Applicant Information

Name ____Elaine Nelson_________ Faculty position: Assistant Professor of History

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Department/School: History_________ College: College of Arts and Sciences________

If team, please complete the following:
Team Leader(s):
Team Members:
(graduate students may be members of the team but cannot be the primary recipients of UCAT funding)

Have you received a UCAT Curriculum Development Grant in the past? _____ Yes  x  No
If yes, please describe in less than 250 words how your UCAT funding has affected your teaching and/or
student’s learning experiences.

Signature of Department Chair/School Director: __________________________

Date Submitted to UCAT Representative: March 29, 2016

Curriculum Development Information

Course(s) Name and Number:

Please mark appropriate line: _____ New Course Proposal  x  Significant redesign of existing course or
curriculum
Budget
(List Requests at left; add more lines as necessary)

- Stipend $1000.00
- Development Materials
- Classroom Materials

TOTAL $1000.00

Less other funding (specify sources and amounts)

TOTAL UCAT REQUEST $1000.00
(maximum UCAT award is $1,000)

Rationale for the Grant Proposal

For curriculum development, applicants should carefully and clearly establish the rationale for the type of funding requested. For stipends, describe the proposed activities clearly, addressing both the scope of the activities, the action steps you will take, and expected outcomes. Explain specifically how you expect your curriculum development activities will enhance the teaching/learning environment at UNO and when you expect to offer the curriculum developed as part of this grant. For materials purchases related to course development/redesign, provide an explicit list of materials, the cost per item, the rationale for purchasing particular materials (e.g., Why a particular brand? Why a certain amount?), as well as a discussion of how such materials will enhance the development activity.

For classroom materials purchases, applicants should carefully and clearly establish the rationale for the grant. As with materials purchases related to course development/redesign, applications must provide an explicit list of materials, the cost per item, the rationale for purchasing particular materials (e.g., Why a particular brand? Why a certain amount?), as well as a discussion of how such materials will enhance the teaching/learning experience. Applicants will be expected to have sought funding from department, college and/or other relevant entities before submitting an application for material purchases to UCAT.
Rationale for the Grant Proposal:
This UCAT proposal is to support the significant redesign of the course History 4060/8066: History of Women in America, 1875-present. I will add a Service Learning component to this class as a way to engage my students with a diverse group of women who represent the history of the greater Omaha community. I am scheduled to teach this class in spring 2017, and I am seeking supplementary funds to organize curriculum and community partners during the summer of 2016.

Background:
There is a growing amount of evidence that supports the implementation of Service Learning curriculum in the liberal arts and humanities. I have integrated this into my teaching pedagogy in the past, and it received high praise from both students and community members. History courses are excellent opportunities for faculty and students to participate in a movement beyond the borders of the classroom and into the community as a way of teaching historical knowledge, contextual analysis, and civic engagement. In the revised History 4060/8066 course, I intend to utilize UNO’s Service Learning Academy to connect my students with individual women, women’s organizations, and other institutions throughout the Omaha metropolitan area. As a result of these partnerships, students will produce research projects that highlight the little-known history of Omaha women.

Course Overview:
During a portion of this course I will provide historical content through traditional means of instruction: readings, lecture, and an overview of research methods. But Service Learning curriculum will make up the bulk of the class. At the beginning of the semester, students will form teams and be paired with an individual woman (or a group or family member related to a woman) from the Omaha community. The major course assignment will consist of students’ abilities to build and produce a “Biographical Sketch” of their assigned community partner. The Biographical Sketch assignment will require each student to conduct oral interviews, gather primary sources, and write a historical overview of the Omaha woman’s life experiences. I have used Service Learning in past gender studies courses, and the Biographical Sketch is a popular project that I have assigned in previous women’s history courses. This will be my first attempt to bring these elements together in one class, and I am very excited about the prospects this holds for my students. (See page 4 of this application for a brief discussion of the use of oral interviews in the classroom.)

Curriculum Enhancement
The proposed course revision will enhance the traditional learning of each student enrolled in this class in numerous ways:

- First, students will be exposed to subject material that is not available or accessible through textbooks and online data libraries. This will challenge them to learn new research methods for investigating historical inquiries about local and national peoples, places, and events.
Second, UNO students will form partnerships between numerous individuals and organizations in and around Omaha. This includes, but is not limited to: Sarah Joslyn (Joslyn Castle), Mildred Brown (Omaha Star), Ree Scholau Kaneko (Kaneko organization), Rose Blumkin (Nebraska Furniture Mart), Anne Stuart Batchelder (Nebraska Republican Party), Helen Boosalis (Nebraska Democratic Party), Kate Dodge (NEI Global Relocation), Mabel Criss, National Federation of Colored Women (five chapters founded in Omaha), Native Indigenous Centered Education (OPS), Circle of Indigenous Grandmothers, Knights and Daughters of Tabor (founded in Omaha), DePorres Club (Creighton University), Rowena Moore (founder of Malcolm X birthsite), Cecilia Olivarez-Huerta (Nebraska Mexican American Commission), Susan LaFlesche Picotte (Omaha Indian Nation), Douglas County Historical Society, and various alumni from Omaha University.

Finally, these projects will add to the history of women in Nebraska—a topic that is largely ignored among both scholarly and general public circles. It is my intention to effectively teach History 4060/8066 as a class that discusses the larger historical narrative of American women, but with a more specific focus on the history of Nebraska women. This will be a class unique to the state of Nebraska, as it will contain information on women who have received very little (or no) attention outside their immediate families and communities. This includes women from African American, Mexican American, Native American, and Euro-American backgrounds and immigrant communities. I ultimately envision how portions of these Biographical Sketches could appear on a digital platform and in a physical exhibit (for example, at Criss Library), so they might be accessible to a much larger audience. But these planning phases will require additional UCAT Development Grants at some point. First, I need to successfully accomplish the implementation of a Service Learning curriculum into the classroom. Then, I can build other aspects into this course as I continue to offer it in the future.

**Student Learning Outcomes**

Student learning outcomes for the course revision include the improvement of communication and presentation skills, research analysis, and the use of applied historical practices outside of the classroom. I also expect that students will learn how to make broader connections using historical knowledge and context, and see clear paths toward becoming civically engaged in the past and present of their community outside the classroom.

**Schedule and Instructor Outcomes for Summer 2016:**

Phase 1, May 2016: I will meet with Lucy Garza in the Service Learning Academy and establish the groundwork for setting up this class for the spring of 2017. Then I will begin to establish new relationships with individuals and organizations in the Omaha community (see preliminary list above). These partnerships are expected to emphasize a group of women with diverse backgrounds who represent various age groups and different experiences of living in the state of Nebraska. Some of these women are no longer living, so it will be important to connect with a surviving family member, or relative, or an organization in which they were/are active.

*Expected Outcome: A rough draft of a list of potential partnerships and contacts for students who enroll in the course.*
Phase 2, June 2016: I will continue to cultivate relationships with these women and organizations and seek permission from family members and others who would like to be involved in the project.

*Expected Outcome:* By the end of June there should be at least 12-15 potential subjects of the Biographical Sketch project.

Phase 3, July 2016: In July I plan to build new curriculum for lectures and research, and choose reading materials that are historically engaging and also encourage Service Learning programs for women’s and gender studies courses. I will also continue to confirm the list of participants from the community and hold a meeting with Lucy Garza to discuss updates and plans for the spring 2017 course.

*Expected Outcome:* Book and article list for students and several newly-written lectures on both American women and Nebraska women. I will also complete a finalized list of community partners.

Phase 4, August 2016: In August I will complete the curriculum development and syllabus schedule for spring 2017. I will also plan to meet with Lucy Garza in the Service Learning Academy to continue to plan course details and perhaps arrange an end-of-the-semester event that honors women from the community and highlights the students’ projects. Finally, I will prepare the first UCAT Progress Report.

*Expected Outcome:* Curriculum development will be complete Enter early planning stages to host an event that highlights the work of the students in the course. I will also submit the first UCAT Progress Report.

Phase 5, Fall 2016: Finalize all details with community partners, curriculum development, and event planning for the course.

*Expected Outcome:* Course prepared for spring of 2017.

Phase 6, Spring 2017: Offer History 4060/8066. Offer course and Service Learning evaluations to students and community partners.

*Expected Outcome:* Suggestions for changes or improvements to the course will be taken into consideration for future course offerings of History 4060/8066.


*Expected Outcome:* Submit final UCAT Report to UCAT Committee, home department, and College of Arts and Sciences.

**End of Grant Proposal**
Use of Oral Interviews for History Research

According to the UNMC Human Research Protection Program Policies and Procedures (see attached), the IRB office does not require review or approval of oral history for the purposes of collecting biographical, documentary, or historical records of an individual’s life or experiences of historical events. See highlighted section 6.5, which states:

6.5 Oral Histories: Oral histories are not considered research when there is a simple recording of information with no attempt to perform a systematic analysis of the data in order to draw conclusions or test a hypothesis for the purpose of developing or contributing to generalizable knowledge. The collection of oral history information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual’s life and experience or of historical events.

Example: An oral historian conducts biographical interviews with a group of Vietnam veterans. The oral histories are conducted with the intent to provide a basis for a better understanding of the myriad ways in which the Vietnam War has influenced American culture. This project is not human subject research.

I have worked with the IRB office numerous times in the past to make sure that my students who conduct oral histories for graduate theses, honors theses, and FUSE grants are doing so with appropriate clearance and approval of the University. I am always referred to Section 6.5 of the IRB policies and procedures to ensure that my students do not need to seek IRB approval for the purposes of conducting and collecting oral histories. Please let me know if you have further questions regarding this issue.
1.0 Purpose
The purpose of this policy and procedure is to describe the Organization’s policy and procedure for determining the investigational activities requiring IRB approval.

2.0 Policy
2.1 It is the policy of the Organization that UNMC IRB approval is required for research involving human subjects (as defined in Section 3.0) which is conducted under the jurisdiction and oversight of the IRB as follows:

A. Research performed within the Organization (i.e., on the premises) by research personnel (faculty, students, staff or other representatives of the Organization.)

B. Research performed elsewhere by personnel specified in Section 2.1A above, as part of their institutional responsibilities. However, with approval of the Institutional Official (IO) an external IRB may be accepted as the IRB of record in accordance with HRPP policies #1.3 and 1.4.

C. Research performed elsewhere by personnel specified in Section 2.1A above where the personnel are identified as being affiliated with the Organization (for example in research documents, publications, or clinical trial listings). However, with approval of the IO after appropriate consultation with other Organizational officials, an external IRB may be accepted as the IRB of record in accordance with HRPP policies #1.3 and 1.4.

2.2 IRB review will be performed in accordance with the authorities granted by institutions within the Organization in accordance with HRPP policy #1.2.

2.3 The IRB does not routinely review activities which do not meet the definition of human subject research, with the exception of research involving human fetal tissue and human embryonic stem cells.

3.0 Definitions
3.1 HHS Regulations
A. Research is defined at 45 CFR 46.102(d) as, “any 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.

The Belmont Report provides further clarification of “research” as follows: “… the term ‘research’ designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).”

B. Human Subject is defined at 45 CFR 46.102(f) 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"

1) **Intervention** means both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research procedures. The intervention was carried out either solely or partially for the purposes of research.

2) **Interaction** means communication or interpersonal contact between investigator and subject. The interaction was carried out either solely or partially for the purposes of research.

3) **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record).

4) **Identifiable information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

C. **Investigator** is not specifically defined by HHS regulations. However, HHS guidance defines “investigator” as the individual performing various tasks related to the conduct of human subject research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an “investigator” to be any individual who is involved in conducting human subject research. Such involvement would include:

1) Obtaining information about living individuals by intervening or interacting with them for research purposes
2) Obtaining identifiable private information about living individuals for research purposes
3) Obtaining the voluntary informed consent of individuals to be subjects in research.
4) Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students about others.

The UNMC IRB broadly defines investigator as an individual who actually conducts human subject research as either a Principal Investigator (PI) or a Secondary Investigator (SI) (see HRPP policy #3.13 for UNMC definitions).

D. **Human subject research.** In order for an activity to constitute “human subject research, all of the following criteria must be met:

1) The primary intent is to conduct a systematic investigation, using an appropriate research design involving human subjects, in order to test a hypothesis.
2) There is an implicit or explicit data analysis plan which will permit scientifically valid conclusions to be drawn.
3) The intent of the activity is to develop or contribute to generalizable knowledge, with the expectation of publication or presentation of the results of the activity.
3.2 FDA Regulations

A. Human Subject is defined at 21 CFR 56.012(e) as "...an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient."

Under FDA’s current regulations governing the conduct of in vitro diagnostic device (IVD) studies, the definition of human subject includes individuals on whose tissue specimens, an IVD is used [21 CFR 812.3(p)]. However, if the specimen is not individually identifiable by the investigator or any other individuals associated with the investigation, including the sponsor, the FDA will exercise enforcement discretion with regard to the requirements for informed consent in accordance with guidance issued April 25, 2006 titled “Guidance on Informed Consent for In Vitro Diagnostic Device Studies using Leftover Human Specimens That Are Not Individually Identifiable.” The UNMC IRB will determine whether subjects can be individually identified and apply 21 CFR 50, 56 accordingly.

B. Clinical Investigation is defined at 21 CFR 56.102(c) as, "...any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit."

"The terms research, clinical research, clinical study and clinical investigation are deemed to be synonymous for the purposes of FDA regulations."

Experiments that must "meet the requirements for prior submission to the Food and Drug Administration under Section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice [21 CFR 312.3(b)].

Experiments that must "meet the requirements for prior submission to the Food and Drug Administration under Section 520(g) of the Federal, Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device [21 CFR 812.2(a)].

Any activity in which results are being submitted to or held for inspection for FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research [21 CFR 50.3(c), 21 CFR 56.102(c)].

C. Test Article is defined at 21 CFR 56.102(l) as, "any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Act or under Sections 351 or 354-360F of the Public Health Service Act."

1) Human drugs: The primary intended use of the product is achieved through chemical action or by being metabolized by the body. A drug is defined as a substance recognized by an official pharmacopoeia or formulary: A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; A substance (other than food) intended to affect the structure or any function of the body; A substance intended for use as a component of a
medicine but not a device or a component, part or accessory of a device. (http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm)

2) **Investigational new drug:** An investigational new drug means a new drug or biological drug that is used in a clinical investigation.

3) **Medical devices:** A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

4) **Investigational Device:** An investigational device means a device, including a transitional device, which is the object of a clinical investigation. As further defined, a device is any healthcare product that does not achieve its primary intended purpose by chemical action or by being metabolized.

5) **Food additives:** In its broadest sense, a food additive is any substance added to food. Legally, the term refers to "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food.

6) **Color additives:** A color additive is any dye, pigment or substance which when added or applied to a food, drug, or cosmetic, or to the human body, is capable (alone or through reactions with other substances of imparting color) (http://www.fda.gov/Food/FoodIngredientsPackaging/ucm094211.htm#foodadd).

7) **Foods:** Foods include dietary supplements that bear a nutrient content claim or a health claim.

8) **Infant formulas:** Infant formulas are liquid foods intended for infants which substitute for mother's milk.

D. **Investigator** is defined 21 CFR 56.102(h) as, "an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."

4.0 **HRPP Definitions of Research Personnel Classifications**

4.1 **Principal Investigator (PI):** This individual assumes **overall** responsibility for 1) development and submission of the Application to the IRB, 2) the obtainment of legally effective informed consent and assent (as applicable) from prospective subjects by all authorized personnel listed on the Application, 3) the performance of research interventions, 4) the safe conduct of the research in full compliance with the protocol,
IRB requirements, HHS regulations, applicable FDA regulations and state law, and 5) the presentation or publication of the data.

Only one PI can be named on the IRB application. Co-PIs (e.g., on NIH grants) must be listed as Secondary Investigators.

If the PI is a student (e.g., medical, dental, pharmacy, nursing, allied health, undergraduate, graduate), a faculty advisor must be listed and must sign the Principal Investigator’s Assurance. The faculty advisor assumes responsibility for overall supervision of the student’s research and must be listed as a Secondary Investigator.

4.2 Secondary Investigator(s) (SI): These individuals may also be termed co-investigators and share responsibility with the PI for 1) development and submission of the Application to the IRB, 2) the obtaining of legally effective informed consent/assent from prospective subjects, 3) performance of research interventions, 4) the safe conduct of the research in full compliance with the protocol, IRB requirements, HHS regulations, applicable FDA regulations and state law, and 5) the presentation or publication of the data.

4.3 Participating Personnel: These individuals are not involved in the development and submission of the Application to the IRB but will interact with subjects of the research and in some cases are authorized by the PI in accordance with HRPP policy # 5.002 to obtain informed consent or assent. All participating personnel must have sufficient knowledge about the protocol to facilitate effective interaction with the subject.

4.4 Lead Coordinator: These individuals are involved in the submission of the initial application, request for change in the protocol and/or consent, adverse events, protocol deviations, protocol violations, unanticipated problems involving risk to subject or others, and continuing review. They serve as the primary contact point for the Office of Regulatory Affairs. These individuals may be authorized by the IRB to obtain informed consent/assent in accordance with IRB policies.

4.5 Administrative and Data Management Personnel: These individuals do not have direct subject contact, but may have access to subject’s identifiable protected health information (PHI) and/or may be involved in preparation and submission of adverse event reports, changes in protocol and continuing review.

5.0 HRPP Classifications of Human Subject Research
5.1 Biomedical Research: Biomedical Research includes all human subject research performed with intent to develop or contribute to generalizable knowledge (i.e., test a hypothesis and draw conclusions) about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods. Subjects may be suffering from a condition or illness or may be healthy, and may or may not be seeking or expecting a health benefit.

5.2 Human Biological Material Research: Human Biological Material (HBM) research utilizes human biological specimens obtained directly from human subjects or from other sources such as a biorepository (tissue bank). The full range of human biological specimens includes sub-cellular structures (e.g., DNA); cells; tissues (e.g., blood, bone, muscle, connective tissue, teeth, and skin); organs (e.g., liver, bladder, heart, kidney, and placenta); gametes (e.g., sperm and ova); and waste (e.g., hair, nail dippings, urine, feces, saliva, and sweat, which often contains shed skin cells).
5.3 Medical Records Research: Medical Records Research utilizes individual medical or clinical records with subject identifiers for both retrospective and prospective studies.

5.4 Social Science and Behavioral Research: Social science and behavioral research includes all research performed with intent to develop or contribute to generalizable knowledge (i.e., test a hypothesis and draw conclusions) about behaviors, attitudes and interactions among and between individuals, groups, and cultures. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research. There may, or may not, be any prospect of direct subject benefit associated with this category of research.

6.0 Activities Which Are Not Human Subject Research

6.1 Systematic investigation involving data or human biological materials (HBM) without investigator access to subject identifiers: A systematic investigation involving data or HBM obtained from living individuals where there are no identifiers which would allow the investigator to readily identify the individual does not require IRB approval (except as described in example 5 below per this policy). Required de-identification (i.e., the number of identifiers which must be removed) before the data or HBM is given to the investigator depends on whether or not the research is subject to HIPAA.

Example 1: The research involves the use of existing clinical outcome data on patients with lymphoma treated at UNMC from 1990-2000. Before the data are given to the investigator by the clinic all eighteen HIPPA identifiers are stripped from the data (i.e., the data is de-identified). This is necessary because the outcome data contains protected health information (PHI) and HIPAA requires de-identification or authorization unless the IRB grants a waiver. This is not considered human subject research under HHS regulations at 45 CFR 46. Note: If, however, the data will be given to the investigator with the identifiers and the investigator then de-identified the data, it would be considered human subject research classified as exempt and subject to ORA review and approval.

Example 2: The research involves the use of existing data on use of the institution's daycare facilities, cost of care, and consumer satisfaction. The data are given to the investigator by the daycare facility with age of the children, dates of service by year, and the classification of the employee as faculty, staff or student. This research is not subject to HIPAA. In this case, the demographic information associated with the data would not allow the investigator to readily identify the participants. This is not considered human subject research under HHS regulations at 45 CFR 46.

Example 3: The research involves lymphoma tissue obtained from a cooperative group tissue bank. The tissue is provided to the investigator with diagnostic data but there are no identifiers. This is not human subject research under HHS regulations at 45 CFR 46.

Example 4: The research involves breast cancer tissue obtained from the UNMC Tissue Bank. The tissue is given to the investigator with a code. The tissue bank has access to the linked code and can, therefore, identify the donors. The investigator, however, will not have access to the linked code and cannot identify the donor. An agreement is in place which prohibits release of the key to the investigator. This is not human subject research under HHS regulations at 45 CFR 46.

Example 5: An investigator wants to obtain ten samples of breast cancer tissue
immediately after the pathology examination is complete. The tissue is excess HBM. The investigator contacts the surgeon and the pathology department who agree to provide the investigator with the ten samples without any subject identifiers. This is not considered human subject research under HHS regulations at 45 CFR 46. However, there is an ethical obligation for the surgeon providing the tissue to obtain informed consent from these patients. Therefore, this is considered human subject research under this policy.

6.2 Innovative Therapy: Physicians and other health care professionals are free to engage in innovative therapy if the innovative procedure is applied solely to enhance the well-being of their patient and is based upon sound clinical judgment. However, when innovative therapy differs significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients through formal IRB review of a promising therapy in the context of a clinical trial. Therefore, in order to validate innovative therapy, the innovative procedure should be subjected early on to IRB review as a formal research protocol.

6.3 Quality Improvement Assessment: Quality improvement projects are not considered research if all of the following criteria are met:

A. The primary intent of the project is to 1) improve the quality of patient care or efficiency of a healthcare operation, or 2) improve the quality or efficiency of a non-health care operation

B. The project design uses established quality improvement methods.

C. The project does not impose any increased physical or psychological risk or burden on patients or other participants.

Note: Publishing or presenting the results of a quality improvement project does not necessarily mean the activity is research. Descriptions of non-research activities (e.g., an account of the quality improvement project) are often an expected outcome of the project. On the other hand, re-analysis of the data derived from the quality improvement project in order to prove or disprove a hypothesis is research. Depending on whether or not subject identifiers are maintained, it may qualify as exempt research.

Example 1: As a matter of policy, the hospital surgery suites introduce a validated surgical checklist which has been shown to reduce surgical errors and actual and “near miss” adverse events. After some period, the hospital QI team is engaged to assess whether this change had a positive impact on surgical mishaps. This is a quality improvement project (not research), and nothing precludes the presenting or publishing of the results found.

Example 2: A surgical fellow develops a UNMC-based surgical checklist that she thinks might lead to a reduction in surgical mishaps. She recruits several surgeons who agree to use the checklist routinely during their surgeries and the plan is to compare surgical mishaps for the “checklist surgeons” and “non-checklist surgeons” during a 6 month period prior to and following the introduction of the checklist. This is a systematic investigation to test a hypothesis with a data analysis plan conducted with the intent to develop or contribute to generalizable knowledge and would NOT qualify as a quality improvement project.

Example 3: The UNMC Center for Healthy Living designs a project to assess the quality and usage of their services. Over the next 30 days all users will be asked to complete a survey which rates the quality and frequency of use of services offered by the Center and identification of any services that are desirable, but not currently offered. This is a
quality improvement project (not research) and nothing precludes the presenting or publishing of the results found.

6.4 **Case Histories:** Descriptive case histories which are published and/or presented at national or regional meetings are not considered research if 1) the case is limited *solely* to a description of the clinical features and/or outcome of individual patients, and 2) the project does not satisfy all the criteria specified in Section 3.1(a) above.

*Note:* When a physician or other health care professional authors a case history that is not research, the following ethical guidelines should, nevertheless, be taken into consideration: 1) Informed consent should be obtained from the patient; and 2) Appropriate safeguards to protect confidentiality should be in place.

*Note:* If a case history involves multiple patients with concomitant analysis and correlation of data as part of a systematic investigation, it is considered research. Depending on whether or not subject identifiers are maintained, it may qualify as exempt research.

6.5 **Oral Histories:** Oral histories are not considered research when there is a simple recording of information with no attempt to perform a systematic analysis of the data in order to draw conclusions or test a hypothesis for the purpose of developing or contributing to generalizable knowledge. The collection of oral history information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual's life and experience or of historical events.

*Example:* An oral historian conducts biographical interviews with a group of Vietnam veterans. The oral histories are conducted with the intent to provide a basis for a better understanding of the myriad ways in which the Vietnam War has influenced American culture. This project is not human subject research.

*Example:* A psychiatrist works with an oral historian to gain insight into the impact of the Vietnam War on veteran's lives. The oral historian conducts biographical interviews and a psychiatrist administers PTSD scales to the participants. Based on the answers and the evaluation of the oral history, the psychiatrist develops generalizations about how future veterans might respond in similar situations in order to better define treatment protocols for veterans. This project is considered human subject research.

6.6 **Student Projects:** A systematic investigation conducted by a student that involves living individuals, but is performed *solely* to meet educational requirements of a single academic course is not considered human subject research providing the results of the investigation are presented only within the confines of the classroom or similar forum and to the students and/or instructors in the class. However, it is recommended that the students' supervisor and/or department exert appropriate review and oversight of the project, including, for example, completion of an IRB application without submission to the IRB.

If the results of the investigation are presented as a "research study" in a public area of the Organization (for example as a poster at a student research forum) this constitutes human subject research, though it may be exempt.

*Note:* If a student conducts a systematic investigation with intent to present the results of the investigation outside of the confines of the institution (e.g., national research conference/forum) this does constitute human subject research.
Note: If a student initially conducts a systematic investigation to meet educational requirements with no intent to present the results of the investigation outside of the organization, but then re-analyses the data derived from the project in order to prove or disprove a hypothesis is research. Depending upon whether the subject identifiers are stripped from the data at the time of re-analysis, the project may be exempt.

7.0 Determination of When an Activity Constitutes Human Subject Research

7.1 Individuals should contact the ORA for guidance in determining whether or not a proposed activity constitutes "research". An IRB Administrator, in consultation with the IRB Chair as necessary, will determine whether or not the planned activities constitute Human Subject Research.

7.2 The IRB Administrators and the IRB Executive Chair/designee will use a) the OHRP Human Subject Decision Charts (September 24, 2004) and b) the criteria in section 3.1(a) and 3.1(b) of this policy.

7.3 If a determination is made that the activity constitutes human subject research, the investigator will be advised to submit the appropriate IRB application for review and approval.

7.4 When there is any question concerning whether or not an investigator will be engaged in human subject research, the IRB Administrators and/or the IRB Executive Chair/designee will consult with OHRP.

7.5 If a determination is made that the activity clearly does not constitute human subject research (e.g. use of immortalized cell lines with no subject identifiers), the investigator will be informed. All decisions will be explained fully in order to ensure the Organization’s faculty, staff, and students understand the criteria used in making the determination.

7.6 If an investigator submits an IRB application and it is determined in accordance with the above-described procedure that the activity does not constitute human subject research, the decision will be documented and the investigator will be notified of this determination. All correspondence related to this determination will be maintained on file. However, the research will not be entered into the IRB database.

8.0 Type of Review

The type of IRB review required depends upon the proposal classification: Full Board (FB), Expedited (EP), or Exempt (EX). The IRB Administrators and/or the IRB Executive Chair/Vice Chairs will use the OHRP Human Subject Decision Charts (September 24, 2004) as necessary in determination of the type of review.

Administrative Approval:
Ernest D. Prentice, PhD. Associate Vice Chancellor for Academic Affairs and Institutional Official
Bruce G. Gordon, MD IRB Executive Chair