Policy Proposal Template

WEST COAST UNIVERSITY

Instructions:

Thoroughly complete the template by filling in any blank cells to the right of the prompt (or as otherwise instructed). Submit the proposal to the University Provost on Fridays for consideration for inclusion in the agenda for the next Academic Council meeting.

Name of policy being proposed:	Policy and Procedures For The Protection of Human Subjects (PHS) In Research Activities
Name of program/committee submitting the policy:	School of Pharmacy
Name of individual submitting the policy:	Dr. Rahmat Talukder and Dr. Naushad Ghilzai
Today's date:	

Policy statement (write policy in cell below):

The Institutional Review Board and Protection of Human Subject Committee (IRB-PHSC) at West Coast University (WCU) shall review research projects which involve human subjects to ensure that two broad standards are upheld: first, subjects are not placed at undue risk; second, they give uncoerced, informed consent to their participation. With representation from a wide range of scientific disciplines and from outside the academic community, the IRB shall give rapid but individualized attention to the research projects supported by the university. The policy and procedures shall be designed to comply with HHS Regulations at 45 Code of Federal Regulations (CFR) Part 46, Subpart E as implemented by United States Department of Health and Human Services (DHHS) "Basic DHHS Policy for the Protection of Human Subjects,"

When research involving human subjects is to be performed by any West Coast University (WCU) investigator, or with the aid of any University resources over which he/she has responsibility or control, that investigator is responsible for meeting the following requirements:

1. The investigator shall not involve human subjects in the proposed research until the IRB has informed him/her of full approval for the use of human subjects in the research.
2. The investigator shall abide by the decisions of the IRB requiring changes (for approval) or disapproving the research.
3. The investigator shall obtain informed consent from all subjects in accordance with the requirements of this policy and of the IRB.
4. The investigator shall ensure that subject consent is documented in the manner prescribed by the IRB.

5. The investigator shall maintain consent documents signed by subjects in a repository approved by the IRB.
6. The investigator shall maintain the confidentiality of data obtained from subjects in the manner required by the IRB.
7. The investigator shall report the progress of the research to the IRB at the intervals and in the manner prescribed by the IRB.
8. The investigator shall promptly report any injuries to human subjects resulting from the research to the IRB. The investigator shall also promptly report any unanticipated problems, which involve risks to the subjects or others. Initial reports may be verbal; additional reports shall be in the manner required by the IRB.
9. The investigator shall promptly report to the IRB any proposed changes in the research which would result in a significantly different involvement of human subjects and shall obtain the approval of the IRB prior to the changes being made.
10. The investigator shall promptly report to the IRB any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans, for subject involvement and shall obtain the approval of the IRB prior to the involvement of any subjects.
11. The investigator shall promptly report to the IRB any serious or continuing non-compliance with the requirements of this policy or of the IRB-PHSC on any research with which he/she is associated.
12. The IRB chair shall determine, based on the application provided whether the use of human subjects would be considered exempt from review or require expedited or full board review.
13. The investigator shall provide the IRB chair with any additional information requested in a timely fashion.
14. An application returned by the IRB-PHSC chair to an investigator for modifications prior to approval must be resubmitted with modifications within the time determined by the IRB or the application will be automatically withdrawn from further consideration.

Specifically describe what issue this policy is intended to address.	This document is intended to set forth the policy and procedures for the protection of human subjects involved in research activities conducted at or sponsored by West Coast University (WCU) including research activities (a) by faculty, staff, and students, (b) performed in WCU facilities, or (c) supported by WCU resources or facilities.
Describe how this proposal supports the institutional mission.	Advancing knowledge through research and scholarship is an important consideration in fulfilling the WCU's mission "To deliver transformational education." Since the essential focus of WCU is to educating health care professionals, it is expected that research with human subjects will take place at some point. Thus it is imperative to have a policy and guidelines in place.
To whom does this policy apply? (e.g. faculty, associates, students)	This policy shall apply to all research activities involving humans subjects conducted at or sponsored by WCU including research activities (a) by faculty, staff, and students, (b) performed in WCU facilities, or (c) supported by WCU resources or facilities.

What office implements and administers this policy? Who will ensure that the policy is followed and determine if it is not?	Office of a senior officer of the university (Provost or a designee shall have signatory authority for the IRB protocol when human participants research is conducted or supported by the university. The authority may be delegated to an elected/selected chairperson of IRB-PHSC, if need arises. An IRB-PHSC must (http://answers.hhs.gov/ohrp/categories/1565): i. have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution; ii. make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women; iii. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas; iv. include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and v. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Please see the regulations at 45 CFR 46.107 for complete information on all of the required qualifications to properly compose an IRB. **IRB-PHSC AUTHORITY AND RESPONSIBILITIES** To fulfill the requirements of DHHS regulations, the IRB-PHSC shall have the following authority and responsibilities: 1. The Institutional Review Board and Protection of Human Subject Committee (IRB-PHSC) shall have the responsibility to review and the authority to approve, require modification in, or disapprove all research activities. 2. (Except when the proposed research has been determined to be exempt from review, the IRB-PHSC shall review proposed research at convened meetings at which a majority of the members of the IRB-PHSC are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting (via electronic communication method this may be accomplished). 3. The IRB-PHSC shall not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting

	interest, except to provide information requested by the IRB-PHSC. 4. The IRB-PHSC is responsible for reporting to the Provost/_/designee any serious or continuing non-compliance by investigators. The Provost or designee is responsible for necessary final actions. 5. The IRB-PHSC shall conduct continuing reviews of research at intervals appropriate to the degree of risk but not less than once per year. The IRB-PHSC shall have the authority to determine which research requires IRB-PHSC reviews more often than annually. 6. The IRB-PHSC shall determine which research projects need verification from sources other than the research investigators that no material changes have occurred since the previous IRB-PHSC review and shall have the authority to obtain that verification. 7. The IRB-PHSC shall have the authority to recommend to the Provost /Designee suspension or termination of approved research that is not being conducted in accordance with this policy. Any recommendation for suspension or termination of approval shall include a statement of reason(s) for the IRB-PHSC action. The Provost/Designee shall notify the investigator of pending action or when warranted of action and shall when appropriate notify the appropriate external agency. 8. The IRB-PHSC will receive from investigators all research protocols, which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them. 9. The IRB-PHSC is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination based on 45 CFR 46 Section 101 . Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigators. 10. The IRB-PHSC will receive from investigators applications with modifications stipulated prior to approval by the IRB-PHSC within six months or pre-determined time or the application will be automatically withdrawn from further consideration. 11. The IRB-PHSC will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other federal departments or agencies as may apply, the Belmont Report, and all other pertinent federal policies and guidelines related to the involvement of human subjects in research. 14. The IRB-PHSC will report promptly to the Provost /Designee/Appropriate institutional officials: a. any injuries to human subjects or other unanticipated problems involving risks to subjects or others, b. any serious or continuing noncompliance with the regulations or

requirements of the IRB-PHSC, and
c. any suspension or termination of IRB-PHSC approval for research.

CRITERIA FOR IRB-PHSC APPROVAL OF RESEARCH

Prior to approving research covered by this policy, the IRB-PHSC shall determine that all of the following requirements are satisfied:
1. Risks to subjects are minimized (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB-PHSC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB-PHSC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB-PHSC should take into account the purposes of the research and the setting in which the research will be conducted.
4. Informed consent will be sought from each prospective subject, or the subject's legally authorized representative following standard procedure.
5. Informed consent will be appropriately documented in accordance with the policy.
6. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

INFORMED CONSENT

Except as provided for in this policy, no investigator may involve a human

	being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence. **Basic Elements of Informed Consent** The following information shall be provided to each subject when seeking informed consent: 1. 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. 2. A description of any reasonably foreseeable risks or discomforts to the subject. 3. A description of any benefits to the subject or to others that may reasonably be expected from this research. 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. 6. 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. 7. A statement of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty, or loss of benefits to which the subject is otherwise entitled.

Waivers of Informed Consent

45 CFR 46.116(c) and (d) include provisions for approval of a waiver or alteration of part or all of the consent process.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116
There are two general instances when an IRB-PHSC may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waives the requirement to obtain informed consent.

(A) In the first general instance (45 CFR 46.116(c)) the IRB must find and document that:

1. The research is to be conducted by or subject to approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not be practicably carried out without the waiver or alteration.

(B) In the second general instance (45 CFR 46.116(d)) an IRB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent or that waives the requirement to obtain informed consent provided that the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent); and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Please describe specific procedures required, if any, to effectively implement this policy. Add attachments as required.	Following the HHS guideline (http://answers.hhs.gov/ohrp/questions/7180), a senior officer of the university (Provost) or a designee shall select members to form a committee for IRB – PHSC. The officer/designee shall initiate the process to register with HHS (http://answers.hhs.gov/ohrp/categories/1565). The IRB/PHSC shall be given the responsibility to develop the policy to comply with the federal and state requirements. The IRB/PHSC shall implement the policy, accordingly.
If required, identify sanctions for non-compliance with this policy.	The investigator must not involve human subjects in the proposed research until the IRB-PHSC has informed its full approval for the use of human subjects in the research. If this policy is violated, IRB-PHSC shall notify the university officer/designee to action as delineated above.
What exceptions to this policy will be allowed, under what circumstances, and who will approve exceptions?	In most cases, class research projects which involve human subjects and which are conducted by students, as exercises to learn how to conduct research do not require review by the IRB-PHSC. Following are a few examples of exceptions: Educational Practices Research Research conducted in established or commonly accepted educational settings, involving normal educational practices, may be exempt from IRB review. Examples of such research are: 1. Research on regular and special education instructional strategies. 2. Research on the effectiveness of/or the comparison among instructional techniques, curricula, or classroom management methods, except when the data obtained may be used to impact educational personnel. Educational Testing Research Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) may be exempt from full IRB review, provided that information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects when the data obtained may be used to impact educational personnel. Survey Research Research involving survey or interview procedures may be exempt from full IRB review, except where all of the following conditions exist: 1. Responses are recorded in such a manner that the human subjects can

	be identified, directly or through identifiers linked to the subjects. 2. The subject's responses, if they became known outside research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability. 3. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
What impact will this policy have on accrediting body, State regulatory, licensing bodies, etc. with respect to compliance?	Accreditation Council for Pharmacy Education (ACPE) recommends that the institution provide research and scholarly opportunity to its faculty and students. The first item in ACPE's Threshold Rubric for evaluation of precandidacy application asks whether the institution has research and scholarship components in its program mission; and the very second item verifies whether the university has infrastructure to support the research mission of the college of pharmacy (that includes IRB, Grant Administration etc.) https://www.acpe-accredit.org/pdf/Threshold_Document.pdf. It is, therefore, critical to have a policy in place to secure accreditation of Doctor of Pharmacy (Pharm.D.) program from ACPE.
What impact may this policy have on non-academic functions of the University (e.g. Financial Aid, Admissions, etc.)	This policy may not have any direct impact on the financial aid, admission, retention etc. It is, however, expected that when the Doctor of Pharmacy (Pharm.D.) program matures, its faculty and students will be involved in various types of research projects, which may generate extramural funds to the university; and some of the projects may involve human subjects requiring full IRB policy.
What financial costs are associated with implementing this proposal (attached cost/benefit analysis if required)? What financial benefits will be derived?	At the beginning there is no cost involved with formation of an IRB/PHSC and development of a policy manual. If the university, in future, allocates sufficient resources to move forward with biomedical and behavioral research, a separate unit with sufficient staffing may have to be developed.
Have appropriate discussions with impacted stakeholders occurred, and do those stakeholders support the policy as drafted?	
If approved, what documents or publications will need to include this policy (e.g. Catalog, enrollment agreement, Faculty Handbook, etc.). How will the policy need to be communicated?	This policy may be included in the University Policy manual.

Policy Implementation:

Please provide the name of the individual who will chair the implementation committee.	Following the HHS guideline (http://answers.hhs.gov/ohrp/questions/7180), a senior officer of the university (Provost) or a designee shall select members to form a committee for IRB – PHSC. The officer/designee shall initiate the process to register with HHS (http://answers.hhs.gov/ohrp/categories/1565). Please nominate individuals for the following positions: Proposed Chair: Dr. Talukder
Please provide the names of the individuals who should sit on the implementation committee. Ensure that all stakeholders are represented.	Following the HHS guideline (http://answers.hhs.gov/ohrp/questions/7180), a senior officer of the university (Provost) or a designee shall select members to form a committee for IRB – PHSC. The officer/designee shall initiate the process to register with HHS (http://answers.hhs.gov/ohrp/categories/1565). Please provide a recommendation for an initial committee structure: One Representative from each of the following department: Nursing, Pharmacy, Dental Hygiene, General Education, Health Care Management, Occupational Therapy, and Physical Therapy.
Which implementation cycle should this policy be added to? If the policy needs an expedited implementation, please justify. Special approval of the Academic Council and the University Provost is required.	Fall 2012 Cycle

Part of this proposal has been adapted from The IRB Policy and procedure manual of University of Texas at Austin.

For Administrative Response:

This policy reviewed by Academic Council on: 5-14-2012
(Date)

Academic Council response:

☑ Vote: 8-0

☐ Returned to submitting group for further review—see notes that follow:

☐ Policy not recommended for the following reasons:

(Provost)
6/1/12
(Date)

For President's Response:

☑ Policy Approved

☐ Returned to Provost for further review—see notes that follow:

☐ Policy not approved for the following reasons:

(President)
6/13/12
(Date)