

**Approved by:** Faculty and President

**Date Approved:** February 10, 2015

1. **Summary:** This policy establishes the requirements and guidelines for research involving human subjects conducted at Criswell College and for the review board that approves such research.
2. **Rationale:** This policy is necessary to ensure the ethical, legal, and professional standards of research conducted by members of the College.
3. **Entities Affected:** students, faculty, staff

4. **Definitions:**

*Human Subject:* a living individual about or from whom an investigator conducting research obtains data and/or identifiable private information through intervention or interaction.

*Principal Investigator:* an individual who directs and manages a research study.

*Research:* a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

5. **Policy:** It is the policy of Criswell College that all research involving human subjects must be conducted in accordance with accepted ethical, legal, and professional standards for research, and that all such research must be approved by the College's Institutional Review Board (IRB).

### **IRB Membership**

The Criswell College IRB consists of five members, including one chair and three other members from the College and one member from outside the College. The Vice President for Academic Affairs (VPAA) selects the members and appoints the chair. The faculty then vote to approve or disapprove the selections and appointment. Appointments are for a three-year period, but members may continue to serve if reappointed and reapproved. When a vacancy occurs, the VPAA appoints a new member, who must be approved by the faculty with a vote.

### **IRB Approval**

The primary goal of the Criswell College IRB is to protect the welfare and dignity of human subjects. A secondary goal is to assist investigators in conducting ethical research that complies with applicable regulations. Thus, when a faculty member, student, or employee of Criswell College wishes to conduct research involving human subjects, his or her research proposal must be reviewed and approved by the IRB.

### **Mandatory Training**

Any faculty member, student, or employee wishing to conduct research involving human subjects also must complete training as stipulated by the IRB in compliance with all appropriate standards. This training requirement applies not only to Principal Investigators, but also to all individuals identified as research assistants who are responsible for the design and conduct of the study. Personnel external to Criswell College who conduct human subject research at or with Criswell College must also complete the required training or provide proof of equivalent training.

### **Exemptions**

Research that exposes participants to minimal risk, or no risk at all, may be considered exempt from the need for ongoing IRB review and approval. Federal law details categories of exempt research. As stipulated by federal regulations, the IRB must make final determination for exemption categories. While not an exhaustive list, the following types of studies may qualify for a determination of exemption by the IRB.

- Studying educational methods
- Interviewing public figures
- Utilizing publicly available data sets
- Utilizing specimens of human tissue stripped of identifiers

### **Expedited Review**

Expedited reviews are conducted as necessary and must meet the following qualifications:

- No use of deception
- No study of minor children, prisoners, pregnant women, or impaired adults
- No study of illegal activities like drug use
- No study of human private activities like sexual behavior

Any research study that qualifies for expedited review must be approved by the IRB Chair before research may be conducted. If a research study does not meet the above criteria it may be referred for review by the convened (full) IRB or assessed to determine if it qualifies for exemption from ongoing review and approval.

### **Approval Process**

Further information on the procedure for obtaining IRB approval for a research study is available from the IRB Chair and on the College website.

## **6. Procedure:**

- a. **Implementation:** The IRB Chair is responsible for maintaining a procedure for implementation of this policy.
- b. **Responsibility for Compliance:** Vice President of Academic Affairs
- c. **Notification:** This policy will be posted on the College's website.

For the Office of Institutional Effectiveness and Research only:

Policy version: 2.0	Policy number: 3.011
Related policies:	

Policy History

Version 1.0	December 22, 2014
Version 2.0	February 10, 2015