



Title Research Administration Oversight	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/24/2016

I. AUTHORITY:

The authority of the Research Institute (RI) is established in the Bylaws of the RI. The Bylaws outline the purpose and responsibilities of the RI, and have been approved by the Board of Directors. Annual reports will be provided to the chief medical officer for review by the Board of Beaumont Health.

II. PURPOSE AND OBJECTIVE:

The purpose of this policy is to define the role of Beaumont Research Institute Administration in the oversight of all research conducted at Beaumont Health (Beaumont).

III. POLICY STATEMENT/SCOPE:

This policy pertains to all research, human, animal, or basic investigation (detailed in Research Policy *Definition of Beaumont Health Research*) characterized by any of the following:

- A. Research based on care delivered within Beaumont Health facilities (its' hospitals, outpatient centers, extended care facilities, or other facilities partially but not exclusively owned by Beaumont).
- B. Research supported by the use of Beaumont resources such as research equipment.
- C. Research which is the work product of Beaumont employees.
- D. Research based on clinical material obtained at a Beaumont facility.
- E. Research based on Beaumont clinical care records.
- F. The only exception to this policy is when Beaumont is determined not to be engaged in research per Research Policy *Institutional Engagement in Research*.
- G. Any investigation involving human participants at Beaumont utilizing Beaumont facilities, patients or staff (including retrospective studies of specimens or medical records) requires prior review and approval by an Institutional Review Board (IRB). Unless specifically authorized, all human participant research must be submitted for review and approval to the Beaumont IRB. This includes but is not limited to:
 - 1. Clinical research conducted at Beaumont facilities.
 - 2. Outcomes studies where data collection is taking place in the private practice, but the surgical procedure being assessed, took place at Beaumont.
 - 3. Studies based on a medical, clinical or other record or report initiated at Beaumont.
 - 4. Registry studies where data is being collected in the private practice, but the intervention took place at Beaumont.
 - 5. The investigator or key personnel are Beaumont employees, residents or fellows.

Components of the human research protection program (HRPP) include the IRB Office and staff, IRB membership, Research Compliance, Research Education and Clinical Research Quality and Process Improvement, Research Administration, investigators and research staff.

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IV. PROCEDURE:

The RI has the obligation and duty to protect our patients and research participants. As a covered entity, Beaumont and the RI are also obligated to protect patient data. The departments within Research Administration work together to provide oversight and advise investigators and staff on matters of funding, compliance, assurance of human participant protection, animal welfare and research integrity in order to assure the highest standards in research conduct are maintained. In order to support this assurance, all research projects, regardless of type (e.g., human, animal, bench, outcomes) and funding source must be given final approval by Research Administration. No research project may begin without this approval.

A. The Offices of the Vice President of Research and Administrative Director

The Vice President (VP) of Research is responsible for the scientific and financial oversight of all research activities being conducted at Beaumont. The Administrative Director, who reports to the VP of Research, is responsible for the day-to-day administrative oversight of the RI and the research being conducted at Beaumont. The primary responsibility for the human research protection program lies with the Research Institute offices of the VP of Research, and the Administrative Director. The VP of Research or the Administrative Director serves as the Institutional Official for the Institutional Review Board (IRB) and the Animal Care Committee (ACC). The Institutional Official signs the Federal Wide Assurance (FWA) on behalf of the institution to comply with 45 CFR 46 for human participant research, and the Office of Laboratory Animal Welfare assurance to comply with PHS Policy on Humane Care and Use of Laboratory Animals. Beaumont, under the direction of the Institutional Official and consistent with federal regulations, may suspend, terminate, or otherwise stop a research study approved by the IRB or ACC, which is considered inappropriate, objectionable or contrary to the mission of Beaumont. The Institutional Official sets the tone for the organization by promoting an institutional culture of respect and conscience, so the ethical conduct of all research, including human and animal research, is supported at the highest levels of the organization.

The VP of Research and Administrative Directors are ultimately responsible for:

1. Creating, establishing and maintaining policies and operating procedures for all Beaumont research, including the HRPP.
2. Overseeing the protection of human participants, animals, regulatory compliance, and the implementation of the HRPP at Beaumont.
3. Ensuring open channels of communication are maintained between the components of the HRPP.
4. Overseeing research investigators and staff, and research management in all research departments.
5. Protocol Review and Scientific Review Committees.
6. Central Beaumont Data Safety and Monitoring structure.
7. Central data safety.

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8. Ensuring the independence of the IRB and other oversight committees, including the authority to act without undue influence.
9. Requiring periodic reviews of the HRPP.
10. Ensuring the HRPP is functional, adequately staffed and funded, involving ongoing review with an annual formal review of the resources allocated to the HRPP (e.g., administrative resources, space, personal, educational, legal counsel, COI, Education, QI, community outreach and the IRB), and participation in development of the annual budget for all components of the HRPP.

All research contracts or agreements, including clinical trial agreements, data use agreements, research services agreements, material transfer agreements, confidentiality disclosure agreements, etc., are negotiated in conjunction with Legal Affairs and Research Administration. The VP of Research and the Administrative Director are the Authorized Signatories for research, on behalf of Beaumont.

The VP of Research, Administrative Director, and the Director of Research Finance, Grants and Contracts are the Authorized Signatories for research grant proposal submissions for Beaumont.

The Principal Investigator (PI) is responsible to Research Institute Administration for following federal and state research and funding regulations and guidelines, and Beaumont research policy. The PI is also responsible to the Institutional Review Board (IRB), Animal Care Committee (ACC), or other research oversight committees and the Chair of his/her clinical department. All research staff, including but not limited to managers, directors, scientists, nurses, coordinators, assistants, associates, etc., are under the direction of the Research Institute. The VP of Research or Administrative Director must approve staffing additions, terminations or transfers. Prior to implementing research department personnel changes, the Clinical Research Manager for the given department will consult with and notify the department Chief and/or the medical director of research. Any concerns raised by the department Chief, medical director of research or the PI, related to personnel changes will be reviewed by the Administrative Director, who will work with those involved to resolve the concern. Plans to ensure patient safety during any staffing transition will be ensured.

1. Whom to contact for additional information:

- a. The office of the Vice President of Research at 248 551-0902.
- b. The office of the Administrative Director at 248 551-1105.

B. Institutional Review Board (IRB): The function of the IRB is to provide regulatory oversight in order to protect the rights, safety, welfare, and research data of all individuals participating in clinical research. The oversight includes but is not limited to ethical, safety, and patient financial issues related to participation. All research involving human participants, including review of existing data or specimens, must be reviewed and approved, or granted Exempt status by an IRB prior to study initiation, as required by Federal regulations (21 CFR



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50, 21 CFR 56 and 45 CFR 46), the International Conference on Harmonization, Good Clinical Practice Guidelines, Federal, State and local laws and Beaumont policy. Beaumont adheres to 45 CFR 46 Subpart B and D and does not enroll prisoners into research trials. IRB oversight is required for all individuals and projects considered to be “engaged in research”. In certain circumstances, as described by IRB policy *Review by an External Institutional Review Board*, Beaumont may authorize the use of an external IRB.

The IRB will conduct continuing review of research at intervals appropriate to the degree of risk involved in the study, but not less than once per year, and will have authority to observe, or have a third party observe, the consent process and the research being conducted. Any changes to the research protocol must be reported to, and approved by, the IRB prior to the change being implemented. The only exception is a change necessary to eliminate apparent immediate risk or injury to study participants.

The IRB will also review reports of unanticipated problems, protocol deviations, and data safety monitoring boards, and will conduct or request periodic audits of individual studies to ensure the safety and welfare of participants and appropriate study record maintenance. The IRB will notify the Institutional Official and Sr. VP of Quality and Safety in writing of all on-site unanticipated problems. Instances of non-compliance are reported to the Institutional Official, who is responsible for reporting to the Office of Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA), as required. The Institutional Official may not reverse sanctions imposed by the IRB, however the Institutional Official may introduce additional sanctions or disapprove research based on organizational risk.

The IRB, Clinical Research Quality and Process Improvement (CRQPI) and/or the research compliance department will conduct periodic internal review or audits of individual IRB study files to assure study records are maintained appropriately.

HIPAA and Research: The Health Insurance Portability and Accountability Act (HIPAA) describes the conditions under which protected health information may be used for research. In order to protect patient confidentiality rights when patient information is viewed via medical records, computer databases or other recorded information sources when developing protocols or recruiting and locating potential participants, a Waiver of Authorization must be approved, in advance, by the IRB. The Waiver of Authorization form is available on the IRB website at Inside Beaumont.

Data generated from research conducted at Beaumont, whether identifiable or de-identified, belongs to Beaumont. Investigators are not authorized to remove research data from Beaumont unless an appropriate data use agreement has been executed.

Research data, including specimens and any form of Protected Health Information (PHI), may not be shared outside of Beaumont without prior authorization from participant via informed consent(s) (or an approved waiver of consent and authorization from an IRB) and



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an appropriate data sharing agreement between Beaumont RI and the recipient. Examples of data sharing agreements include clinical trial agreements, Limited Data Use and Release Agreements, data use agreements (for identifiable or de-identified data sets) and material transfer agreements.

1. **Where to find additional information:** IRB page of RI website at Inside Beaumont.

2. **Whom to contact for additional information:**

- a. Chair, Institutional Review Board, 248 551-0662.
- b. Manager, Institutional Review Board, 248 551-0653

C. **Animal Care Committee (ACC):** The function of the ACC is to oversee all aspects of research and educational activities using live animals on Beaumont premises. The Committee shall assure the humane care, use and treatment of animals according to the standards and regulations of the United States Department of Agriculture Animal Welfare Act and the PHS Policy on Humane Care and Use of Laboratory Animals.

The ACC will conduct initial and continuing review of all research and educational activities involving the use of live animals. Continuing review will be conducted at intervals appropriate to the degree of risk, but not less than once per year. The ACC will prospectively review and approve all significant protocol changes prior to those changes being implemented.

The ACC will conduct semi-annual inspections of the animal care facility and the animal care programs. A written report summarizing the inspection and all findings will be provided to the VP of Research and the Administrative Director. The ACC is responsible for providing recommendations to the VP of Research and the Administrative Director of the RI regarding any aspect of the animal care and use program.

1. **Where to find additional information:**

- a. The United States Department of Agriculture *Animal Welfare Act*
- b. Michigan Department of Agriculture Regulations
- c. Michigan Department of Public Health Regulations
- d. Public Health Service Policy *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*
- e. National Research Council *Guide for Care and Use of Laboratory Animals*
- f. Research Services Policies
- g. Beaumont's *Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Report*
- h. Beaumont's Office of Laboratory Animal Welfare (OLAW) Assurance Document.

2. **Whom to contact for additional information:**

- a. Chair, Animal Care Committee, 248 551-0213.
- b. Assistant Director, Research Services, 248 551-0666.

D. **Institutional Biosafety Committee:** The Institutional Biosafety Committee (IBC) serves to assure safe and ethical use of recombinant or synthetic nucleic acid molecules and potentially

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infectious or toxic agents in research or education at Beaumont. Any investigation involving DNA or potentially pathogenic organisms must be evaluated and approved by the IBC prior to implementation and prior to approval by the IRB or ACC (when human or animal use is planned); and if required, prior to approval by appropriate State or Federal regulatory agencies.

1. Where to find additional information:

- a. Research Policy 110 *Biosafety Committee Operations*
- b. IRB Policy 214 *Recombinant DNA Research*.

2. Whom to contact for additional information:

- a. Chair of the Biosafety Committee 248 551-3170 or 551-2560.

E. Research Compliance Committee: Beaumont is firmly committed to providing our patients and physicians the opportunity to participate in research conducted with integrity, the highest ethical and clinical standards, in compliance with institutional and government regulations, and with the uppermost interest for protecting our patients. The RI Compliance Committee (RICC), a subcommittee of the corporate Business Ethics and Corporate Compliance Committee, provides general oversight and review of research activities to assure their conduct adheres to applicable legal and financial guidelines. All investigators and their research projects are subject to Federal and local regulations in addition to the RI policies and procedures. The RICC is responsible for developing and updating the RI Compliance Plan, managing the research conflict of interest program, monitoring educational and quality activities and advising Research Administration and the IRB, when needed. The RICC does not review or approve the conduct of any research; however, they may impose specific requirements in order to conduct research in response to compliance concerns. Requirements imposed by the RICC supplement the requirements of oversight committees responsible for approving each study (IRB, ACC, Biosafety, etc.).

Research Institute Compliance Plan – Due to the complexities of conducting biomedical research, the RI has been identified by the organization as a high risk area. As such, a departmental compliance plan is required. The RI Compliance Plan identifies primary risks to the organization and our patients and outlines steps taken to assure compliance within each risk area. The plan includes:

1. An outline of the processes and procedures in place to manage identified risks;
2. The identification of a designated department compliance coordinator;
3. A summary of written policies and procedures related to the conduct of research at Beaumont;
4. Details of the training and education programs offered;
5. The established methods of communicating important information to our researchers;
6. An outline of our monitoring efforts, our methods for investigating reported potential misconduct and the disciplinary mechanism(s) in place in the event misconduct is identified.

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The RI Compliance Plan is updated annually to reflect changes in regulations, ICH Guidelines, policies and practices. Research Administration is responsible for coordinating the compliance efforts of the RI.

1. Whom to contact for additional information:

- a. The Director of Research Regulatory and Billing, 248 551-7366.

F. Research Finance, Grants and Contracts: The PI for each study is responsible for all aspects of grant and fiscal management. Research Finance, Grants and Contracts is responsible for overseeing the finances of each project to ensure adherence to all corporate policies governing approval and commitment of financial resources for personnel, equipment, supplies, animals, laboratory tests, patient charges, travel, etc., in accordance with the project budget.

Each research project must have a budget prepared and approved by Research Finance, Grants and Contracts regardless of funding source. For unfunded studies, a budget must be prepared with all of the true costs to the health system identified. Budgeted expenses for unfunded studies must receive approval from the appropriate Department Chair and Research Administration.

For externally sponsored studies, there must be a clinical trial agreement negotiated with the study sponsor by Research Finance Grants and Contracts and a representative of Legal Affairs, signed by the VP of Research or Administrative Director. All research funding must be directed through the RI.

As part of the budget process, Research Finance, Grants and Contract staff are also responsible for identifying any non-Division 08 personnel who will be working on a study and ensuring approval is given by the appropriate Hospital Administrators for the staff to participate.

1. **Grant Proposals:** Beaumont requires all proposals, pre-proposals, concept papers, letters of intent, contracts and subcontracts submitted to external agencies requesting funds and/or committing health system resources (e.g., personnel, space, funds, equipment and facility use, etc.) for the purpose of research activities be reviewed and approved by the RI Authorized Signatories prior to submission, even when the sponsoring agency allows direct electronic submissions from the investigator. In order to obtain RI approval, a copy of the complete and final proposal must be submitted to the RI Grants Development representative at least five (5) business days prior to the sponsor's deadline.
2. **Accounting for Research Activities:** Research Finance, Grants and Contracts will recognize revenue and track expenses within the Research Institute Division responsibility center (R/C) established for each project. Research Finance, Grants and Contracts is responsible for invoicing and collecting payment for study activities. Research Finance, Grants and Contracts is responsible for the review of financial activities and transactions, adjustments to transactions as appropriate, and reporting

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financial results to PIs, Department Chiefs, Research Administration, Corporate Administration and others as needed.

3. **Accounting for Federally Funded Projects:** Most National Institute of Health (NIH) grant awards provide for cost reimbursement and are subject to government-wide or Department of Health and Human Services (HHS)-wide cost principles. The cost principles establish standards for the allowability of costs and provide detailed guidance on the cost accounting treatment of costs as direct or indirect costs.

Research Finance, Grants and Contracts is responsible for understanding the cost principles established by Federal regulatory agencies and monitoring transactions related to federally funded projects to ensure strict adherence to cost principles. Research Finance, Grants and Contracts is also responsible for charging and collecting payments for federal projects, monitoring actual expenses compared to budgets to ensure billings do not exceed approved awards, and facilitating the submission of required progress reports for each grant, in conjunction with and on behalf of the PI. All individuals working on federally funded research who are not paid via eTime are required to maintain and submit detailed time and effort reports to Research Finance, Grants and Contracts on a monthly basis.

Prior to acceptance of a federal award or execution of a federal sub-contract, Research Finance, Grants and Contracts will confirm annual conflict of interest disclosures (COIDs) have been submitted for all individuals listed on the grant and conflict of interest training is current (taken within the last 4 years). Any positive COIDs will be referred to Research Compliance prior to acceptance or contract execution. Research Finance, Grants and Contracts will monitor time and effort reporting for personnel working on federally funded projects.

4. **Auditing of Federally Funded Grants and Contracts** - Research Finance, Grants and Contracts will participate in an annual A-133 audit of federally funded grants to ensure compliance with NIH rules and regulations, as well as participation in annual external audit, under the aegis of the Internal Audit Department.

5. Where to find additional information:

- a. Research Policy 304 *Establishing a Research Study Budget and Management of Research Funds.*
- b. Research Policy 302 *Employees Working on Beaumont Research Outside of their Normal Employment Duties.*
- c. Research Policy 103 *Competitive Grant Proposal Development and Submission.*
- d. NIH Grants Policy Statement, Cost Considerations, pgs. 80-133.

1. Whom to contact for additional information:

- e. Director of RI Financial Services, 248 551-2476.



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G. Clinical Trials Offices:

Clinical trials offices (CTOs) have been established to efficiently support investigators and assure studies are conducted in accordance with Good Clinical Practices, Beaumont policies, and research regulations. CTO's are primarily aligned by medical specialty. Each CTO is led by a clinical research manager (CRM) in partnership with a research director/primary principal investigator (PI). CRM's report to the Administrative Director of the Research Institute and collaborate with the director/primary PI on department goals and finances. The CTOs are staffed by a mix of licensed and unlicensed clinical research staff, who report to the CRM. Responsibilities of the CRMs include, but are not limited to, managing CTO staff and resources to ensure studies are completed timely, accurately, safely, and in compliance with all applicable policies and regulations; study participants are cared for appropriately during their research participation and their rights as research participants are upheld; serving as gatekeeper for CTO resources; acting as a liaison with research sponsors; participating in study budget development and determining feasibility of new studies; overseeing submissions to the research oversight and review committees (e.g., IRB, Protocol Review Committee, Scientific Review Committee); managing study start up processes; collaborating with departments and services system-wide, for protocol implementation; and managing the finances of the CTO. All Beaumont clinical research is run through a CTO. Any greater than minimal risk clinical trial will be staffed by Research Institute CTO employees.

1. Where to find additional information:

- a. Research Policy 304 *Establishing a Research Study Budget and Management of Research Funds*
- b. Research Policy 127 *Protocol Review Committee Process*
- c. Research Policy 128 *Scientific Review Committee Process*

2. Whom to contact for additional information:

- a. Administrative Director of the Research Institute, 248 551-1105.

H. Research Education and Clinical Research Quality and Process Improvement (CRQPI):

Due to the many regulations and potential risks associated with research and the RI's commitment to ensuring the protection of our research participants, all investigators and key personnel must complete the applicable mandatory education requirements as determined by Research Administration and provided by Research Education, prior to conducting research activities. Examples of mandatory education include Human Subjects Protection (*Collaborative Institutional Review Board Training Initiative* or "CITI" on-line training), Packaging and Shipping of Laboratory Specimens, Research Compliance, Research Patient Billing, Research Services, etc. For further information, please refer to Research Administration policy *Training and Education for Individuals Involved in the Conduct of Clinical Research*.



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Research Education staff will provide clinical research orientation and in-servicing as needed, information dissemination, and tracking of certifications and mandatory education completions.

Under the CRQPI, inspections are performed to assess compliance with Federal, State and local regulations, as well as RI policies and procedures. The audits are performed through review of participant medical and research records, departmental documents and IRB files. Inspections may be requested by the RICC to meet the objectives of the RI Compliance Plan, including review of Conflict of Interest Management Plans, the Conflict of Interest Disclosure process, and record keeping. For-cause inspections are also requested by the VP of Research, the Administrative Director or the IRB in response to concerns, e.g., complaints, protocol deviations or unexpected problems being reported with increasing frequency. Investigator-initiated studies are supported through performance of monitoring visits following enrollment of the first subject. The outcome of these quality assurance assessments include improved departmental and RI processes, in addition to providing support and education to the clinical research departments. Reports from all audits or monitoring of clinical research are provided to the IRB.

1. Where to find additional information:

- a. Research Policy 113 *Clinical Research Quality And Process Improvement Program*(
- b. Research Policy 500 *Training and Education for Individuals Involved in the Conduct of Clinical Research*.

2. Whom to contact for additional information:

- a. Administrative Nurse Manager of Clinical Research Education and Quality and Process Improvement, 248 551-1535.

I. Outcomes Research: The Center for Outcomes Research conducts research focusing on the end results of health care practices and interventions of importance to decision-makers, including patients, providers, and payers. End results include patient and provider-centered outcomes such as functional status, length of stay, level of pain, cost of care, etc. The Center for Outcomes Research can provide assistance with research study design and implementation, database development, data coding in preparation for statistical analyses, and some statistical analyses related to outcomes research projects.

1. Whom to contact for additional information:

- a. Director of Outcomes Research, 248 551-8687.

J. Research Patient Billing: The RI is committed to appropriately billing all patient care provided as part of research participation. Research Billing Coordinators are responsible for managing and tracking patient visits through the Reveal or DDOTS Clinical Trial Management System, processing research charges through the Hospital billing system and conducting research billing compliance audits.

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1. **Where to find additional information:**
 - a. *Medicare Coverage Manual – Clinical Trials – Final National Coverage Decision Memorandum*
 - b. *Clinical Trials Billing Cycle*
 - c. Research Billing web page on Inside Beaumont.
2. **Whom to contact for additional information:**
 - a. Director of Research Regulatory and Billing, 248 551-7366.
 - b. Research Billing and Data Systems Coordinator, 248 551-7985.

V. FEDERAL NOTICES: As a recipient of Federal contracts/subcontracts which include the Federal Acquisition Regulation (FAR 52.222-50), Beaumont Research Institute must notify its employees of the United States Government's zero tolerance policy regarding combating trafficking in persons. Contractors and contractor employees shall not (1) Engage in severe forms of trafficking in persons during the period of performance of the contract; (2) Procure commercial sex acts during the period of performance of the contract; or (3) Use forced labor in the performance of the contract. Actions that will be taken against employees for violations of this policy may include, but are not limited to, removal from the contract, reduction in benefits, or termination of employment.

VI. SUMMARY: All research activities conducted at Beaumont fall under the purview of Research Administration. It is the goal of the RI to assure all research is conducted with integrity and the highest regard for scientific merit, participant respect, safety and well-being, and in compliance with all applicable laws, rules, regulations and RI policies and procedures. The RI serves to create an environment conducive to the performance of quality research by providing scientifically appropriate equipment, facilities, trained personnel and research infrastructure. Researchers and research staff are encouraged to express concerns and convey suggestions regarding the HRPP. Contact information for this purpose is provided on the Research Institute and IRB webpages, the Research Institute Monthly Newsletter, within specific Research policies, and IRB approval letters. Refer to Research policy 116 *Contacts, Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research* for additional information.

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.