

JOB DESCRIPTION

Beth Israel Deaconess Medical Center

Position Title: Clinical Research Assistant II

Department/Section: Department of Medicine/Division of General Medicine and Primary Care

Reports To: Mara Schonberg, MD, MPH, Principal Investigator

Program Manager, Division of General Medicine and Primary Care

Grade: 6 Job Code: A1635 FLSA Status: Non-Exempt

Date Prepared: May 11, 2011

Expectations for All Employees:

Supports the organization's code of excellence and values by exhibiting the following behaviors: integrity, respect, compassion, excellence, stewardship and community.

Age Specific Care Requirements:

This position interacts with adult women aged 65 and older, including elderly, frail women, their physicians, and family members.

Blood Borne Pathogen Category:

No potential exposure. The position requires performance of duties that involve no potential for exposure to blood, body fluids, or tissues. Tasks that do involve exposure are not an expectation of employment.

Position Summary:

Reporting to the Program Manager, under the direction of the Principal Investigator, the incumbent is responsible for recruitment, screening and enrolling of patients for participation in clinical research studies, and ensuring compliance with federal, state, and institutional guidelines. Monitors the progress of protocols and assists with the grant application and reporting process. Coordinates the recruitment, screening and enrolling of patients across multiple sites, including Brigham and Women's Hospital, Boston Medical Center, and Beth Israel Deaconess Medical Center. Conducts a variety of routine and specialized research duties including literature searches and reviews, project coordination, data management and analysis, and presentation and manuscript preparation. Works with statistical software (SAS) to create data sets for analysis.

Primary Duties and Responsibilities:

The Clinical Research Assistant II will work closely with the Principal Investigator on various research projects including: "Psychological Impact and Decision-Making of Elderly Women after an Abnormal Mammogram", funded by the National Institute on Aging. The purpose of this study is to describe and compare the psychological impact and decision-making experience of women aged 65 and older following a newly interpreted abnormal mammogram. Among topics to be explored are: 1) the immediate impact of an abnormal mammogram on elderly women's quality of life; 2) the extent to

which elderly women rely on their physicians and family members to help make decisions about diagnostic work-up and breast cancer treatment; and 3) physician and family member perspectives about their role in oldest-old women's decisions after an abnormal mammogram. Another project on which the candidate will work closely with the Principal Investigator is: "A Decision Aid for Women Aged 75 and Older." The purpose of this study is to evaluate a decision aid that is acceptable to women aged 75 and older, and improves their knowledge around mammography screening, improves targeting of screening to older women by life expectancy, and decreases patient and physician decisional conflict around screening. The CRA II works to prepare graphs and tables to present data to participants in the decision aid.

- <u>IRB Responsibilities:</u> Assists in the execution of new IRB applications and processes annual reviews for the IRB. Working with the Principal investigator, submits protocols, amendments, notices, suspensions and terminations to the IRB for review and approval.
- Research Protocol and Materials: Assists the PI with the development of study protocols and related study and research materials e.g., survey and medical record review, web-based instruments etc.
- <u>Subject Recruitment and Enrollment:</u> Responsible for recruitment activities for the project including developing, updating and maintaining lists of study subjects; respondent mailings; coordinating interview logistics; collating subject eligibility and participation; and maintaining excellent documentation of research decisions and tasks. Interacts with patients prior to entering the study and throughout the entire protocol. Discusses and obtains informed consent with patients. Revises protocol consent form to comply with federal, state and IRB guidelines. Some family interaction is also required. Performs related administrative tasks including processing compensation and incentives payments to study subjects.
- <u>Interviews and Scheduling:</u> Completes initial and follow-up interviews of subjects by phone and in person, including at off-site clinics and patient homes as necessary. Responsible for scheduling appointments in conjunction with IRB protocols.
- Data collection, management and analysis: Performs data collection activities including conducting in-person and telephone interviews; abstracting medical records; and compiling information from the online medical record. Performs data management tasks including database development and data entry using Microsoft Access, Excel and other related software. Creates graphs, charts, queries and reports in Access; exports data for use with SAS. Performs routine quality assurance tasks. Monitors quality and timeliness of data submissions. Ensures data extracts are in compliance with protocols. Performs basic data analysis including frequency distributions and cross-tabulations, seeking assistance when necessary. Verifies accuracy of study forms, updates study forms per protocol, and maintains study codes. Accurately records patient information on standardized data forms.
- <u>Collaboration:</u> Provides liaison between key project personnel (principal investigator, co-investigators, mammography technicians, etc.).
- <u>Grant preparation:</u> Assists Principal Investigator with grant submissions and the preparation of annual progress reports for funded grants.

- <u>Literature and bibliographies:</u> Performs ongoing reviews of the medical and health services literature online and/or at Countway Library and maintains a bibliography on related publications using software such as EndNote. Retrieves and photocopies journal articles and book chapters from hospital and medical school libraries. Arranges interlibrary loans when necessary. Maintains bibliographic database, includes data entry and filing original articles.
- <u>Manuscripts and presentations:</u> Assists with preparation of manuscripts and professional presentations. Responsibilities include creating tables, charts and graphs; editing, proofreading, and uploading to the journals for peer review.
- Other research-related administrative tasks: Organizes activities to efficiently meet study needs, protocol requirements, and Division of General Medicine and Primary Care responsibilities. Assists with other research-related tasks as directed by the PI.

Qualifications/Skills and Knowledge Requirements:

The candidate must have excellent organizational, communication and analytical skills normally acquired through a BA/BS degree or equivalent. Masters level degree or related coursework in public health or nutrition related field a plus. The candidate should have one or more years of experience in a medical setting and/or clinical trials. The candidate must have demonstrated proficiency with Microsoft Word, Excel, and PowerPoint; a general knowledge of research methods; and a broad familiarity with and interest in current health care issues. Experience with statistical software such as SAS preferred. Must be attentive to detail and able to communicate effectively, orally and in writing; be able to take direction well but also set own priorities and work both independently and collaboratively with research investigators, staff and hospital personnel. Incumbent must possess excellent English language and interpersonal skills, and have a professional and effective telephone presence. Independent judgment is required to plan, organize and prioritize a diversified workload and to seek supervisory assistance as appropriate. Previous clinical research experience is required, including data collection, management, and analysis, and a familiarity with literature searches and scientific procedures preferred. Knowledge and/or interest in women's health and aging is also preferred; knowledge of quantitative and qualitative research methods is a plus. Position will have a flexible schedule based on study needs. Enthusiasm, responsibility and a strong sense of teamwork are essential. Must be able to travel to study clinics and/or patients homes as needed. Incumbent must be compassionate and possess excellent interpersonal skills, as he/she will conduct interviews with women aged 65 and older who have been recently informed of an abnormal mammogram.

Supervisory or Management Responsibility: None

Physical Requirements: None

The above statements are intended to describe the general nature and level of work being performed by individuals assigned to this position. They are not intended to be an exhaustive list of all duties, responsibilities, and skills required of personnel so classified.

The incumbent must be able to work in a fast-paced environment with demonstrated ability to juggle and prioritize multiple, competing tasks and demands and to seek supervisory assistance as appropriate.

Incumbents within this position may be required to assist or find appropriate assistance to make accommodations for disabled individuals in order to ensure access to the Medical Center's services (may include: visitors, patients, employees, or others).