladder• Urinary incontinence (UI)• Interstitial cystitis (IC) | } All Participants |
| <ul style="list-style-type: none">• Erectile dysfunction (ED)• Benign prostatic hyperplasia (BPH)• Prostatitis• Hypogonadism | } Men only |

Site:

Subjects are recruited from throughout the city of Boston. For sampling purposes, we have divided the city into four geographic areas (North, West / South, Roxbury / Mattapan and Dorchester) and classified blocks within these areas as low-density, high-density Hispanic, or high-density African American depending upon the demographic characteristics of the residents. This results in 12 (4 areas x 3 densities) strata in which we are sampling.

Field method:

Interviews typically take place in the Respondents' homes. Alternatively, Respondents may choose to have the interview conducted at another location in their community or at NERI. Because of diurnal variation in hormones, male subjects are interviewed within 4 hours of awakening. Multi-cultural, bilingual interviewers (who are certified and experienced in phlebotomy and trained in interview techniques) visit Respondents in their homes.

Research design:

Type:	Observational study
Eligibility criteria:	<ol style="list-style-type: none">1) Age 30 – 792) Non-Hispanic Black American, Non-Hispanic Caucasian, or Hispanic race/ethnicity3) English- or Spanish- speaking4) Residence at selected address
Stratification:	24 equally-sized cells defined by age, race/ethnicity, and gender
Sample size:	6000 subjects (i.e., 250 per age, race/ethnicity, and gender cell), recruited in 6 batches of 1000 each. The goal is to have sufficient power to detect race/ethnic differences.
<u>Schedule of measurement:</u>	
Baseline:	Includes physical measurements, socio-demographics, medications, health history, health care utilization, quality of life, physical activity psychosocial factors, tobacco and alcohol consumption, urological symptoms, and self-administered questionnaire on sexual functioning. Data collection will span approximately 21 months (including clean up of difficult dispositions).
Follow-ups:	To be decided when funding is sought

Protocol:

Addresses are selected using a stratified cluster sample design. Residents at selected addresses are then screened to determine if they meet all eligibility criteria. If they do and are willing to participate, they are then enrolled and complete interviewer- and self-administered questionnaires.