

Bradley University Senate
Agenda
Fifth Regular Meeting of the 2008-2009 Senate
3:10 P.M. February 19, 2009
Michel Student Center Ballroom

- I. Call to order
- II. Announcements
- III. Approval of Minutes
 - A. Fourth Regular Meeting 2008-2009 December 10, 2008
- IV. Call for items to be added to the Agenda
- V. Reports from Administrators
 - A. President Glasser
 - B. Interim Provost Bolla
 - C. VP Business Affairs Gary Anna
- VI. Report from Standing Committees
 - A. Committee on Curriculum & Regulations
 - i. **Concentration Deletion** – International Concentration in Family and Consumer Science
 - ii. **Course Additions**
 - a. FCS 235 Apparel Product Development and Analysis
 - b. IB 205 Business in Indian Culture
 - iii. **Course Modifications**
 - a. FCS 133 Apparel Production
 - b. FCS 330 Fashion Merchandising
 - c. FCS 331 Fashion Merchandising Laboratory
 - d. FCS 333 Advanced Textiles
 - e. FCS 334 Visual Merchandising and Promotion
 - f. FCS 303 Nutrition
 - g. FCS 306 Community Nutrition
 - h. FCS 307 Life Cycle Nutrition
 - i. FCS 405 Food Service Systems
 - j. FCS 407 Nutrition Assessment
 - k. FCS 408 Management in Food Service
 - l. FCS 410 Advanced Nutrition
 - m. FCS 411 Medical Nutrition Therapy
 - n. FCS 461 Practicum in Foods, Nutrition, and Dietetics
 - o. FCS 400 Senior Seminar in FCS
 - p. ATG 585 Contemporary Issues in Accounting
 - q. MTH 224 Elementary Differential Equations

- iv. **Course Deletion**
 - a. MTH 202 – Introduction to Numerical Methods
- v. **Major Deletion**
 - a. FCS – Foods, Nutrition, and Dietetics
- vi. **Major Addition**
 - a. FCS - Food, Nutrition, and Wellness
 - b. FCS – Dietetics
- vii. **Major Modification**
 - a. FCS - Retail Merchandising

VII. Reports from Ad Hoc Committees
A. CUSHR ad hoc committee

VIII. Unfinished Business

IX. New Business

X. Other Business
A. Report from Student Senator
B. Adjournment

Bradley University Senate
Minutes
Fourth Regular Meeting of the 2008-2009 Senate

3:10 P.M. December 10, 2008
Michel Student Alumni Dining Room

I. Call to order

The meeting was called to order at 3:13 p.m.

II. Announcements

Jennifer Gruening announced that in August of this year (2008) Bradley had been accepted into the Higher Learning Commission's Assessment Academy. The commitment is for four years and Bradley is one of fifteen schools that will be part of this program that will assess student learning through a student learning project. The first step is to put together the student learning project. A team, consisting of Kelly McConnaughay, Bob Wolffe, Joe Emmanuel, Wayne Evens, and herself, attended at roundtable meeting facilitated by the Higher Learning Commission; it will begin drafting Bradley's project. The focus will be on Bradley University's core (curriculum) experience. The team has taken the core competencies from the 2004 general education document, Bradley's mission statement, and the first BUCCS conversation. On January 20th, 2009, there will be an open forum to provide feedback on this. After this, there will be a period of open comment. Details will be forthcoming.

III. Approval of Minutes

A motion was made to approve the minutes of the Third Regular Meeting of the 2008-2009 Bradley University Senate from November 20, 2008. The motion was seconded. It carried.

IV. Call for items to be added to the Agenda

Molly Cluskey asked that the topic of how best to distribute the Senate Agenda be added to the agenda for today's meeting.

V. Reports from Administrators

A. President Glasser

President Glasser began by announcing that on Friday, Dec. 11th, 2008, she and Dr. John Irwin of Illinois Central College would hold a press conference at 11:00 a.m. in order to announce a new type of scholarships, the Presidents' Partnership Scholarship, for which students transferring from ICC to Bradley will be eligible. This is one of the many new initiatives that Dr. Glasser is trying to implement in order to help jumpstart enrollment at Bradley. Each of these new scholarships will be worth 3,500 dollars. Students who have had a 3.25 grade point average at ICC, after a minimum of thirty hours, and who come to Bradley to major in engineering, education, entrepreneurship, nursing, or pre-professional health, will be able to compete for the scholarship. While at Bradley, the student will have to maintain a grade point average of 3.0 in order to continue to be eligible to receive the scholarship.

President Glasser also reminded senators that U.S. attorney Patrick Fitzgerald, who is heading up the trial of Illinois Governor Rod Blagojevich will be speaking at Bradley's December

commencement exercises; he will receive an honorary degree at the event. He's excited to come. However, there are certain topics about which he will not be able to talk.

On a more personal note, President Glasser wanted to thank everyone for the cards and e-mails that she has been receiving. Her surgery is finished and she will begin radiation treatment after the first of the year. This treatment will last for six weeks.

B. Interim Provost Bolla

Provost Bolla did not address this month's meeting.

Brian Huggins addressed a question about the policies concerning the use of the new Markin Center to either President Glasser or to Provost Bolla. More specifically, he wanted clarification about who will have access to the data obtained as part of the proposed wellness check-ups and about what affect these data may or may not have insurance premiums for Bradley employees. Provost Bolla answered that "HIPPA" laws will be followed and that no Bradley administrators will receive data pertaining to any individual at Bradley. He then deferred to Gary Anna. Mr. Anna mentioned that Bradley will only receive aggregate data pertaining to all of the users of the wellness program. These data will, hopefully, help Bradley to provide better health choices for Bradley employees and will help Bradley and Bradley employees keep costs pertaining to health care under control.

VI. Report from Standing Committees

A. Committee on Curriculum & Regulations - Graduate School

i. **Program Addition** – PMA in Environmental Education

Alan Galsky made a motion to accept the proposed PMA in Environmental Education. Claire Etaugh seconded the motion. Discussion ensued.

Brian Huggins mentioned that he had voted against another PMA. He was inquiring into the type of students who would be in the program as well as into the nature of the instruction. In particular, he is worried about giving graduate-level credit for a course that really has just undergraduate content in it.

Kelly McConnaughay said that she would be glad to address Brian's first question as to make-up of students, but that she would not discuss the second part of Brian Huggins' question because an earlier senate had already acted on that and that she did not feel like she should address that. As concerns the PMA program that has already begun, there is a cohort of 25 teachers, from the elementary or early childhood level. They were selected from an applicant pool of roughly 40-50 teachers. They have already lost three of the initial graduate students because they could not complete math portion of the program. The remaining 22 find course-work challenging.

Brian Huggins wanted to know more about the directed research in science and math.

Kelly McConnaughay mentioned that the first summer consists of a mini-immersion experience, where the students worked for 45 hours with a mentor. This is designed to give the students exposure with how to do research, hypothesis testing, etc. In the second summer, the students will do between 150 and 200 hours of research work.

Brian Huggins wanted to know if calculus is a prerequisite for the MTS 616 course that is part of the PMA program that is being proposed for acceptance here.

Kelly McConnaughay replied that the students of this particular program will be high school science teachers. As such, they should have had calculus in college, although they may not

remember much of it. She mentioned that the students will need to take a placement exam and that it may be necessary for some students, as a result of the placement exam, to take steps toward remediation.

Mat Timm related to members of the Senate his experiences with the math class (for a previously approved PMA program) that he taught this summer. He said that the content for that course was really the content of Math 101 and that the 600-level distinction of the course does not reflect the content. He was hoping to elevate the level of the content. But the problem is that he is compressing a normal 14-week course into a five-week summer course. As a result, he only covered about 2/3 of the material that he would normally cover in Math 101. He speculated that he would have a similar problem—of getting through all of the material—with the math course proposed for the PMA in Environmental Education. The level of that course is equivalent to Math 121, a math modeling course. He expressed concern that there really is not way to “soup up” the level on it. Mat admitted that he had fun teaching the math course (for the other PMA program) this past summer. The students approached the course in an adult perspective and so they got something more from it that someone who was fresh out of high school and taking Math 101 would obtain.

He expressed concern about the level of math skills that he sees with our incoming students. On the first week of classes this fall, Mat gave a basic math quiz to the students in his Math 121 course. The quiz dealt with some basic algebra, and a little trigonometry; there was one problem on logarithms and exponentials. The median for the quiz was 2 correct out of ten and the high score was 6.5. Mat stressed that we have a serious problem with competency level in math of incoming students. So, anything that we can do to help them might be worth doing. As senators, he stressed, we need to decide how important it is to do something to help teachers who are sending us their students, when doing so may amount to lowering the level of the content of some of the courses. Yet, he also cautioned that if we keep offering watered down our master’s degrees in order to attract students so as to try to help people who are struggling, then what does that say about our master’s programs. Illinois could change laws so that if a teacher completes a certificate program, he or she can move up the pay scale. Likewise, District 150 could revise its policies. If they would do this, then we would not have to worry about our master’s programs.

Bob Podlasek wanted to know about the sample teachers in the present PMA program. Mat Timm responded that the teachers would most likely be from District 150. Mat said that this past summer, he taught 15 students and Larry had 8-9 students.

Kelly McConnaughay responded most of the students—18 or so—were from District 150 and the rest were from outlying areas. But, we have not yet had enough students to do much in the way of analysis of the group.

Tim Koeltzow wondered why there was no university-wide discussion on level of difficulty of our of master’s degree programs. He understands that there are compelling reasons (revenue generation perspective and contributing to the social good) to have master’s degrees such as we have, but he is worried about the Bradley brand. He said that psychology has wanted to reinstate the rigorous and highly successful M.A. program that it once had, but there is worry about how Bradley may be perceived if expectations in graduate programs are lowered. At any rate, he argued that there needs to be some consensus on who we are and how we present our programs.

Joan Sattler responded that the purpose of PMA is to be a terminal degree, and the target population is middle school and high school teachers. The goal is not to prepare these people for doctoral programs; it is to expand their knowledge as school teachers. We have a national problem with math and science education. Hopefully, we are contributing to teachers’ broad knowledge. As to the content of these PMA programs, there should be continuing discussion in the graduate executive committee.

Mat Timm replied that his students did not know what the difference was between a PMA and an MS. In conversations with students, this was clear.

Claire Etaugh brought up her recent study of the “TIMSS” analysis from Boston College. This is a 500-page report on math and science around the world. The U.S. is lagging behind. The only way to address this is to improve math and science education of our children. We, at Bradley, are attempting to do this by educating teachers who will educate students. There are assessment measures in place. We will know how successful our efforts have been after they have been in place after a while. Some of anecdotal evidence of today’s discussion is just that. We cannot yet fully assess yet how these programs are doing. Helping educate teachers to educate students in math and science is part of Bradley’s mission. She said that she disagrees with her colleague, Tim Koeltzow [she probably meant Mat Timm], because we know what the difference is between a PMA and an MS, even if students don’t. These programs benefit and enrich us here at Bradley.

Marty Craig mentioned that when the first PMA program was approved the Senate was told that the level of the math course would be more than Math 101.

Mat Timm responded that we don’t have time to go through the entire make-up of the course but that the closest thing to this math course that we all would have had is high-school geometry. He said that his course is done in a fairly rigorous way. They do not do all formal proofs but that students learn to show why the square root of 2 is irrational. This is what 18year olds do in Math 101. The older students are having some trouble with content

There was a brief conversation about the relevance and propriety of discussing a graduate program that had already been approved by the University Senate in a previous year.

Marty Craig wanted to know the differences between this PMA program and the one that was previously approved.

Kelly McConnaughay reiterated that the focus of the program under discussion is environmental science and not elementary math and science education. The student will mainly be high school science teachers. They will already hold bachelor’s degrees in science..

A motion was made to call the question. It was seconded. The motion passed.

A vote was now taken. The PMA program in environmental education was approved.

ii. Course Additions

MST 615 Introduction to the Interdisciplinary Nature of Environmental Science

MST 616 The Mathematics of Environmental Science

MST 640 Water: The Human Perspective

MST 641 Nanotechnology in the 21st Century

MST 661 Directed Research in Environmental Science

MST 666 Environmental Systems II

MST 662 Research in Environmental Science

MST 665 Environmental Systems I

MST 686 Environmental Sciences Research Project

iii. Course Modifications

MST 635 The Science of Global Climate Change

MST 637 Scientific Myths and Misconceptions

MST 670 Action Research: Methods and Practice

Molly Cluskey reminded senators that because these courses carry the number of 600 or higher, they are not voted upon by the senate. This information is only for our knowledge.

VII. Reports from Ad Hoc Committees

VIII. Unfinished Business

No unfinished business at this time.

IX. New Business

Molly Cluskey wanted to gauge people's feelings on whether or not it would be acceptable to distribute the monthly agenda for University Senate meeting only in electronic form. She believed that this might save on the time, paper, and money associated with printing off copies of the agenda and then sending them to senators via campus mail.

Dave Quigg wondered about how many people normally print out a hardcopy version of the electronic version of the documents and whether this actually ended up being more costly to Bradley than one, mass printing of the agenda and its accompanying documents.

Tim Koeltzow pointed out that he often prints off the agenda only then to receive it again in printed form via campus mail.

Molly Cluskey then whether she was correct in understanding that, on the whole, senators would like to continue to receive a hardcopy of the agenda in the mail. She will continue to send hardcopy versions of the agenda through campus mail.

X. Other Business

A. Report from Student Senator

Eric Swanson reported that he is receiving good feedback about Student Senate from students. There have been few complaints.

Student Senate has been working with food services in order to find an adequate replacement from Blimpie's, which has left. Student dining will be opening up a sandwich shop of its own.

Mr. Swanson announced that TSA and Academic Affairs are working with the library and IRT in order to facilitate printing at the library. Student Senate also has plans to improve public relations. Mr. Swanson reported that there has been interest shown in pre-law center. Finally, efforts are being made to advertise on-campus activities more effectively.

He expressed pleasure over the improved snow removal efforts on campus this winter and wished everyone a happy holiday season.

B. Report from Dr. Alan Galsky, VP Student Affairs

Dr. Galsky spoke on the issue of the current status of enrollment for next year's freshman and transfer class. He mentioned that a handout pertaining to enrollment was being passed out to the senators. This year Bradley is making efforts to correct problems that had been encountered in previous years. Some of those were out of Bradley's control and some were not. He underscored that there was no way of knowing just yet what effect the bad economy would have on the financial situations of students and their families.

Bradley's enrollment goal for 2009 was to bring in between 1080 and 1100 students and to increase out-of-state enrollment by twenty percent. The decrease in the number of graduating high school students and the economic downturn would make these goals more of a challenge. However, Dr. Galsky added that with the new sports communications major, the new pre-law center, the Markin recreation center, new recruiters, and new enrollment management strategies (among other things), we can address the challenges well. He did underline the fact that all members of the Bradley family need to help with

Dr. Galsky indicated that there were concerted efforts to increase enrollment from several areas: the northern suburbs of Chicago, the contiguous states, and the coasts. He expressed confidence that some of the new majors and programs (sports communication and pre-law, for example) would draw new students. In the end, the goal was to increase the number of students in the upcoming freshman class by 130 people.

The admissions data, at this early juncture, look encouraging. Vice-President Galsky attributes some of this to the new policy of informing students of admittance much earlier than had been done in the past. With the exception of the business school, Dr. Galsky said that admissions are up in all the colleges. He tracked admissions into several programs—AEP, Nursing, Sports Communication, Political Science, Civil Engineering, and Psychology—and was happy to see that the numbers for all of these were up. Likewise, numbers of admissions were up, as well, as concerns the targeted geographical goals that the University had set for itself.

Brian Huggins wanted to know the status of potential students wanting to be part of AEP: Specifically, was there any change in the profile of students interested in AEP.

Alan Galsky mentioned that the profile is roughly the same as in previous years. ACT scores are up among applicants and among those admitted. He went on to note that ACT scores among those who had put down a deposit to come to Bradley was slightly down; this, however, is due to the fact that less than 10% of the number of students who will eventually come to Bradley have already paid a deposit.

Brian Huggins also wanted to know if there would be increased financial aid for out-of-state students. Vice-President Galsky mentioned that there would be increased financial aid opportunities for students from contiguous states, as increasing enrollment of student from contiguous states has been one of the goals set for this year. But there were no increased financial aid opportunities for students from other parts of the country, even though there was a concerted effort to recruit students from certain targeted states, metropolitan areas, and high schools.

Mat Timm wanted to know if it would be possible to give attach the Powerpoint slides to the minutes for this meeting. Alan Galsky said that this would not be a problem and that he would send the slides to Molly Cluskey.

James Schopf wondered how it was that we were down admitted students in certain areas but that the average ACT score for applicants was actually higher. Dr. Galsky responded that this had to do with those who were accepted early admission. He stressed that we are not accepting less qualified students than we were in previous years. The only difference is that we are now accepting students sooner than we had done in previous years.

XI. Adjournment

A motion to adjourn was made and seconded at 4:20 p.m. The motion passed.

Bradley University Senate
Fourth Meeting 2008-2009
December 10, 2008
Attendance Sheet

FACULTY
(please initial)

Andersh, Brad	BA	Goitein, Stephen	BF	Morris, Marty	MM
Arquette, Cecile		Hertich, Alexander	AH	O'Brien, Kevin	
Banning, Steve	SB	Hill, Donna	HD	O'Brien, Matt	MOB
Bhandari, Shyam	SB	Hindi, Riyadh	HA	Podlasek, Bob	PAB
Brown, George	GB	Huggins, Brian	BDA	Quigg, David	QD
Brubaker, Cindy		Johlke, Mark		Risen, Mike	
Cady, Craig	CU	Kelley, Andrew	AK	Rossen, Doug	RD
Carlson, Randy		Kelly, Todd	TK	Salamini, Leonardo	LS
Cluskey, Molly	MC	Kerr, Stephen		Schmidt, Roy	RS
Craig, Martha	HSC	Koeltzow, Tim	TK	Schopf, James	JS
Dannehl, Charles		Krishnamoorthi, K	KK	Spires, Todd	TS
Davidson, Jeanette	JD	Kuester, Deitra		Timm, Mat	
Dolins, Steve		Lozano, Jose	SL	Tippett, Steve	ST
Dusenbery, Peter	PFD	Malinowski, Aleksander		Walker, Bill	WB
Ferolo, Jim		McGehee, Bill		Williams, John	WJ
		Mehta, Paul		Young, Margaret	MY

EX-OFFICIO
(please initial)

Anna, Gary	GA	Galsky, Alan	GA
Baer, Rob		Glasser, Joanne	GB
Beaty, Kathie	KB	Huberman, Jeffrey	HB
Bolla, Robert	RB	Johnson, Richard	JR
Epstein, Shelley	SE	McAsey, Mike	MA
Etaugh, Claire	CE	Perry, Sandra	SP
Fan, Sam		Roberson, Nicki	NR
Field, Kurt		Ruch, Chuck	RC
Galik, Barbara		Sattler, Joan	ST

STUDENTS
(please initial)

Swanson, Eric	ES		

To: Molly Cluskey, University Senate President
From: Joe Emanuel, Undergraduate Curriculum Subcommittee Chair
Re: Changes in undergraduate programs
Date: January 28, 2009

The C&R Committee met yesterday and approved the following changes that had been approved by the Undergraduate Curriculum subcommittee. The program and course changes are being forwarded to the University Senate for final approval.

Family & Consumer Sciences

Deletion of International Concentration in Family and Consumer Sciences

Modification in Major in Retail Merchandising

Addition of one 3 hour required course (FCS 235 – Apparel Product Development and Analysis)

Modification of five courses

Course Addition

FCS235 – Apparel Product Development and Analysis- 3 hours

Course Modifications

FCS133 – Apparel Production – 3 hours

Change in title from Apparel Production & Analysis

Change in course description

FCS330 – Fashion Merchandising – 3 hours

Elimination of FCS233 as a Prerequisite

FCS331 – Fashion Merchandising Laboratory – 1 hour

Elimination of FCS233 as a Prerequisite

FCS333 – Advanced Textiles – 3 hours

Change in Prerequisite from FCS133 to FCS233

FCS334 – Visual Merchandising and Promotion – 3 hours

Change in Prerequisite from FCS330 and FCS331 to FCS235

Deletion of major in Foods, Nutrition and Dietetics with two concentrations:

(1) Food and Nutrition, (2) Dietetics

Addition of major in Food, Nutrition and Wellness

Addition of major in Dietetics

Modification of nine courses to support the two new majors

FCS303 – Nutrition – 3 hours

Change in course description

Change in prerequisites from BIO121-124, CHM100&101 or CHM116-117

To BIO200

FCS306 – Community Nutrition – 3 hours

Change in description

Change in Prerequisites from FCS220, 303

To FCS104, college level nutrition course

FCS307 – Life Cycle Nutrition – 2 hours
Slight change in title (Lifecycle to Life Cycle)
Change in description
Change in Prerequisites from FCS104, 303
To FCS306

FCS405 – Food Service Systems – 3 hours
Slight change in description
Change in Prerequisites from FCS104 or consent of instructor
To FCS104, BIO202, sanitation certification

FCS407 – Nutrition Assessment – 2 hours
Change in course description

FCS408 – Management in Food Service – 3 hours
Change in course description

FCS410 – Advanced Nutrition – 4 hours NOTE: Prerequisites no longer have min GPA for science courses
Change in course description
Change in Prerequisites from FCS303, BIO200, CHM151,152
To CHM 151, 152; BIO 200, 205; FCS 307; B in FCS 303

FCS411 – Medical Nutrition Therapy – 4 hours
Change in course description
Change in Prerequisites adding FCS407

FCS461 – Practicum in Foods, Nutrition, and Dietetics – 3 hours
Change in course description
Change in Prerequisites from Family consumer sciences major, consent of department chair
To Senior standing in Foods, Nutrition and Dietetics major, consent of department chair

FCS400 – Senior Seminar in Family and Consumer Science – 1 hour
Change in Title – spelling out Family and Consumer Science instead of FCS
Change in Prerequisite restricting course to family and consumer sciences major

Family and Consumer Science Core Curriculum

FCS 400 – Senior Seminar in family and Consumer Sciences

change in prerequisites limiting course to family and consumer science majors

Accounting

ATG 585 – Course Modification – adding “May be repeated for a maximum of 6 hrs. credit

International Business

Course Addition - IB205 – Business in Indian Culture – 3 hours

Mathematics

Course Deletion - MTH 202

Course Modification - MTH 224 — changing course description (matrix algebra removed) and credit hours reduced from 4 to 3.

To Whom it May Concern:

The Recommended Processes (process 1, 2 or 3) for modification of Handbook material appear below regarding "F. Committee on use of Human subjects in research - Policies and Procedures " that were prepared at the request of the Senate President.

It should be noted that the Handbook provides three processes for Handbook modification: Process 1 (proposal presented to Senate);

Process 2 (reviewed by Senate President after discussion with administrative officer(s) and appropriate faculty committee(s); and

Process 3, where proposed changes are reviewed by an appropriate advisory committee.

Sincerely,

Ad hoc Committee

B. Goitein, Chair S.

Perry

R. Fink

R. Bertram,

J. Lozano, Jose

W. Schweigert

PROPOSAL

F. Committee on use of Human subjects in research
Policies and Procedures

Recommended Section Process for modification

1-5	1
6	2
7	3
8	3
9	2
10A	3
B	3
C	2
D	3
E	3
F	2
G	1
11-14	3
15	2

The committee notes that pp 201-202 of the Faculty Handbook refers to Process 3 proposed changes.

Under Process 3, proposed changes are reviewed by an appropriate advisory committee. These committees are now listed as a-f. We recommend that the Handbook specify the advisory committee "G," that should advise CUHSR regarding proposed Handbook changes under Process 3.

F. Committee on the Use of Human Subjects in Research

Archive version of Human Subjects in Research, changed 05-05-04

Archive version of Human Subjects in Research, 05-05-04 through 12-08-06

Policies and Procedures

1. Institutional Authority

Bradley University's Institutional Review Board (IRB), the Committee on the Use of Human Subjects in Research (CUHSR), is an official committee of the University appointed by *the Associate Provost for Research*. CUHSR *was designed to meet* all appropriate laws and regulations of the Federal Government for research using human subjects. Members and investigators are expected to be familiar with said guidelines. Federal Guidelines are generally considered minimal standards; institutions and their IRBs typically have additional rules, regulations and policies that may be more restrictive, require higher levels of ethical conduct or risk regulations or are deemed necessary for the effective accomplishment of their mission.

2. Definition and Purpose

The purpose of the CUHSR is to minimize the risk and ensure the informed consent procedures to human subjects participating in research conducted by the Bradley University faculty, staff, students and other allied healthcare professionals according to the Code of Federal Regulations for Protection of Human Subjects (45 CFR 46).

Research means 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 CFR46.102d)

All human subjects' research reviewed by the CUHSR will be conducted in accordance with the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) Regulations.

The definition of "human subject" published in the U.S. Code of Federal Regulations (U.S. 1987, 46 CFR 45 102F) is the following:

"Human subject" means 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.

Note that the definition includes not only medical research conducted by physicians, but also other research activities involving interactions with individuals or the use of private information, e.g., private student or patient records or sociological surveys regarding students' sexual habits. Mention should be made here that any private use of student records for research purposes are protected under Federal regulations ("Buckley Amendment, "U.S.C., 1987, Title 20, Section 1232G, Public Law 93-380, 88 Stat, 484, Section 513)

The U.S. Food and Drug Administration (FDA) definition, applicable to studies of investigational drugs or devices, is:

"Human subject" means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A Subject may be either a healthy human or a patient.

Both the FDA (21 CFR 50, 56) and the U.S. Department of Health and Human Services (DHHS) (45 CFR 46) now have established regulations for the use of human subjects in research. DHHS regulations apply to research using human subjects in any research (Federal Policy for the Protection of Human Subjects, The Federal Register 56 CFR 812, June 18, 1991). FDA regulations "apply to research involving products [novel drugs and medical devices] regulated by the FDA, "regardless of the source of funding for the research activity. Both agencies require review of the applicable project by an institutional review board (IRB). In addition, state or local regulations or institutional policies may be more stringent and may require IRB review of all research projects involving human subjects.

3. Principles which Govern CUHSR

The CUHSR is guided by the principles outlined in the Belmont Report that defines these three principles. These fundamental principles are inherent in the conduct of research using human subjects. They are: (1) respect for person, (2) beneficence and, (3) justice. The first of these principles, respect for person, involves the autonomy of individuals to consent to participate in the research activities and the protection of individuals with a diminished capacity for autonomy (e.g., the mentally ill, prisoners, children). This would include the writing of consent forms in language which the research subject can understand.

The second principle, beneficence, involves doing no harm (based on the Hippocratic oath) and ensuring that the benefits of the research outweigh the possible risks. Since even determining what may be harmful can sometimes involve risk, the latter of these two points (assessing and justifying the risk/benefit ratio) merits the bulk of consideration.

The third principle, justice, requires that persons be treated fairly. With regard to scientific research activities, justice requires giving adequate consideration in the selection of subjects for participation so that no particular class of people is more likely to be selected than others and so that a representative sample of individuals likely to benefit from the research is included in the study population.

4. Authority of Bradley's CUHSR

The Committee on the Use of Human Subjects in Research (CUHSR) holds and maintains the authority to:

- a. Determine if a submitted proposal needs to go through CUHSR at all. Some proposals may fall outside the bounds of CUHSR's mission to protect human subjects in research, including those which involve university policy or procedures, and CUHSR maintains the right to not process those proposals.
- b. Determine if a submitted proposal is exempt, expedited or if it requires full review. Researchers may request that a research proposal be processed as exempt, but CUHSR maintains the right to ask for full review if it is deemed necessary or appropriate.

c. Ask individuals submitting a proposal to make revisions to their documents, procedures, and/or other materials. Researchers may not proceed with their research until given final approval by CUHSR.

d. Reject a submitted research proposal entirely. In this case the researcher may not conduct the research specified in the rejected proposal.

5. CUHSR's Relationship to Bradley University

CUHSR operates under the authority of the Associate Provost for Research, with the Chair reporting directly to the Associate Provost for Research.

The Department Chair or unit administrator verifies the integrity of the proposal and the adequacy of the resources and facilities and signs the application.

CUHSR provides review of research proposals to ensure that human subjects are reasonably protected.

It is the researcher's responsibility to notify the committee of any changes in the protocol, report untoward effects in a timely manner, request continued review at least annually, and submit a final status report.

CUHSR operates under policies established by the Department of Health and Human Services and U.S. Food and Drug Administration.

6. Membership

Consistent with Department of Health and Human Services (DHHS) requirements "Each IRB shall have at least five members..." Federal regulations require attendance by a majority of IRB members to conduct a full committee meeting. Majority means more than half. Consistent with federal regulations, CUHSR members must include at least one scientist, one non-scientist, and one person not affiliated with the institution. In addition, both sexes and multiple professions must be represented. An attempt will be made to have representation from every college on the committee. All members are expected to have sufficient expertise and diversity to evaluate ethical issues.

7. Management of CUHSR

a. Chairperson

The Chairperson will be appointed by the Associate Provost for Research to serve a renewable three-year term.

Duties include:

Have an in-depth understanding of ethical issues, institutional policy and federal regulations that are applicable to studies that are reviewed by IRB.

Play a leadership role in establishing and implementing IRB policy.

Review all protocols presented for full committee review. Direct the proceedings and discussions of full-committee review. Vote at full committee meeting only in tie-breaking situations.

Assist in drafting all correspondences.

Review and sign all correspondences.

Oversee the maintenance of IRB records.

Review and make decisions about responses to condition for IRB approval in a timely manner.

Act as a resource to faculty members and students.

Removal: By the Associate Provost for Research

b. Members

Members are appointed to CUHSR by the Associate Provost for Research to serve a three-year, renewable term. Alternate members may be identified to serve as needed.

Duties include:

Review all protocols presented for full committee review.

Vote at full committee meeting.

Attend at least half of the scheduled meetings.

Serve as primary reviewer for proposals that are discipline appropriate.

Removal: By the Associate Provost for Research

c. Training of CUHSR Chair and members

At a minimum, all current and future committee members are referred to the Faculty Handbook. In addition, members will complete the online tutorial, Human Participant Protection Education for Research Teams (<http://www.nih.gov>) or an equivalent ethics offering.

d. Consultants

Outside expertise may be sought from individuals who have no conflict of interest when the chairperson and / or committee members deem it necessary to inform the committee's decision regarding a proposal. Requests for Consultation will be made through the Associate Provost for Research.

e. Secretarial I administrative support staff

Secretarial support Duties include:

Screen protocols for completeness before CUHSR review

Agenda preparation / packet distribution

Taking minutes

Drafting correspondence

Assisting with record keeping

8. Conflict of Interest Policy

During convened meetings, members of the committee who have a conflict of interest regarding a proposal under review (e.g.; personal research or faculty advisor

to student research) will excuse themselves from the meeting by physically leaving the room until discussion has ended and the vote has been tallied.

For exempt / expeditable proposals that are guided by the Chair, a vice chair who is appointed by the committee, will review those studies and sign off on them.

9. Functions of the IRB

a. Initial Review

The initial review process is begun by the submission of the completed Approval statement and Application to include: application form, project description, anticipated risks and benefits to the subject, how subjects will be selected, how data will be monitored, how privacy of subjects will be protected, and how confidentiality of data will be maintained, a copy of the proposal and a copy of informed consent document as well as other research information as applicable (proposal, advertising material).

There are three levels of IRB review: i) Exempt from full review, ii) Expedited review for minimal risk protocols, and iii) Full review for all other protocols. The Chair of CUHSR or a Primary reviewer determines the appropriate level of review by evaluating proposed research approaches, risks, benefits, safety, and protection of human subjects. See IIRF 10C for Criteria for Exempt, Expedited, and Full Board Review

The possible actions that may be taken by the IRB are:

- 1) Approval of the proposal
- 2) Approval with stipulations
- 3) Table pending receipt of additional information
- 4) Disapproval

b. Continuing Review

1) CUHSR conducts continuing review in accordance with HHS regulations not more than every 365 days. Continuing review by full IRB is required unless the research is otherwise appropriate for expedited or exempt review. All members of CUHSR will receive and review a protocol summary and a continuing report on the progress of the research that will include:

- a) The number of subjects accrued;
- b) A summary of adverse events and any unanticipated problems involving risks to subjects or others, and an explanation for any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- c) A summary of relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- d) A copy of the current informed consent document and any newly proposed consent document.

2) The actions that may be taken by CUHSR are the same as for outlined for the initial review.

3) All findings and actions of the IRB are communicated in writing (e-mail or letter) to the investigator. The Chair will oversee all communications that include:

- a) The protocol name and CUHSR number
- b) List of documents being approved (protocol, consent, advertisements, etc)
- c) Approval date
- d) Expiration date
- e) Adverse event reporting expectations and
- f) Protocol deviation / non-compliance issues reporting expectations

4) Approval is given for one year, unless otherwise specified, commencing with the approval date. Research activities may not continue past the one-year anniversary of CUHSR approval date unless the protocol is renewed. For certain projects CUHSR may specify a period of continuing review shorter than one year.

5) Approximately two months prior to expiration of the current project approval, the investigator is notified by CUHSR that they are required to complete the Continuing Review Form and return it to CUHSR. The form is due one week prior to the meeting closest to the expiration date to allow for review. If the investigator does not respond, an e-mail reminder will be sent. If there is no response, the protocol will be closed to enrollment or recruitment and the investigator cannot collect data effective on the expiration date.

6) CUHSR requires that changes in the approved research are not initiated without prior CUHSR approval and requires the investigators to promptly report any changes in research activities.

7) In the written approval, CUHSR ensures the investigator is aware of their responsibility to submit a written report of local serious and unexpected adverse events using the Adverse Event Report within five working days. Incidence of death is required to be submitted within three working days or when the researcher(s) become aware. CUHSR will assess the need for changing the scheduled interval at which status reports are to be requested on the project as well as determine if changes need to be made to the informed consent document.

8) A serious adverse event is something that leads to physical or emotional harm to the participant requiring hospitalization or medical/psychological treatment.

9) An unexpected adverse event is something not mentioned in the protocol.

c. Modifications

1) Protocol amendments, modifications, and general changes in the conduct of a study must be reviewed and approved by CUHSR prior to implementing the change.

2) Modifications include but are not limited to: procedural changes to a protocol, adding or removing investigators, changing the title of the project, requesting additional subjects beyond the original approved number, new funding sources, new or revised advertisements, changes to Informed Consent Documents, inclusion/ exclusion criteria, surveys, questionnaires, correspondence with potential or current subjects, and / or additional new items.

3) The Chair or designee may approve minor modifications, such as title changes, changes in investigators, and changes in funding source. More extensive modifications may require full board review. Procedures for expedited or full board review, criteria for approval, and revision prior to approval, are identical to those described for initial review.

10. Operations of the CUHSR

a. Scheduling of meetings

CUHSR meetings are scheduled at least monthly during the academic year and the secretary will distribute advance notification of the dates to the members. The members, prior to each individual meeting, will receive the place and time of meetings, agenda, and the study materials to be reviewed.

b. The Review Process

Applications for consideration of initial full review are distributed to members one week prior to the meeting. The project description, informed consent, and advertising are included in the packets and sent to each of the members. The Chair maintains one copy of the materials that becomes the official record for future reference. All members are required to familiarize themselves with the application and the informed consent form in advance of the meeting in order to participate in discussion and voting.

c. Expedited / Exempt Review Process

Applications for expedited / exempt review are submitted to the Chair who serves as primary reviewer or delegates primary responsibility to an appropriate committee member. The Primary reviewer makes a determination regarding the appropriateness of less than a full review. Applications meeting Federal guidelines for exempt or expedited review are processed accordingly.

Criteria for Exempt and Expeditable Review:

Only CUHSR can establish if a study is exem^{Pt} or ex^Peditable.

Categories of Exempt Research

The following are the six categories of exempt research specified by DHHS.

Category 1 Exemption: Normal Educational Practices and Settings 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.

Category 2 Exemption: Anonymous Educational Tests, Surveys, Interviews, or Observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures, or observations 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.

Category 3 Exemption: Identifiable Subjects in Special Circumstances

Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures, or observations 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 statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 Exemption: Collection or Study of Existing Data

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.

Category 5 Exemption: Public Benefit or Service Programs

Research and demonstration projects that 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 service under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 Exemption: Taste and Food Evaluation and Acceptance Studies

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 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.

General Eligibility Criteria for the above six categories

- 1) Research activities that present no more than minimal risk
- 2) "Minor changes in previous approved research during the period (of one year or less), for which approval is granted."

Criteria for Approval of Research Using Expedited. Review

- 1) The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on subjects should be utilized. For example, obtaining an additional amount of blood at the time of routine venipuncture is preferred rather than doing an additional needle stick to obtain the research sample.
- 2) The risks of the research must be reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may be gained.
- 3) Subject selection must be equitable.
- 4) Informed consent should be sought and documented unless a waiver of consent and/or documentation of consent has met the waiver criteria at 45 CFR 46. ^{1(sec.116(d),117(c))} The requirements for informed consent found at 45 CFR 46 ^{1(Sec.116)} and 21 CFR 50 ^{4(Sec.20,25,27)} must be met.
- 5) Where appropriate, there is a plan to collect and monitor data to ensure subjects safety.
- 6) The privacy of subjects and maintenance of confidentiality of data is protected.
- 7) Where necessary, additional safeguards have been included to protect vulnerable subjects.

Adjunct List of Categories Qualifying for Expedited Review

Category 1

Clinical studies of drugs and medical devices only when condition (a) or (b) is met, (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

Prospective collection of biological specimens for research purposes by noninvasive means, Examples: (a) Hair and nail clippings in a non-disfiguring manner; (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) Permanent teeth if routine patient care indicates a need for extraction; (d) Excreta and external secretions (including

sweat); and (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) Placenta removal at delivery; (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) Supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) Sputum collected after saline mist nebulization.

Category 4

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subjects or an invasion of the subject's privacy. (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

Research involving materials (data, documents, records, or specimens) that have been collected for any reason or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs, or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies).

Category 8

Continuing review of research previously approved by a convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified or (c) where the remaining research activities are limited to data analysis.

Category 9

Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where categories 2 through 8 do not apply but the IRB has determined and documented **at** a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The actions the Chair or primary reviewer may approve the study independently, to approve with stipulations or request additional information. If the Chair or primary reviewer evaluates the appropriate action is to disapprove the application; instead, the application is forwarded for full review.

The Chair or primary reviewer **may** request additional information by telephone or in writing but notifies the investigator of the review process in writing. The Chair or primary reviewer may also approve modifications to ongoing studies involving no more than minimal risk. All expedited and exempt reviews are recorded on agendas and in the minutes, typically at the next meeting following review..

d. Approval Process

CUHSR approval process ensures that (45 CFR 46):

- 1) Risks to subjects are minimized: (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to the risk, and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment proposed.
- 2) Risks to subjects are reasonable in relation to anticipated benefits, **if** any, to subjects and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, CUHSR considers only those risks and benefits that may result from the research. CUHSR does not consider the long- term effects of applying knowledge gained in the research.
- 3) Selection of subjects is equitable. In making this assessment, CUHSR takes into account the purposes of the research and the setting in which the research will be conducted and of the special problems of research involving vulnerable populations.
- 4) Vulnerable populations include but are not limited to children, prisoners, pregnant women, elderly, handicapped or mentally disabled persons or disadvantaged persons..
- 5) The informed consent from each prospective study subject or the subject's legally authorized representative is obtained.
- 6) The informed consent is properly documented.
- 7) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 8) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

CUHSR requests that copies of federal grant applications be submitted with protocols. The Department of Health and Human Services (DHHS) regulations **at** 45CFR46.103 require that each application or proposal for HHS-supported human subject research be reviewed and approved by CUHSR.

e. Voting Requirements

A majority of the members shall constitute a quorum (51%) for the transaction of business at any meeting of CUHSR, providing that the majority includes at least one member whose primary concerns are in the nonscientific areas. In the event a quorum is not present, no official business may be conducted. Members with a conflict of interest will absent themselves from the meeting room during discussion. These members cannot be counted in the quorum for the motion.

Each member of CUHSR is entitled to one vote on all official actions. All votes require a 51% majority to approve a protocol. No proxies are permitted.

f. Communication from CUHSR

1) All investigators will be informed in writing of the decisions made by the Board. In the event of a project for which approval is pending stipulations, the stipulations required by the Board are documented in writing from the CUHSR Chair to the investigator(s). The following items maybe considered nonsubstantive changes:

- a) Spelling or grammatical errors;
- b) Specific additions or subtractions to the consent form or additional materials that lower the risks for subjects or clarify procedures;
- c) Changes of technical terms to lay language in consent forms;
- d) Letter of cooperation from institutions;
- e) Deletion of questions from a survey or questionnaire;
- f) Changes in contact names, addresses, telephone numbers, advisors, end date, and researchers;
- g) Changes in the title of the proposal;
- h) Changes in compensation to the subjects;
- i) Addition of subjects from the same population as indicated in the original proposal.

2) If the proposal is approved with stipulations, the staff informs the investigators in writing of the stipulations and the actions required by the investigator. When the response to stipulations is received by CUHSR, it is reviewed by the Chair or designee (if the changes required are non-substantive) or submitted to the full CUHSR for re-consideration.

3) A proposal is tabled when CUHSR requires more information to take action on the proposal. The investigator is informed, in writing, as to the specific additional information required.

4) In advance of the meeting, when the Chair believes that a specific proposal may be disapproved, an effort is made to discuss the perceived problem with the investigator prior to the meeting to identify potential solutions. In the event that such problems cannot be resolved and the proposal is subsequently disapproved at the meeting, the investigator is informed in writing.

g. Appeal of IRB Decisions

If an investigator feels that his/her research proposal was denied or restricted unnecessarily, he/she may initiate the following procedure:

- 1) Request of the Chair of CUHSR, in writing within ten days, that an evaluation be completed.
- 2) The Chair requests an ad hoc Liaison Committee be appointed by the Associate Provost for Research to review the project in question.

- 3) The subcommittee reviews the project and sends a written report to CUHSR with their recommendations
- 4) CUHSR will again review the project and deliver its decision, considering the report of the subcommittee, while not bound by its recommendation.

NOTE: The decision of the CUHSR on a reconsidered protocol is final. While the administration of any Institution may disapprove the conduct of a research study that has been approved by CUHSR, the decision of CUHSR to disapprove the conduct of a research study is final.

11. IRB Records

- a. The Chair and Secretary will maintain a current CUHSR membership roster showing qualifications of each member by name, gender, earned degrees(s), primary scientific or nonscientific specialty, and any affiliation between each member of Bradley University.
- b. The current written procedures and guidelines will be available to members of the committee and faculty members in the Faculty Handbook.
- c. Minutes of meetings are recorded in compliance with FDA regulation CFR 21 56.115(a) and under 45 CFR 46 including: attendance at the meetings, a summary of discussion on debated issues; CUHSR decisions; and voting (showing votes for, against and abstentions) the bases for requiring changes in or disapproving research. In addition to studies requiring full review, all studies that have been expedited or deemed exempt from full review will be listed in the minutes. Annual reviews require a vote and will be recorded accordingly. When final reports are submitted, studies will be recorded in the minutes as "closed."
- d. Retention of protocols: Active protocols containing current consent documents (those that have been reviewed, approved, and not yet closed) will be housed in a locked file in the CUHSR Chair's office.
- e. The Chair, with the assistance of the secretary will be responsible for communication to and from CUHSR. All decisions of the committee will be communicated in writing either electronically or by letter.
- f. In the event of an adverse event to subjects or others, (something that is unexpected and harmful), the Principle Investigator is responsible for informing the CUHSR Chair of the incident in a timely manner (within three working days). The Chair will review the adverse advent with the principle investigator and the Chair has the authority to stop the study.
- g. CUHSR will review any adverse events that are reported to the Chair at the next scheduled meeting.

Closed files will be maintained for three years after completion and then they will be destroyed. The Associate Provost for Research will decide where the closed files will be stored.

12. Information the Investigator provides to CUHSR

Application materials can be found on the CUHSR website at <http://cuhsr.bradley.edu/> (Forms link)

The Investigator and faculty sponsor, if appropriate, will provide to CUHSR:

- a. A current curriculum vita showing qualification to conduct research
- b. The Department Chair or equivalent signature on the application
- c. CUHSR requires evidence of training of all investigators. CUHSR encourages National Institutes of Health (NIH) training or approved alternate training is accepted. Certificates of Training are collected by CUHSR for record keeping.
- d. If the investigator believes the protocol is exempt or expeditable, submit one copy of the application materials to the CUHSR Chair with a request that the protocol be considered for exempt / expedited review. If the Chair determines a full review is needed, the investigator is responsible for providing the additional 12 copies. Copies must be received at least one week prior to the scheduled meeting for full review.

Or

For studies requiring full review, the investigator will provide to the Chair of CUHSR, at least one week prior to the meeting, 13 copies of the study protocol, typewritten, which includes addresses:

- ii. Title of the study
- ii. Purpose of the study
- iii. Sponsor of study (if relevant)
- iv. Results of previous related research; rationale for present study
- v. Subject selection and inclusion / exclusion criteria
- vi. Justification for use of any special / vulnerable subject population
- vii. Study design
- viii. Description of procedures to be performed that are research
- ix. Provision for managing adverse reactions
- x. The circumstances surrounding consent procedure
- xi. The procedure for documenting informed consent including any procedures for obtaining assent from minors, using witnesses, translators and document storage. If consent is waived, provide the narrative that will explain the study to participants
- xii. Compensation (if applicable) to subjects for their participation
- xiii. Any compensation (if applicable) for harm to research subjects
- xiv. Provision for protection of privacy
- xv. Extra costs to subjects for their participation
- xvi. Extra costs to third party payers (if applicable)

e. The investigator will provide the CUHSR the proposed informed consent that will include all the required elements using the adopted consent form as a guide.

These eight elements are required. The elements are:

- I. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental
- II. Description of any reasonably foreseeable benefits or risks to the subject

- III. Description of any risks or benefits to others that may reasonably be expected from the research
- IV. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- V. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so what they consist of or where further information may be obtained.
- VI. Statement describing the extent, if any, to which confidentiality of records identifying the subject (shall be maintained
- VII. An explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of research-related injury to the subject
- VIII. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled

f. If a consent form is not used, please supply the narrative that will be provided to participants containing the required elements of informed consent (see previous section)

g. If applicable, advertisements will be submitted by the investigator to CUHSR. Generally, content should be:

- 1) The name and address of the research investigator
- 2) The purpose of the research
- 3) A summary of the eligibility criteria that will be used to admit subjects into the study
- 4) The location of the research
- 5) The person to contact for further information
- 6) The time or other commitment required of subjects
- 7) A brief list of benefits, if any

h. The investigator will also provide any requests for changes in study after initiation, reports of unexpected adverse events, progress reports, and final status reports. In addition, no deviations from or changes of the protocol should be initiated without prior written CUHSR approval.

13. **Prospective Review** No proposed study is exempt from prospective review at Bradley University.

14. **Emergency Review** There will be no emergency research consent exception.

15. **Process for Changing Policies and Procedures**

The policies and Procedures will be reviewed at least annually. Policies and procedures changes can be changed with a majority vote of those present at CUHSR meetings.
Any changes that require updates to the Faculty Handbook will follow that procedure.

Page 163 of 217