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Observers & Observerships Policy

Type

Institution (relates to structure and infrastructure of the organization)

I. Rationale

Baylor College of Medicine (BCM or College) is responsible for the activities of Observers, which must be conducted in accordance with College policies as well as applicable laws, regulations, and standards ([see Section X](#), below).

II. Stakeholders Affected by this Policy

Compliance with this policy is mandatory for all BCM Community Members, Employees, Observers and Virtual Observers. This policy does not apply to international residents and fellows who are seeking to observe BCM Graduate Medical Education (GME) programs, or BCM Employees interested in hosting an international residents and fellows as observers, which are governed by the [GME International Observers Policy \(27.2.7\)](#).

III. Definitions

- (a) **BCM Community Members** refers to current BCM patients, officers and board members, volunteers, and guests.
- (b) **BCM Employees** refers to faculty, staff (including course directors, clerkship directors, and attending physicians), residents, clinical fellows, and contractors, who receive employment compensation from BCM.
- (c) **BCM Information** refers to all information owned by the College, including that which could adversely affect the organization if lost, misused, modified, or accessed without authorization, but which is not limited to, any information that is labeled by the College as “confidential;” any contract or agreement to which the College is a party; proprietary research; clinical, academic, administrative, affiliate institution, and business partner information; financial information; intellectual property; employee and student identifiable information; human subject research participant and patient protected health information.
- (d) **BCM Learners** refers to students currently enrolled in any BCM school or degree-granting program, and includes postdoctoral and predoctoral trainees who are invited to complete time-limited training or learning experiences that are administered by designated BCM departments and do not require enrollment.
- (e) **Hazardous Areas** refers to BCM locations where potentially hazardous materials (e.g., select agents, infectious agents, blood borne pathogens, radioactive materials, etc.) or conditions exist. This includes research laboratories, clinical laboratories, clinics and shop areas (e.g., machine shop, carpenter shop).
- (f) **Host** refers to the BCM Employee, who must be a faculty member or have a title at Director-level or higher, accepting responsibility for the oversight of all onboarding requirements and activities of the Observer. For research activities, the Host must be a Principal Investigator.

- (g) **Laboratory** refers to a workplace where relatively small quantities of hazardous materials (i.e., substances and chemicals) are stored and used under controlled conditions with the intention of performing scientific or technological research experiments or measurements.
- (h) **Minor** refers to a person under the age of 17
- (i) **Observer** refers to a person who enters a BCM Laboratory, clinical area, animal facility, or other facility owned or operated by BCM, on the express or implied invitation of a BCM Host, to observe BCM operations and evaluate a potential interest in pursuing a career in that job field. This on-campus experience is referred to as an Observership. Observers do not include:
- Learners and Volunteers, including individuals seeking to participate in experiments (See Guidelines for Visitors/Volunteers Participating in Research);
 - Medical students visiting through the School of Medicine Visiting Student Program;
 - Students who are enrolled in a high-school program, undergraduate program, or graduate program outside of BCM, and attending a BCM-approved elective (as a visiting student), internship program (see 02.6.40 – Internships at BCM for College or High School Students), or research endeavor (e.g., Rice graduate thesis research); or
 - Individuals employed by institutions with which BCM has a Business Associate Agreement and written Affiliation Agreement.
- (j) **Protected Health Information (PHI)** is defined in the [HIPAA Glossary of Terms](#).
- (k) **Virtual Observer** refers to an Observer who accesses the BCM campus through virtual means only (e.g., internet, phone). Virtual Observerships do not require physical entrance into the BCM campus or the campus of a BCM affiliate institution in order to participate, and never involve sharing or exchange of BCM Information. Examples of Virtual Observerships include attending an online BCM education module, lecture, lecture series, or forum; telecommuting to an audio/visual educational event hosted at BCM or an affiliated institution; watching the simulated performance of a technique or service by a BCM employee for educational purposes, i.e., participating in learning experiences that do not include BCM patients or BCM protected health information.
- (l) **Volunteer** refers to any person who provides services to BCM with no monetary or material compensation.

IV. Policy

- A. Observers and Virtual Observers must comply with all College policies, as well as any federal, state, and local laws or regulations that apply to Observership experiences or activities. Compliance with applicable policies and laws is a condition of continued admission to the BCM campus, completion of the Observership, and continued virtual access to BCM events and information systems or assets from remote locations.
- B. Before starting an Observership at BCM, Observers must complete the appropriate documents and training modules as outlined in this policy. All Observers must wear a BCM-approved Identification badge, which must remain visible at all times while they are at a College location. Virtual Observers will not receive BCM Identification badges or training outlined in this policy because Virtual Observerships do not include access or exposure to human subject research, patient encounters, or BCM PHI.
- C. Each Observer or Virtual Observer must have a designated Host.
- D. Observers must comply with policies of BCM affiliates before going to an affiliate's site.
- E. Observers are considered members of BCM Workforce under the HIPAA Privacy rules and who are subject to all BCM policies pertaining to the privacy and security of PHI.
- F. Observers who have ever had a positive Tuberculosis (TB) Test are required to provide adequate documentation of no signs of active TB at a minimum of 1 year before the start date as a BCM Observer. Adequate documentation includes documentation of the Positive TB test and a Negative Chest x-ray.
- G. Virtual Observers are not permitted to access or observe BCM Information. Although Virtual Observers are exempt from policy requirements and procedures related to an Observer's physical presence on campus, as described in [Section IV.F](#) (above) and [Sections VI.B-C](#) (below), Virtual Observers must comply with all other applicable provisions of this policy.

V. Responsibilities

- A. **Hosts** are responsible for:
 - 1. Designing steps to place the Host's laboratory, facility, or clinic in full compliance with all applicable BCM safety policies and procedures;
 - 2. Monitoring personal compliance with this policy;
 - 3. Verifying that any Observer or Virtual Observer in the Host's Department or Area meets the requirements outlined in this policy, in addition to complying with applicable affiliate policies (e.g., applicable to the hosting site, facility, or activity);
 - 4. Reviewing this policy with Observers, and providing appropriate Personal Protective Equipment (PPE), where required for the location, with instructions on proper use and disposal. Hosts are not required to review this policy with Virtual Observers or provide them with PPE, although Hosts must monitor the Virtual Observer's compliance with applicable observation standards ([see Section VI.A](#), below);
 - 5. Verifying that the Observer is assigned and completes the required training modules for Non-Paid Personnel outlined on the [Human Resources intranet](#), as well as the required safety training for Minors who will be in a Hazardous Area;
 - 6. Collecting all Observer ID badges at the end of the Observership and promptly returning them to the BCM Security Office; and
 - 7. Promptly notifying BCM Risk Management if an Observer is injured while on BCM premises.
- B. The **Office of Environmental Safety** is responsible for addressing questions concerning general hazards present at BCM.
- C. The **Center for Comparative Medicine** is responsible for addressing questions regarding hazards associated with animal work.

VI. Procedures for Implementation and Review

- A. **Observation Standards.**
 - 1. Observers and Virtual Observers are subject to the following restrictions and approvals, when and as applicable:
 - a. May not observe human subjects research without the prior approval of the College's Institutional Review Board (IRB) and completion of appropriate training as required by the College or IRB, including HIPAA Privacy & Security (HIPAA) training;
 - b. May not be in the patient treatment room without the patient's verbal consent and in those cases may only observe and may not be involved or assist in patient care activities. Consent must be documented in the patient's medical record.
 - c. May not have access to Protected Health Information (PHI) at the College, including clinical areas, without completing HIPAA training;
 - d. May not observe work with research animals without prior approval of the College's Institutional Animal Care and Use Committee (IACUC) and completion of appropriate training and health clearance as required by the College or IACUC;
 - e. May not observe work with recombinant DNA or infectious agents without prior approval from the Office of Environmental Safety (OES) and must be listed as an Observer on the protocol submitted by the Principal Investigator;
 - f. May not handle, or be in areas with, radioactive materials or radiation-producing equipment without prior approval from OES. The individual must complete required training and be added to the Radiation Safety Committee research or clinical protocol as an "Observer" before he/she can enter areas with hazardous materials; and
 - g. Must obtain institutional approvals or credentialing (as applicable) at the location where the individual will be observing (e.g., affiliate hospitals, clinics, schools).
 - 2. The following individuals are not eligible to be Observers or Virtual Observers at or on behalf of the College:

- a. Former BCM Employees who were dismissed from employment at BCM for cause;
- b. Foreign nationals who require an export license to be in places where the Observer will have access to export controlled information or equipment.
- c. Individuals identified as debarred, disqualified, or otherwise restricted, based on state and federal agency exclusion lists used by BCM in its Sanction Screening process.

B. Guidelines for Observation in Potentially Hazardous Work Areas.

1. Prohibited Access and Activities.

- a. Minors are prohibited from being in the following laboratories, facilities, or clinics:
 - 1) Any laboratory designated as Biosafety Level 3 (BSL-3);
 - 2) Any laboratory where select agents and toxins (SA) or explosives or energetic compounds are used or stored; and
 - 3) Any areas within BCM that require additional security clearances for access beyond the background investigation activities performed by BCM's Office of Human Resources ([see Section C](#), below).
- b. Minors are prohibited from being around or exposed to any of the following materials:
 - 1) Radioactive Materials and radiation generating equipment such as x-rays, lasers, fluoroscopes, etc.;
 - 2) Acutely toxic chemicals, defined on page 10 of the [BCM Chemical Hygiene Plan](#) (Section 1.4 – “Chemicals with high degree of acute toxicity”);
 - 3) Biological agents requiring Biosafety Level 2 (BSL-2) containment (unless written authorization is received from OES and Occupational Health Program (OHP)); or
 - 4) Animal facilities/rooms where the animals have been infected with BSL-2 agents.

2. Restricted Access. No Minor is allowed to enter a potentially Hazardous Area unless the minor is either:

- a. A BCM employee or enrolled student;
- b. 15 years of age or older and part of a group or individual educational program that has been approved in advance by the educational institution that they belong to, as well as by the Director/Principal Investigator of the area and the Chair of the Department where the program will take place; or
- c. 15 years of age or older and all the following exist:
 - 1) The BCM Faculty Member or Principal Investigator is the Host of the Minor;
 - 2) The Minor will not be in the potentially Hazardous Area for more than two (2) months; and
 - 3) The Host, Minor and Minor's parent/legal guardian have agreed in writing to the Minor's role as an Observer and that the Minor will not participate in any activities beyond the Minor's role as an Observer.

3. Additional Responsibilities. Hosts of Minors observing in Hazardous Areas must:

- a. Discuss this policy with all Minors working in the laboratory, facility, or clinic area;
- b. Provide hazardous specific training to the Minor as approved by OES as set forth on Schedule 1 (Minors) (See Attachment A, below); and
- c. Ensure the Minor is personally supervised at all times while in the laboratory, facility, or clinic and is not left alone.

C. Procedure for Establishing an Observership.

1. The Observer must complete and sign:

- a. The Visitor/Volunteer Authorization Form (see Attachment B, below) and, where applicable, Minor Forms, which are submitted to the VP of Human Resources for approval. In addition, the following approvals are required by:

- 1) SVP and Dean for Research, if the individual will be in a laboratory or observing research activities;
 - 2) Dean of the School of Medicine, if the individual will be observing in BCM clinical areas or in clinics owned or operated by a BCM affiliated institution;
 - 3) Dean of the School of Health Professions, if the Observership is related to one of its programs;
 - 4) Office of General Counsel and ISO-Human Resources, if the individual is a foreign national and will have access to any laboratory or research activity, and ISO-Human Resources must verify any visa restrictions.
2. A Position Action Form (PAF) is not required. The Host is responsible for creating a Position Request in SAP using the "Observer" title and Employee Group 9 – Voluntary.
 3. A badge will be issued by BCM Security after the Observer has been entered into SAP.
 4. The Host is responsible for implementing the [Non-Paid Personnel Training and Enrollment](#) steps for on-boarding for the Observer.
 5. Observers must complete the on-line Compliance Training and courses as set forth on Schedule 1 (Visitors) (See Attachment "C" below).
 6. All required training must be completed before the Observer is given access to BCM laboratories, facilities or clinical areas. The Security Office issues a badge after the individual has been entered into SAP.
 7. The Observer must provide documentation of their flu vaccination status (required for Observers September 1 through April 1) and current immunization status to the Host. The Observer cannot start until that information is provided. (See Attachment D, below).

VII. Stakeholder Compliance

- A. Failure of an Observer to comply with the requirements of this policy will result in revoking the Observer's privilege of access to BCM laboratories, facilities, and/or clinics. Failure of a Virtual Observer to comply with applicable provisions of this policy or other BCM policies will result in revocation of their virtual access to BCM, and may prevent future participation in Virtual Observerships offered through BCM.
- B. Failure of a Host to comply with this policy may be a lapse in professionalism. Hosts who fail to comply with the requirements of this policy may be denied permission to host Observers and Observerships in their setting.
- C. Failure by BCM administrators to oversee compliance with this policy and procedures can result in reputational harm to BCM, loss of research funding, monetary penalties, or violation of federal labor and employment and immigration laws.

VIII. Tools

- [Attachment A, Visitor Minor Training](#)
- [Attachment B, Visitor/Volunteer Authorization Form](#)
- [Attachment C, Visitor Training](#)
- Attachment D, Observer Immunization Check List

IX. Related Policies

- [02.4.34 – Student Workers](#)
- [02.6.40 – Internships at BCM for College & High-School Students](#)
- [28.1.06 – Elective Course Requirements for International Visiting Students](#)

X. Applicable Laws, Regulations & Standards

- Occupational Health and Safety Act (OSHA), 29 U.S.C. §651, et. seq.; 29 C.F.R. Part 1910
- Export Control Laws: Export Administration Regulations (EAR), 15 C.F.R. Parts 730-774 and
- Internal Traffic in Arms Regulations (ITAR), 22 C.F.R. Parts 120-130.
- HIPAA Privacy regulations 45 CFR Parts 160-165
- Texas Medical Record Privacy Act, Texas Health and Safety Code, Section 181