

Title: Training and Education for Individuals Involved in the Conduct of Clinical Research	*Applicable to: Beaumont Health	Effective Date: 04/04/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 04/04/2018 Functional Area: Clinical Research Education and Training, Research Institute

***For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

I. PURPOSE:

The purpose of this policy is to ensure individuals conducting clinical research at Beaumont Health are appropriately trained and educated to identify appropriate training mechanisms, and to ensure appropriate documentation of training and education.

II. SCOPE:

This policy applies to all individuals (Beaumont employees, non-employees and external researchers) who are key research personnel involved in the conduct of clinical research at Beaumont Health.

III. RESPONSIBILITY:

This policy represents minimum training and education standards. All individuals involved in clinical research conduct are responsible for collaborating with their principal investigators (PIs), other key research personnel, clinical research department management, and Research Administration to identify and meet learning needs.

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IV. BACKGROUND:

All individuals participating in the conduct of clinical research must maintain compliance with the federal, state, local and institutional regulations governing clinical research in order to safeguard human research participants. Education and training are a crucial component of compliance.

V. GENERAL INFORMATION:

Research Institute Staff Involved in Clinical Research Conduct / New Hires:

Employees newly hired to Beaumont must complete hospital orientation appropriate to their classification, as outlined by Human Resources. Online Corporate Mandatory Education including the Research Institute Compliance Module, must be completed within the first two weeks of hire or transfer to the Research Institute.

- A. **Annual Hospital-Wide Mandatory Education** - Employees are responsible for completing annual Corporate Mandatory Education requirements appropriate to their classification, as outlined by Human Resources.
- B. **Human Subject Protection Program** - All key research personnel must complete the Collaborative Institutional Review Board Training Initiative (CITI) BASIC Human Subjects Protection Course for Biomedical Research Investigators and Key Personnel Group. This web-based program must be completed prior to engaging in research and within one week of hire or transfer date. The CITI BIOMEDICAL REFRESHER module is required every three years thereafter. The Institutional Review Board (IRB) will not process a project application unless all key research personnel have completed CITI training.
- C. **Good Clinical Practice Training** – New clinical research staff complete the CITI Good Clinical Practices (GCP-U.S. FDA Focus Course [Drugs, Biologics, and Devices] Course. This web-based program must be completed during orientation. The CITI GCP REFRESHER module is required every three years
- D. **Clinical Research Orientation for Research Institute Clinical Research Personnel** - Attendance at the two-day central clinical research orientation is mandatory for all Research Institute employed clinical research personnel within ninety (90) days of hire.
- E. **Research Informed Consent Training** - Informed consent training is required for all first time consent providers prior to providing consent to a participant. Training is required for informed consent using a signed document and informed consent using an information sheet (unsigned document). Consent training must be complete before the IRB will approve an individual as an authorized consent provider on any study. Once the Research Institute employee is approved to

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provide consent, repeat training is not required for subsequent studies. Training is completed during orientation or on a 1:1 basis. Training is coordinated by the Research Education department manager.

- F. **Phone Script Training** - When a research study involves contacting prospective participants by phone for recruitment, the IRB requires callers to follow an IRB-approved phone script. Research Institute employees must complete phone script training before the IRB will approve their participation. Once an individual completes phone script training for one study, repeat training for subsequent studies is not required. Training is coordinated by the Research Education department manager.
- G. **IRB Brown Bag Seminar Series Attendance** - The IRB and Research Education offer an educational series focusing on practical advice related to working with the IRB and other topics of interest to researchers. Select seminars are mandatory for clinical research staff.
- H. **Research Institute (Departmental) Compliance Training** - In addition to Corporate Compliance training, new Research Institute hires receive initial Research Institute-specific Compliance training. Thereafter, the Research Institute Compliance Plan is reviewed with all Research Institute personnel on an annual basis.
- I. **Specimen Packaging and Shipping Training** - All personnel (as identified by their manager) who package and ship specimens must complete training and become certified in accordance with Federal Regulations. Records of training (certificate and a copy of the test) must be kept in the department's "Specimen Processing and Shipping Certification Records" file in the event of an audit. The certified individual must also retain a copy of their training records. Bi-annual re-certification is required.
- J. **Research Billing Inservice** - A Research Billing Inservice is included in the Clinical Research Orientation. The clinical trials management software program, Reveal or DDOTS, is used to ensure research-related patient charges are allocated appropriately and third party claims are appropriately identified. Designated individuals who are responsible for reporting patient charges through Reveal or DDOTS, but who do not attend an inservice during orientation must contact a Research Billing Coordinator to arrange training.
- K. **Department and Protocol-Specific Training** - Additional training requirements may be necessary to meet individual departmental needs or the demands of particular protocols. Individuals involved in clinical research conduct are responsible for collaborating with their principal investigators (PIs), other key research personnel, clinical research department management, and Research Administration to identify and meet such learning needs.

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- L. **Additional Mandatory Requirements** - Additional education and training needs may be identified due to changes introduced by regulatory bodies or Research Administration. Training modules will be designed and completion made mandatory as necessary.
- M. **Basic Life Support (BLS) Certification** - Certain job classifications within clinical research (e.g., Assistant II, Coordinator I, Coordinator II, Research Nurse Clinician, Senior Research Nurse Clinician and Clinical Research Manager) are required to maintain BLS certification (see Job Descriptions for clarification). This requirement may be extended to other job classifications at the manager's discretion.
- N. **Leadership Initiative** - All managers will attend appropriate leadership courses through Beaumont University in accordance with Hospital Administration's Leadership Development Initiative and Research Administration requirements.
- O. **Documentation of Training** - Clinical Research Managers will review documentation of training as part of the annual performance appraisal process for Research Institute personnel.
 1. CITI Human Subject Protection Program Completion Certificate. Re-certify every three years.
 2. Orientation completion.
 3. Current Specimen Packaging and Shipping Certification for personnel who perform these functions. Recertify bi-annually.
 4. Documentation of Research Grant Billing training for personnel responsible for reporting patient charges.
 5. Documentation of department-specific or protocol-specific learning needs, including a description of how these needs have been met.
 6. Documentation related to additional mandatory requirements.
 7. Current BLS certificate for personnel as required per Job Description.

Non-Research Institute Beaumont Employees, Non-Employees and External Researchers Involved in Clinical Research Conduct / Human Subject Protection Program:

All Non-Research Institute personnel, non-employees and external researchers involved in the conduct of clinical research must complete the Collaborative Institutional Review Board Training Initiative (CITI) on-line Human Subject Protection Program prior to engaging in the research. A refresher module will be required every three years thereafter. The IRB will not process a project application unless all investigators and key personnel have completed the CITI training.

- A. **Informed Consent Training and Policy Review Attestation** – Non-Research Institute and non-employees (including residents, fellows and external collaborators but excluding other physicians and mid-level providers) must complete informed consent training and attest to review of key policies. Training is required for informed consent using a signed document and informed consent using an information sheet (unsigned document). The *Consent Providers*

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Attestation Form for Non Research/Non Beaumont Employees form (available on the Research Manager website) is completed during training. Training is coordinated by the Research Education department manager.

- B. **Phone Script Training** – When a research study involves contacting prospective participants by phone for recruitment, the IRB requires callers follow an IRB approved phone script. Individuals (excluding non-resident and non-fellow physicians and mid-level providers) must complete phone script training before the IRB will approve their participation. Once an individual completes phone script training for one study, repeat training for subsequent studies is not required. Training is coordinated by the Research Education department manager.
- C. **Specimen Packaging and Shipping Training** - All individuals who package and ship specimens must complete training and become certified in accordance with Federal Regulations. Records of training (certificate and a copy of the test) must be kept in the principal investigator's study files so they are available in the event of an audit. Both the principal investigator and the certified individual must retain records of training. Re-certification is required bi-annually.
- D. **Research Billing/Grant Form Inservice** - Research grant forms are used to ensure research-related patient charges are allocated appropriately and third party claims are appropriately identified. Designated individuals who are responsible for completing these forms must contact a Research Billing Coordinator to arrange training.
- E. **Department and Protocol-Specific Training** - Additional training requirements may be established specific to individual department needs or the demands of particular protocols.
- F. **Additional Mandatory Requirements** - Additional education and training needs may be identified due to changes introduced by regulatory bodies or Research Administration. Training modules will be designed and completion made mandatory as necessary.
- G. **Documentation of Training** - Principal Investigators are responsible for maintaining records of training for individuals associated with their trials. When trials are conducted under the auspices of a clinical research department, the clinical research manager is also responsible for ensuring training by non-division 08 and non-employed individuals is complete and documented.
- H. **Department of Defense Studies** When involved with a Department of Defense (DOD) study, initial and continuing research ethics education is required for all personnel who conduct, review, approve, support or manage human subjects research. The CITI online Human Subjects Protection Training initial course (with refresher/renewal course every three years) is required of all Beaumont researchers, key personnel, clinical research managers, IRB members and IRB staff. When research involves a DoD component under the purview of the Under Secretary of State (Personnel and Readiness), all investigators and research staff directly involved with human subjects research must complete **annual** training on human subjects protections (CITI); this is a more frequent training interval than required by the IRB requirements for other research

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projects. Additionally, the DoD component may evaluate the education policies to ensure personnel are qualified to perform the research, based on the complexity and risk of the research. Researchers conducting DoD research are made aware of specific requirements contained in DoD regulations when they complete the Appendix K to the IRB application (*Requirements for Research Involving or Supported by the Department of Defense.*) The IRB chairperson or designee makes a presentation to the convened IRB and IRB staff, reviewing specific requirements contained in DoD research prior to review of any DoD project. DoD-specific criteria are part of the IRB reviewer checklists. Additionally, Clinical Research and Process Improvement (CRQIP) monitors conduct annual reviews of DoD studies, to assure compliance with specific requirements.

I. Key Personnel on NIH-Funded Clinical Trials CITI Good Clinical Practices (GCP-U.S. FDA Focus Course [Drugs, Biologics, and Devices] Course:

NIH policy requires GCP training for key personnel on NIH-funded clinical trials. Completion of the web based CITI Good Clinical Practices (GCP-U.S. FDA Focus Course [Drugs, Biologics, and Devices] Course is mandatory for those listed on a study funded, wholly or partially, by the NIH.

VI. ASSOCIATED POLICIES:

Beaumont Policy 240 *Mandatory Education and Competency*
Beaumont Policy [Compliance Education and Communication](#)

VII. APPLICABLE REGULATIONS AND GUIDELINES:

NIH Frequently Asked Questions on the Requirement for Education on the Protection of Human Subjects http://grants.nih.gov/grants/policy/hs_educ_faq.htm
49 CFR 172 Transportation: Research and Special Programs Administration
<http://www.access.gpo.gov/nara/cfr/waisidx/49cfr172.html>
IATA 1.5 International Air Transport Association <http://www.iata.org/Pages/default.aspx>
Under Secretary of Defense (Personnel and Readiness) and Department of Defense (DoD) Requirements http://tricare.mil/hpae/_docs/P&RDoDRequirements.pdf
NIH policy: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>
NIH definition clinical trial: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

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CORPORATE AUTHORITY:

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.