



Request for Exemption from IRB Review

Date: April 13, 2010

Proposal Number:
(to be assigned by IRB administrator)

Submit this completed form to the IRB as an email attachment: irb@harding.edu.

Title of Project: Impact of the Curricular Program to Increase Reading Abilities and Critical Thinking Skills in Student Pharmacists

Principal Investigator(s) and Co-Investigator(s): Forrest Smith 279- Susan Grace 279- fsmith1@ sgrace@

I request exemption from IRB approval for my project. The basis upon which I claim my exemption is (mark one):

- (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 [§46.101(b)(1)].
(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 [§46.101(b)(2)].
(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 §46.101, 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 [§46.101(b)(3)].
(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 [§46.101(b)(4)].
(5) Research and demonstration projects 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 [§46.101(b)(5)].
(6) Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture [§46.101(b)(6)].

I have attached a one-page synopsis of my project.

Signature of Principal Investigator Date

MEMORANDUM

TO: Cheri Yecke, Ph.D.
Chair, IRB
Harding University, Searcy, AR

FROM: Forrest L. Smith, Ph.D.
ADAA
Harding University College of Pharmacy

DATE: April 7, 2010

RE: Human Subjects Research Exemption Request

1. Administrative Information

Title of Protocol: Impact of the Curricular Program to Increase Reading Abilities and Critical Thinking Skills in Student Pharmacists

Principal Investigator: Forrest L. Smith, Ph.D.
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Associate Investigators: Susan M. Grace, M.A.Ed.
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Organization: Harding University College of Pharmacy
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Category for exemption - Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) and survey procedures. The information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

2. Summary of Research: Reading is considered a basic learning skill and the cornerstone for academic success. Educators have assessed the reading abilities of undergraduate college students, as well as the readability of required textbooks throughout the curriculum. The Nelson-Denny Reading Test (NDRT) is a standardized test to assess a students' reading ability in three areas: vocabulary, reading comprehension and reading rate (Brown et al., 1993). During the first year of college, reading should average grade 12 of a high school senior. Four years later, most college students graduate at grade equivalent (GE) 16 because of the curricular program (Brown et al., 1993). Health professions identify reading as important in the admissions process. Medical students score the highest with a GE of 18.7 compared to pharmacy (16.5), dental (17.2) and physical therapy (17.9) students (McCabe et al., 1995; Haught and Walls, 2002; Fuller et al., 2007).

Formulas such as the Flesch Reading Ease Score and Gunning FOG Index (SMOG) that measure textbook readability, indicate that health professions textbooks and primary literature are above the reading level of most entering students, with the exception of medical students (e.g., student NDRT total GE = 16.0-17.9 vs. textbooks >18.0 and primary literature >19.2) (Fuller et al., 2007; McCabe, 1995). Textbooks and primary literature could significantly increase reading abilities in student pharmacists by forcing them to read above their current grade level.

Finally, critical thinking is clearly linked to reading abilities. For example, undergraduate students with lower verbal abilities could identify individual words and facts, but were unable to combine information in the text with previously acquired information. Critical thinking requires students to integrate ideas

and draw inferences from their reading, and to check ideas for contradictions. Critical functioning requires reading comprehension that can integrate Bloom's Taxonomy (Epstein et al., 1984; Glover, 1989; Dymock 1993; Baker, 1985; Brown, 1983; Farley and Elmore, 1992). Critical thinking might increase along with reading abilities as student pharmacists' advance through the program. The Health Sciences Reasoning Test (HSRT, Insight Assessment, Division of California Academic Press, Millbrae, CA) measures critical thinking skills in four major areas: analysis, evaluation, inference, and deductive and inductive reasoning. Pearson's correlation analysis will measure for significant associations between HSRT and NDRT values.

The overall hypothesis of this project is that pharmacy textbooks and primary literature with Flesch Reading Ease Score and Gunning FOG Index (SMOG) scores of >17 will induce significantly higher NDRT (and HSRT scores) after the first (P1) and third (P3) years.

3. Methods and Data Collection

- a) The NDRT (Form G) will be administered to the cohort of 60 P1 students during orientation week to obtain baseline data. On another orientation day, students will go online to complete the HSRT. Each test takes about 30-45 min to complete.
- b) At the end of the first (P1) year the entire cohort of students will take the NDRT (Form H) and retake the online HSRT. 3) At the end of the third (P3) year the cohort will re-take the NDRT (Form G) and the online HSRT [a three year separation should ameliorate the effects of retaking NDRT (Form G)].
- c) Students may obtain a copy of their data from the Director of Student Affairs, who will direct students with reading difficulties to the Academic Resource Center.

4. Subjects and confidentiality. All names will be purged from cumulative data prior to analysis. Paper copies with subject identifiers will be kept in a locked, secure location. Electronic copies will be kept on a password protected computer. After completion of the study, electronic and hardcopy data will be destroyed.

5. Data Analysis. Up to four years of cohort data (i.e., 240) will be combined for ANOVA (SPSS™) comparing baseline NDRT and HSRT scores in P1 and P3 students, with the IRB renewed annually as needed. The Flesch Reading Ease Score and Gunning FOG Index (SMOG) will be calculated on textbooks, primary literature and lecture sources appropriate to the P1 and P3 years. This data will be correlated with HSRT and NDRT data. The investigators will contact the textbook publishing companies to obtain these values. Ultimately, the findings will be presented at local, regional and/or national conferences, and in published form in a peer-reviewed journal.

References

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- Brown, J.A., Fishco, V.V., & Hanna, G. (1993). *Nelson-Denny Reading Test: Manual for Scoring and Interpretation, Forms G & H.* Rolling Meadows, IL: Riverside Publishing
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Signature of Principal Investigator: _____

Forrest L. Smith, Ph.D.

Date: 4/7/10