MARTHA E. BELLIN, B.S.N., R.N.
ABBREVIATED C.V. (12/06/2017)

PROFESSIONAL EXPERIENCE:

2017-present IRB Coordinator
Institutional Review Board
Azusa Pacific University, Azusa, California

- *Keeps current with governing and guiding documents and publications for the protection of human subjects, including the Code of Federal Regulations (45 CFR 46), Guidance from Office of Human Research Protections (OHRP), and regulations generally referred to as the Revised Common Rule*
- *Maintains resources for information and education regarding IRB issues*
- *Attends a Public Responsibility in Medicine and Research (PRIM&R) or similar conference at least annually*
- *Coordinates all IRB applications through the IRBManager online portal and assists faculty, staff, and students in the submission process with substantive and technical questions by phone, email, and in person as needed*
- *Acts as a liaison between IRB members and researchers to assure compliance with regulatory and institutional requirements in the application and renewal procedures*
- *Screens submissions for the proper level of review; contacts applicants to correct and complete applications, and requests any additional documents as needed*
- *Prepares IRB meeting agendas and completes minutes using the IRBManager system*
- *Researches information from NIH, OHRP, and other regulatory bodies as well as best practices from other institutions regarding topics of interest and areas of challenge in the protection of human subjects in research*
- *Manages the IRB budget and reports to the executive director of the Office of Research and Grants accordingly*
- *Maintains records of correspondence with applicants per federal guidelines*
- *Ensures all applicants and those who review applications have current CITI certification.*
- *Coordinates through the IRBManager online portal all renewal and revision applications from projects still holding current approval and closure reports from applicants whose approval has expired*

2011-2017 Regulatory Coordinator
Regulatory Support Services
City of Hope National Medical Center, Duarte, California

- *Responsible for all aspects of clinical research regulatory compliance, including document preparation, submission, and management, for a specified portfolio of clinical trials.*
- *Coordinate the preparation and timely submission of regulatory documents to the City of Hope review committees, other internal committees, national cooperative groups, industrial clinical research sponsors, and Contract Research Organizations as necessary to meet all internal and external regulatory compliance standards.*
- *Initial review of research protocols and informed consent documents. Drafts initial consent.*
- *Preparation and submission of protocol amendments, continuations, adverse events, and document addendums*
- *Assistance with FDA and NCI submissions in collaboration with other City of Hope departments and Regulatory Affairs Offices.*
- *Organized Department Presentation for Research Protections Staff Meeting*
- *Interact with principal investigators and staff*
- *Familiar with different Cooperative Group documents and accessing them through the appropriate web site.*
- *Participating member of the Pediatric team reporting on regulatory activity.*
- *As part of Pediatric Team attended Children's Oncology Group conference in 2012 in Atlanta, Georgia*

2010 - 2011 Nurse Coordinator, Unrelated Donor Program
Nursing Support – Hematology/Hematopoietic Cell Transplantation (HCT)
City of Hope National Medical Center, Duarte, California

- *Organize the successful deliver of marrow, stem cells, or cord blood for transplantation*
- *Plans, implements, coordinate and evaluate matched unrelated donor (MUD) patient care*
- *Collaborates with medical and nursing personnel, case management, social services, the HLA lab, the MUD Financial Coordinator, and with coordinators from the National Marrow Donor Program (NMDP)*
- *Educate patients on the donor search process*
- *Processed and sent specimens to NMDP*
- *Participated in NMDP Education Planning Committee updating training materials*
- *Served as interim lead NMDP Coordinator*

2002– 2010 Clinical Research Coordinator
Hematology/Hematopoietic Cell Transplantation
City of Hope National Medical Center, Duarte, California

- *Managed Department of Hematology/HCT and Pediatric protocols for approximately 25 investigators*
- *Responsible for all aspects of clinical research regulatory compliance, including document preparation, submission, and management of Hematology and Pediatric clinical trials.*
- *Assisted Investigators with protocol process, consents, continuations, amendments and adverse events*
- *Assisted investigators with writing new protocol sections*
- *Drafted and revised consents*
- *Organized meetings, prepared agendas, and generate minutes for the fourteen Hematology Disease Committees, Associate Directors, and Hematology/HCT Quality Council*
- *Trained and provided support for secretarial staff related to protocols*
- *Served as a resource expert*
- *Entered protocol information into database*
- *Gathered, tracked, and maintained data and quality indicators for departmental use and presentation at Hematology/HCT Quality Council*
- *Organized and conducted continuous improvement projects*
- *Arranged pharmaceutical site initiation visits*
- *Responsible for submitting FDA Form 1572, curriculum vitae, and financial disclosures for investigator and co-investigators*
- *Served as liaison between Hematology and the Department of Information Science, IRB, CPRMC, Sponsored Research, the Clinical Trials Office (CTO), and the Clinical Trials Network*
- *Served on the CPRMC committee as a non-voting member*
- *Assisted with the Cancer Core Grant and Program Project process*
- *Worked with Marketing to update disease descriptions on the Hematology/HCT website*
- *Served as liaison for outside collaborating centers*
- *Participated on the Clinical Trials Office (CTO) Regulatory Working Meeting under Doug Stahl*
- *Organized meetings and site initiation visits between City of Hope staff and Pharmaceutical Companies, scheduling meetings with City of Hope Departments as needed, booking and setting up meeting rooms, and arranging for food services utilizing City of Hope or outside vendor*
- *Assisted staff with protocol searches for specific diseases*
- *Searched for publications as requested*

2002 Clinical Trial Monitor
Data Safety Monitoring
City of Hope National Medical Center, Duarte, California

- *Conducted intensive monitoring of high-risk institutional clinical trials*
- *Wrote reports based on monitoring results*
- *Discussed reported findings with Investigator and staff*
- *Maintained knowledge of regulatory standards*

1998 - 2002 Research Protocol Analyst
Research Subjects Protection
City of Hope National Medical Center, Duarte, California

- *Responsible for administrative protocol review and coordination of research subjects protection activities, including institutional policies, communication with research investigators and their staff in an effort to facilitate protocol submission and review processes*
- *Prepared agendas for the Institutional Review Board's (IRB) meeting and developed minutes reflective of the committee's protocol review activity and decision-making*
- *Maintained audit ready files*
- *Interacted with Principal Investigators (P.I.s) and their administrative staff*
- *Responsible for Web site maintenance*
- *Coordinated data base activities relative to the Research Subjects Protection Area using Visual D Base and InfoEd*
- *Maintained knowledge of regulatory standards*

1993 – 1998 Quality Control Coordinator
Biostatistics Department
City of Hope Medical Center, Duarte, California

- *Train Clinical Research Associate (CRA) staff*
- *Assisted Clinical Trials Coordinator with CRA performance evaluations*
- *Performed CRA audits*
- *Provided supervisory coverage for the Clinical Trials Coordinator overseeing the CRA's*
- *Audited Protocols for compliance*
- *Resource person*
- *Entered IRB information into Biostatistics Information and Tracking System (BITS)*
- *Entered protocol information into BITS*
- *Entered protocol synopsis and eligibility information into BITS database*
- *Ran data base searches and queries as requested*
- *Helped write BITS user instruction manual*
- *Ran and distributed various reports*
- *Organized and Chaired committees*
- *Provided support for the CRA staff*

1989 - 1993 Data Manager/Clinical Research Associate (CRA)
Biostatistics Department
City of Hope Medical Center, Duarte, California

- *Responsible for an assigned set of protocols*
- *Reviewed and confirmed subject eligibility requirements*
- *Registered eligible patients on protocols*
- *Monitored treatment and toxicity per protocol*
- *Collected data and completed case report forms*
- *Processed specimens required per protocol*
- *Maintained regulatory binders for assigned studies*
- *Designed data collection forms for in-house esophageal study*
- *Submitted continuations, amendments, and adverse events to the required committees*

1988 - 1989 Medical Program Specialist

Blue Cross of Southern California
Woodland Hills, California

- *Reviewed Medicare Outpatient, Skilled Nursing Facility, and Home health claims according to Government regulations.*

1981 - 1988 Staff R.N.
CIGNA Healthplans
Glendale, California

- *Wide variety of Nursing experience including Front and Back office Adult/Pediatric Ambulatory Clinic, Phlebotomy, Allergy injections, EKG's, Patient Education, and Home Health Care*
- *Float Nurse for three offices for two years.*
- *Staff clinic nurse for OB/GYN office for three years*

PROFESSIONAL LICENSE:(NURSING)

1977 California #E 280715

CERTIFICATES

1996 Clinical Research Associate Certificate
1984 Phlebotomy Certificate
1981 Public Health Certificate

TRAINING

2009 National Marrow Donor Program (NMDP) Transplant Center Coordinator Training

MEMBERSHIPS

1995 Society of Clinical Research Associates
1996 Southern California Clinical Research Professionals
2008 Regulatory Affairs Professionals Society (RAPS)
2009 Oncology Nursing Society

AWARDS

1977 Superior Service in Nursing Award

COMMITTEE MEMBERSHIPS

2000 ARENA Planning Committee, IRB Conference, San Diego, California
2001 ARENA Council

PUBLICATIONS

1. Casagrande, C., Niland, J., **Bellin, M.**, Roach, L., and Maryon, T. A Data Manager Training Program for Oncology Clinical Trials. Controlled Clinical Trials, April 1996. Page 42S.

2. Roach, L., Niland, J., Hilger, J., **Bellin, M.**, Brown, A., and Farino, G. "Training Program for Introduction to Data Management in Oncology Trials". Presented at the 19th Annual Meeting of the Society of Clinical Trials, Atlanta, Georgia. May 17-20, 1998.

3. Niland, J., Stahl, D., Jimenez, A., Cole, S., Miller, S., Yip, R., Carroll, B., Wein, M., Roden, S., **Bellin, M.**, and Rickard, K. "Web-Based Systems for Protocol Document Management", 20th Annual Meeting of the Society of Clinical Trails, Anaheim, California, May 2-5, 1999.

POSTERS

1. **Bellin, M.**, Brown, A., and Farino, G. "Informed Consent: The Eight Required Elements", Presented at the Southwest Oncology Group Meeting, Dallas, Texas. April 2-6, 1997

2. **Bellin, M.**, Brown, A., and Farino, G. "Computerized Advancement in Data Management at the City of Hope", Presented at the Southwest Oncology Group Meeting, Seattle, Washington. October 18-20,1997

3. **Bellin, M.**, Farino, G., Hyde, S., and Clinkenbeard, D. "Radiation Therapy: A Guide for CRAs" Presented at the Southwest Oncology Group Meeting, Atlanta, Georgia. April 23-27, 1998

LECTURE PRESENTATIONS

April 10, 2003	Protocol Tips. Southwest Oncology Group Clinical Research Associate Round Table. San Diego, California.
Aug. 19, 1993	Behind the Scenes in Clinical Trials: Making Research Work - Data Management & Quality Control. Clinical Trials: How to Approach a Study. Southern California Tumor Registrars Association. Duarte, California,
April 14, 1995	Quality Control and Maintaining a Research Record. Clinical Trials Data Management. Duarte, California,
November 15-16, 1995	Evaluating Toxicities: How to Recognize/Grade Them. Introduction to Data Management for Oncology Clinical Trials. Duarte, California,
November 4-6, 1996	Evaluating Toxicities: How to Recognize and Grade Toxicities. Introduction to Data Management for Oncology Clinical Trials. Duarte, California,
November 9-12, 1998	Evaluating Treatment Toxicities. Introduction to Data Management for Oncology Clinical Trials. Duarte, California.
April 19, 2003	Protocol Tips. Southwest Oncology Group (SWOG) Clinical Research Associates Open Forum.
August 2, 2005	The Protocol Process. City of Hope – City of Duarte – Duarte Unified School District Regional Occupational Program Presentation.
July 13, 2006	City of Hope – City of Duarte – Duarte Unified School District Regional Occupational Program Presentation.
August 16, 2006	Role of the Clinical Research Coordinators
September 29, 2017	IRB - Research with Human Subjects presentation at Responsible Conduct of Research Seminar, Azusa Pacific University.