



## **The Role of Institutional Review Board**

The Institutional Review Board (IRB) at Chesapeake has the responsibility of overseeing procedures for carrying out Chesapeake's commitment to protect human subjects in research. The role of the IRB is

- to review proposed research projects that involve the use of human subjects;
- ensure that the individuals involved in the project are treated ethically;
- ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study;
- and that all private information will be handled with anonymity and confidentiality.

The IRB can review, approve, and require modifications in, or disapprove research activities conducted by or through Chesapeake using human subjects. The IRB does not assume the role of evaluating the merits of the research design nor the potential contribution of the research to scholarly literature.

Rather, the IRB is charged with evaluating each project's compliance with standards in regard to issues such as informed consent, confidentiality, and any risk to participants, and compliance with Chesapeake procedures.

## **Policies and Procedures**

The committee will be convened when needed. Meetings may take place via phone, email or in person. Action will be taken on most requests within 2 weeks of submission. Exceptions to this will be requests requiring further information or documentation.

Decisions by the IRB are made by a majority vote of the voting members in attendance at the meeting. Alternate IRB members may only vote in the absence of the regular member for whom they are substituting. Consultants may attend the meeting and provide comments, which will be documented in the minutes; however, they do not vote.

A regular or alternate member or consultant present at the meeting having conflicting interest (e.g. involved in the study) in a matter cannot vote on that matter and must be absent from the meeting during the deliberation and voting. They can, however, be in attendance to present information or answer questions if the IRB requests it. The IRB Chair will call for IRB members and others present at the meeting (e.g. guests, consultants) to identify any additional conflicts not already identified on the agenda.

The IRB may invite individuals (e.g. alternate IRB members or consultants with specific expertise that does not exist in the regular IRB member expertise area, as identified by the IRB membership lists) with competence in special areas to assist in the review of complex issues that are beyond the expertise of the IRB.

## **Types of Research for the IRB**

As stated in the Code of Federal Regulations, Title 45, Part 46, 46.101, IRB policy applies to all research involving human subjects. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

**(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.**

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or  
(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

### **Applicable Regulations and Guidelines**

[45CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) Protection of Human Subjects  
(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)

[21CFR50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50) Protection of Human Subjects  
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50>)

[21CFR56](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=56) Institutional Review Boards  
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=56>)

### **Institutional Review Board Membership**

The IRB consists of Chesapeake College faculty, administrators, and staff with areas of expertise in various disciplines, including scientific and non-scientific fields.

Director, Institutional Research, Planning and Effectiveness (Chair)  
Director, Academic Assessment  
Director, Student Life  
Faculty Representatives (2)  
Human Resources Representative  
Learning Resource Center Representative  
Registrar  
Vice President for Workforce and Academic Programs