

The background of the page features a large, semi-transparent seal of Elms College. The seal is circular and contains a shield with a crown on top and a monogram 'M' in the center. The shield is divided into two halves: the left half is gold with three green leaves, and the right half is purple with a white crown and monogram. The seal is surrounded by a green border with gold text. The text at the top reads 'ELMS COLLEGE' and the text at the bottom reads 'INSTITUTIONAL REVIEW BOARD'.

ELMS COLLEGE
INSTITUTIONAL REVIEW BOARD
HANDBOOK
FALL 2009

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I. PURPOSE of the Elms College IRB:

The purpose of the Elms College Institutional Review Board is to:

1. Ensure the protection and rights of human research subjects
2. Review research involving human subjects
3. Review federal mandates and policies regarding ethical standards for research,
4. Update guidelines and procedures according to these federal guidelines
5. Disseminate policies and procedures for conducting ethical research to faculty and students.
6. Generate reports to faculty and administration regarding activities of the IRB committee.

WHAT is an Institutional Review Board?

IRBs are boards, committees, or groups formally designated by an institution to conduct initial and continuing review of research involving human subjects.

All IRB committees are governed by Title 45 Part 46 of the Code of Federal Regulations (CFR) (<http://ohsr.od.nih.gov/guidelines/45cfr46.html>) and are regulated by the Food and Drug Administration and the National Institutes of Health's (NIH) Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services (DHHS) (<http://www.hhs.gov/ohrp>). The DHHS requires institutions, who receive federal funding (ex.: federal financial aid to students), to have an IRB committee as do a number of other agencies.

The IRB must also follow the regulations, laws, and policies set down in the Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>) and the Nuremberg Code (<http://ohsr.od.nih.gov/guidelines/nuremberg.html>).

The above codes as well as International Review Boards were developed in response to the various research abuses that occurred in the early twentieth century. The two most notorious cases were the experiments conducted by the Nazi physicians, as noted in the post-World War II Doctors' Trial, and the Tuskegee Syphilis Study, which was conducted between 1932 and 1972 by the U.S. Public Health Service.

Title 45 of the Code of Federal Regulations defines both Research and Human subjects. **Research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities" (45 CFR 46.102(d)). **Human Subjects** is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. (45 CFR 46.102(f))

In compliance with the Title 45 Act institutions "engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy." (45CFR 46.103 (a))

According to the Department of Health and Human Services (2005) section 46.107, IRB membership should include at least 5 members "with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution."

II. Guidelines for Committee Composition

1. The composition of the committee is pre-determined by The Department of Health and Human Services Federal Regulations (Title 45 Part 46 of the Code of Federal Regulations (CFR) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107>)).
2. Federal Requirements require membership to be a mix of genders and races
3. Federal Requirements require the number of members in the committee to be **at least 5** or more and may include additional individuals when requested for help in assisting in the review process

Required members (one from each category):

- a. 1 member from the scientific area (ex. Nursing, Biology, Chemistry, etc) {Required}
- b. 1 member from the nonscientific area (ex. Humanities) {Required}
- c. 1 member not affiliated with the institution {Required}

Additional 2 members from any 2 of the following categories:

- d. 1 member from social sciences
 - e. 1 member from education
 - f. 1 member from communication sciences & Disorders
 - g. 1 member from the library
4. Terms of Office: 3 years.
 5. The committee will report all meeting minutes to the Faculty Development and Governance committee and will submit an annual report to faculty and Vice President of Academic Affairs.

III. Investigator Training in Protecting Human Rights (REQUIRED)

- a. This course includes training on critical issues such as informed consent, risk assessment, confidentiality, social justice,
- b. The National Institute of Health provides a free training course entitled "Protecting Human Research Participants". The IRB committee requires ALL investigators/researchers (including students conducting studies/surveys) must complete the NIH training program and show evidence of **certification number** (given upon completion of the training). The training course is located on the internet at <http://phrp.nihtraining.com/users/login.php>

IV. Instructions for IRB review and approval.

Investigators should NOT begin data collection before IRB approval is obtained.

PRIOR to data collection, all studies (including exempt) must comply with the following guidelines:

1. All research conducted with human subjects must be reviewed by the IRB committee before data collection.
2. All investigators/researchers must complete the NIH training program "Protecting Human Research Participants" and show proof of **certification number** (given upon completion of the training) <http://phrp.nihtraining.com/users/login.php>

3. Investigators must submit the “**Notification of Research with Human Subjects**” form (see attached) **prior** to data collection.
4. Investigators will be given an **IRB study number** indicating that the proposed study has been reviewed and approved by the Elms College IRB.

V. Categories of Risk (categorized from least to greatest)

Research studies will be assessed and approved based on the level of risk to the participants and the ability of the researcher(s) to minimize or remove the risk involved. Three issues in risk include the necessity of the risk, the benefit of the knowledge gained, and the procedures used to reduce or remove the risk.

A. Exempt: Studies that include little to no risk to participants.

Studies that are exempt include: no distress or harm to participants

- a. Participants remain anonymous
- b. Adults aged 18 or older who are capable of giving informed consent.
- c. No inducements for participation are given
- d. Does not involve tape recording, videotaping
- e. Does not involve animals
- f. No deception
- g. Use Recruitment Statement Form (no signature required)

B. Expedited (partial committee review): Studies that include more than minimal risk

- a. Analysis of voice recordings (could be identifiable)
- b. Moderate exercise (physical risk)
- c. Group behavior
- d. Must include adults aged 18 and older, capable of consent
- e. Use Informed Consent Form (signature required)

C. Full committee review: Studies that involve greater risks

- a. Blood samples, bodily fluid
- b. Deception (provide debriefing form)
- c. Sensitive information
- d. Non-anonymity
- e. Funding from outside source
- f. Special populations (e.g., children, animals)
- g. Use Informed Consent Form (signature required)

VI. Appendix

- a. Recruitment Statement (no signature required)
- b. Informed Consent Form (signature required)
- c. Sample of Internet study informed consent (electronic signature required)
- d. Debriefing (required when deception is risk in study)

Appendix A. Model Recruitment Statement

Please print the following information on ELMS letterhead

Elms College

(list other facilities in which research will take place)

Recruitment Statement for Research Participation

1. [Name(s) and rank(s) of Investigator(s)] is/are inviting you to participate in this research study.
2. The title of this study is [*title of study*]. The purpose of this study is to [*state purpose and rationale for the research*].
3. Your participation in the study will involve [*describe the activities and duration of the research*].
4. The risks to you as a participant are minimal. These include [*describe any potential risks associated with the study and what will be done to minimize these risks*].
5. The results of this study may be published in scientific research journals or presented at professional conferences. However, your name and identity will not be revealed and your record will remain [*anonymous OR confidential*]. [*Describe the steps taken to provide anonymity OR confidentiality*].
6. Participation in this study may/will benefit you by [*state benefits. Incentives and/or compensation should NOT be listed as benefits*]. *If participants will not receive any direct benefit, state so (participation in this study will not provide benefit to you directly)*. Your participation [*may/will*] benefit others by [*describe benefits to society*].
7. You can choose not to participate. If you decide not to participate, there will not be a penalty to you or loss of any benefits to which you are otherwise entitled. You may withdraw from this study at any time.
8. If you have questions about this research study, you can contact [*name of investigator(s)*] at [*provide contact information*].
9. Report complaints/grievances regarding this study to the Academic Dean (phone#)

Appendix B. Model Informed Consent

Please print the following information on ELMS letterhead

Elms College

(list other facilities in which research will take place)

Informed Consent for Research Participation

1. [Name(s) and rank(s) of Investigator(s)] is/are inviting you to participate in this research study.
2. The title of this study is [*title of study*]. The purpose of this study is to [*state purpose and rationale for the research*].
3. Your participation in the study will involve [*describe the activities and duration of the research*].
4. The risks to you as a participant are minimal. These include [*describe any potential risks associated with the study and what will be done to minimize these risks*].
5. The results of this study may be published in scientific research journals or presented at professional conferences. However, your name and identity will not be revealed and your record will remain [*anonymous OR confidential*]. [*Describe the steps taken to provide anonymity OR confidentiality*].
6. Participation in this study may/will benefit you by [*state benefits. Incentives and/or compensation should NOT be listed as benefits*]. If participants will not receive any direct benefit, state so (*participation in this study will not provide benefit to you directly*). Your participation [*may/will*] benefit others by [*describe benefits to society*].
7. You can choose not to participate. If you decide not to participate, there will not be a penalty to you or loss of any benefits to which you are otherwise entitled. You may withdraw from this study at any time.
8. If you have questions about this research study, you can contact [*name of investigator(s)*] at [*provide contact information*].
9. Report complaints/grievances regarding this study to the Academic Dean (phone#)

If you are 18 years of age or older, understand the statements above, and freely consent to participate in the study, sign the "I agree" statement. If you do not wish to be in the study, sign the "I do not agree" statement.

I agree to participate in this study

Signature

I **do not** agree to participate in this study

Signature

Appendix C. Sample of Internet Study - INFORMED CONSENT (requires an "electronic signature")

The Psychology of Golfing

Welcome to "The Psychology of Golfing," a web-based experiment that examines some of the finer points of golfing. Before taking part in this study, please read the consent form below and click on the "I Agree" button at the bottom of the page if you understand the statements and freely consent to participate in the study.

Consent Form

This study involves a web-based experiment designed to understand why people enjoy watching small round objects drop into holes in the ground. The study is being conducted by Professor W. Wundt of Leipzig University, and it has been approved by the Leipzig University Institutional Review Board. No deception is involved, and the study involves no more than minimal risk to participants (i.e., the level of risk encountered in daily life).

Participation in the study typically takes 50 minutes and is strictly anonymous. Participants begin by answering a series of questions about golf, after which they watch several randomly assigned computer animation sequences that show balls dropping into holes. These animated sequences involve either golf contexts or neutral contexts, and they vary in the size of the ball and the hole depicted. After watching 9 computer-animated "holes," participants rate how enjoyable the experience was.

All responses are treated as confidential, and in no case will responses from individual participants be identified. Rather, all data will be pooled and published in aggregate form only. Participants should be aware however, that the experiment is not being run from a "secure" https server of the kind typically used to handle credit card transactions, so there is a small possibility that responses could be viewed by unauthorized third parties (e.g., computer hackers).

Many individuals find participation in this study enjoyable, and no adverse reactions have been reported thus far. Introductory Psychology students at Leipzig University will receive one hour of research participation credit for taking part in the study and may write a three-page research paper if they prefer not to participate in this study (see the course syllabus for details). Other visitors to this web site are welcome to complete the study, although they will receive no credit or monetary compensation. Participation is voluntary, refusal to take part in the study involves no penalty or loss of benefits to which participants are otherwise entitled, and participants may withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled.

If participants have further questions about this study or their rights, or if they wish to lodge a complaint or concern, they may contact the principal investigator, Professor W. Wundt, at (555) 123-4567; Professor S. Freud Chair of the Psychology Department, at (555) 555-5555; or the [Institutional Review Board](#), at (555) 987-6543. **If you are 18 years of age or older, understand the statements above, and freely consent to participate in the study, click on the "I Agree" button to begin the experiment.**

Appendix D. Debriefing

Researchers do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

A **debriefing form** is required if **deception** (omission of critical information OR commission of deceptive information) is an integral feature of the design of the study.

The researchers must **fully disclose** the nature of the deception to participants *as early as is feasible*, preferably at the conclusion of their participation, but **no later than at the conclusion** of the data collection, and permit participants to withdraw their data.

Researchers must:

- (a) provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.
- (b) If scientific or humane values justify delaying or withholding this information, researchers take reasonable measures to reduce the risk of harm.
- (c) When researchers become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.