The Clinical Compliance Committee (“Committee”) is an oversight group for clinical compliance issues that relate to the OHSU Health Care System. The Committee advises and assists the OHSU Chief Integrity Officer and recommends appropriate modifications to the Clinical Compliance Program. The term "clinical compliance" is used in this charter to refer to compliance with federal, state, and local laws and regulations that impact or relate to the OHSU Health Care System. The Committee is composed of members representing the components of the Health Care System defined below.

The components of the Health Care System include the Schools of Medicine, Dentistry, and Nursing; the Child Development and Rehabilitation Center; the clinical research enterprise; the School of Medicine Faculty Practice Plan (FPP); and the Hospitals. As used in this charter, the term "OHSU" is used to refer to all of these components. Each of these components has the following individual responsibilities:

1. Assessing and monitoring clinical compliance within their respective areas;
2. Maintaining current knowledge of compliance issues related to the activities and relationships of that component;
3. Designating someone to be the Compliance Officer (or similar position such as compliance coordinator). This position will be the liaison to the Committee.

The Committee will have the authority to establish subcommittees that will be charged with the responsibility of addressing particular issues or concerns or a particular area of compliance and providing expertise to the Committee on an ad hoc basis. Currently the subcommittees include the Hospital Compliance Committee and the Faculty Practice Plan Compliance Committee. Each of these subcommittees will be assigned specific areas of oversight and each has a separate charter.

The Committee will authorize, review, and approve a detailed risk assessment approximately every two years. At the direction of legal counsel, this assessment may be implemented as a privileged document that guides clinical compliance activities and provides advice to OHSU.

The Committee will be advisory to the OHSU Chief Integrity Officer who, in turn, will report issues to the Executive Director of Healthcare for Hospital and Clinics and to the Dean of the School of Medicine for the Faculty Practice Plan. In addition, the Chief Integrity Officer will provide appropriate, periodic reports to the executive leaders of the other schools and operational units that engage in clinical activities. The OHSU Chief Integrity Officer will provide an annual report to the OHSU Board of Directors and will include a clinical compliance component in that report. This report will be coordinated with the work of the Committee and will reflect the major areas of clinical compliance that have been addressed by it. While the purpose of the report is not to provide detail regarding specific compliance issues, it will include sufficient specificity to allow the
OHSU Board of Directors to engage in meaningful oversight. Further reporting will occur to the OHSU Integrity Program Oversight Council, which meets quarterly and is chaired by the OHSU Chief Integrity Officer.

The Committee will retain authority in those areas where policy confers it on the Committee. A chair of the Committee will be appointed by the Chief Integrity Officer from among the committee members. A co-chair will also be appointed. The chair’s and co-chair’s terms will be indefinite.

The Committee will meet on a quarterly basis. However, if there are pressing issues or matters of an urgent nature, the chair may call meetings more often. On advice of counsel, less than the full Committee may meet to discuss matters subject to attorney-client privilege.

Members of the committee have the responsibility to attend the meetings, representing the departments and staff from their area(s) and to actively participate in the committee meetings. Members who cannot attend a meeting are not allowed to send a representative in their place.

The Committee will decide upon recommended actions by consensus of the members. In some cases, the chair may decide to conduct Committee business via electronic means and the consensus rule will still apply.

Advisory responsibilities of the Committee include: 1. Approving and overseeing the implementation, monitoring, and enforcing of a written program for compliance with regulations and guidelines of federal and state authorities, applicable to clinical activities (the Clinical Compliance Program).

2. Working with appropriate areas within OHSU to assure development of policies and procedures to promote compliance with the Clinical Compliance Program.

3. Approving and overseeing a communication plan for personnel regarding the development, implementation, and monitoring of the Clinical Compliance Program.

4. Authorizing the compliance risk assessment of areas of clinical activities at OHSU, including reviewing and approving the assessment and prioritizing high-risk areas of concern.

5. Recommending monitoring, overseeing reviews and the development and implementation of plans for acting on results of the reviews.

6. Recommending internal systems, controls, and monitoring to ensure compliance with the standards, policies, and procedures of the Clinical Compliance Program.

7. Promoting and maintaining a system to solicit, evaluate, and respond to clinical
compliance complaints, inquiries, and problems.

8. Assuring timely response to clinical compliance problems in a manner that resolves immediate issues and prevents future issues of the same type.

9. Overseeing a continuous education program that explains the compliance program, specific requirements, and relevant laws and regulations for all OHSU personnel involved in clinical activities.

10. Periodically monitoring the effectiveness of the compliance program through a variety of measures and making recommendations to improve effectiveness.

Voting members of the Clinical Compliance Committee include:

1. The Associate Hospital Director of Finance;
2. The Chief Operating Officer Healthcare System;
3. The Director of Quality Management;
4. The Director of Clinical and Translational Research;
5. A Compliance Representative School of Nursing (appointed by Dean SON);
6. A Compliance Representative CDRC (appointed by Director CDRC);
7. The UMG Chief Operating Officer
8. Chief Health Information Officer
9. The Lab Compliance Committee Chair
10. A physician from the School of Medicine (SOM) Faculty Practice Plan;
11. A compliance representative from the School of Dentistry (appointed by Dean SOD);
12. Additional representatives from clinical areas (the Faculty Practice Plan, Hospitals, SoD, SoN, CDRC, or other clinical areas) as deemed appropriate and useful by the Committee; and
13. The Chair of the Faculty Practice Plan Compliance Committee or his/her designee.

Non-voting members of the Clinical Compliance Committee include:

1. The OHSU Chief Integrity Officer;
2. The Clinical Compliance Officer for the Hospitals and Clinics;
3. The Clinical Compliance Officer for Professional Services; and
4. The OHSU Chief Information Privacy and Security Officer.

In addition to the above membership, legal counsel will attend and participate in Clinical Compliance Committee meetings as necessary and appropriate for the rendering of legal advice to the institution. It is permissible for one representative to fill more than one of the identified roles for the Committee.