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Valencia College's Institutional Review Board (IRB) – Written Procedures 12/9/2019 LB

- **This overview of Valencia College's written IRB procedures** reflects the 2018 changes to the federal policy and it has been structured by the "Guidance for Institutions and IRBs" https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#2085 (2018) from the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP).[1]

- **Context** regarding this guidance from the HHS, OHRP is included in Appendix I.

- **A list of related definitions** is provided at the end of this document in Appendix II.

- Separately there is a **Valencia IRB Frequently Asked Questions (FAQ)** which is a working document that addresses questions raised about the IRB by faculty and staff members over time – it is posted online and recently added / revised entries are shown in Appendix III.

- **There are is a checklist used when processing the applications** that the administrative support staff follows that is kept internal to the office and it is not included here. It includes, for example, directions noting how the application folders should be complied, when the hardcopy determination should be mailed, etc.

- **Our IRB is an institutional review board** established in accord with and for the purposes expressed in the Health and Human Services (HHS) regulations for the protection of human subjects in research (45 CFR 46), the Common Rule (45 CFR 46 Subpart A). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

- **IRB approval** is the determination of our IRB that the research has been reviewed and may be conducted at Valencia College within the constraints set forth by: (a) the college's IRB; (b) our other institutional requirements; and (c) any applicable federal requirements. Examples of institutional requirements include 6Hx28:1-10 our policy against Improper Activities and 6Hx28:7B-02 our policy related to Student Records. While this document provides an overview of procedures, the IRB follows the federal policy available online, which provides more extensive detail about the regulations.

- **The Valencia College - IRB - Revised Common Rule Checklist**, which is based on the revised Common Rule regulations that structure the review process, is used by the Chair in determining the appropriate designation for submitted applications (see Appendix IV).

[1] This guidance has been prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) to enhance human subject protection and reduce regulatory burden. OHRP and FDA believe that when institutions and IRBs develop and follow clear written procedures, there is an increased likelihood that the rights and welfare of human subjects will be protected. This document has been adapted for Valencia College with a stronger focus on OHRP rather than FDA regulations. **OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes OHRP's and FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited**.

Written Procedures: Valencia College's Institutional Review Board (IRB)

Our IRB follows written procedures for the following functions and operations:

(a) Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution; (b) determining which projects require review more often than annually; (c) ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects; (d) ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head; (e) unanticipated problems involving risks to human subjects or others; (f) instances of serious or continuing noncompliance with the applicable HHS regulations or the requirements or determinations of the IRB; (g) suspension or termination of IRB approval. HHS regulations allow flexibility in both format and content of written procedures, which gives IRBs the ability to establish procedures best suited to their own operations. HHS regulations allow flexibility in both format and content of written procedures, which gives our IRB the ability to establish procedures best suited to our own operations and in compliance with college-specific policies and practices.

Contents

I. How is an application for IRB review processed?

a. Researcher applications for IRB review trigger the review process: Researchers who are employees take the online screening survey – The Key Questions Checklist -- to determine if they should submit an IRB application. Non-employees are asked to submit an IRB application; they cannot self-screen using the online survey. Researchers (also referred to as "principal investigators" - PIs) who are required to submit their applications for review to the IRB submit a hardcopy with signatures signed in ink (including e.g., protocol, informed consent form, recruitment materials). Hardcopies have been required over the past seven years because we have found them more reliable, accountable, and accessible as researchers have varying access to the tools needs for digital signatures. We have received digital applications that are missing documents, e-mailed and reported sent, but not received, and where signatures have been typed in without the supervisor's knowledge. IRB form submission does not provide researchers access to the college, serve as a gatekeeper for the studies, or match researchers with sponsors at the college. The IRB chair and members do not provide access to the college. For non-employees who do not have access / need a sponsor they must first obtain permission from the office of the Vice President for Analytics and Planning before applying for IRB review.

b. An IRB review application form is provided for researchers: It outlines all items needed, the responsibilities of the researcher, and it provides sample templates (such as an informed consent document). The application also includes a listing of all Valencia College policies that the applicant should be aware of and comply with (for example 6Hx28:1-10 our policy against Improper Activities and 6Hx28:7B-02 our policy related to Student Records). Following federal guidelines the determination is made within the constraints set forth (a) by the college's IRB; (b) within Valencia's institutional requirements; and (c) according to any applicable federal requirements. All researchers must follow the same procedures at Valencia for accountability purposes and to ensure consistent application of the regulations. We provide an "Online Key Questions Checklist" so that a researcher can quickly determine if the study needs review. The questions follow the federal policy and provide a follow-up e-mail so researchers know whether or not they need to apply for review.

c. What the researcher can expect once materials are submitted: Beginning in February, 2019, applicants from within the college (faculty and staff, internal) are being asked to submit their materials and conduct their related correspondence through the college's new online "request management" system. Through this they will be kept updated related to the status of their applications whenever needed. The online system is not an application management system; it is a "help desk ticket" system that tracks and documents communication. Researchers who are non-employees (external) will be contacted and communicated with through E-mail as the current system does not permit use of the online "request management" system for those outside of the college. The office's administrative assistant contacts the lead researcher (principal investigator) by e-mail and by phone to let the person know of the receipt of the application and if any materials are missing. The assistant informs the IRB chair if an applicant is not responsive, if help is needed in working with an applicant, or if questions arise that are outside the scope of the assistant's role. Once the office's administrative assistant receives the complete packet, a folder is created and it is sent to the IRB Chair. The IRB Chairperson is the primary reviewer and applies the determination guidelines in order to designate the application as "exempt," "expedited," or in need of full review. Please see the Frequently Asked Questions (FAQs) for definitions of these categories and the Valencia College - IRB - Revised Common Rule Checklist, which is used when reviewing applications. Related college policies and practices are also taken into consideration, for example 6Hx28:1-10 our policy against Improper Activities and 6Hx28:7B-02 our policy related to Student Records.

II. What elements are considered when applications are reviewed?

d. How the Chairperson reviews the application: The person in this role determines whether or not the criteria for IRB approval of research are met, including a review of the informed consent form and the informed consent process, taking into consideration any request for waiver or alteration of the consent procedure. The Chairperson considers whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional safeguards have been included to protect the rights and welfare of these subjects. The IRB Chair reviews research involving children as subjects in accordance with applicable regulations. The Chairperson reviews the qualifications of the investigator(s) and the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies, if applicable. In this process the IRB Chair applies general criteria within the Federal policy used to make these determinations (e.g., the nature of the study and risks posed by the study; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; and the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor). The IRB Chair applies the Valencia College - IRB - Revised Common Rule Checklist, which is based on the revised Common Rule regulations that structure the review process. Please see the criteria for each designation excerpted from the federal policy and included in response to

"Who determines whether an application is exempt, expedited, or requires full review?" in our Frequently Asked Questions (FAQs).

e. Steps taken in the review of an application that requires full review from the IRB: If an application is in need of full review, a meeting of the IRB would be convened in person with a video-conferencing option, with at least 50% of the board in attendance, not including the IRB Chair. IRB members with conflicting interests are expected to recuse themselves from any review. The meeting is conducted and minutes are recorded following "Guidance for Institutions and IRBs - Minutes of Institutional Review Board Meetings" 2017 (HHS -OHRP). https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0 The IRB cannot disprove or reject a study. Instead feedback is provided to the researcher for the protection of human subjects and questions may also be raised. A response is expected within two weeks. If the researcher is unresponsive to the feedback / questions asked, then the IRB will recommend to the Vice President for Analytics and Planning or other responsible administrators that study should not be permitted. Questions about the steps taken by the Vice President for Analytics and Planning or other responsible administrators are outside of these procedures and questions should be directed at them directly.

f. Steps taken for proposals designated as exempt or expedited: The IRB is not convened to review proposals designated as exempt or expedited. The corresponding designation packet is created and sent by E-mail from the office of the IRB Chair to the researcher who submitted the application. The packet includes the IRB file number, the signature of the Chair, and the IRB stamp related to the designation. Any subsequent directions for researcher next steps or follow-up are included. The Chairperson in this role determines and documents the effective date of initial approval and determines the date for subsequent continuing review, the frequency of review needed, and whether or not others should be consulted in order to review the status of continuation. The Chairperson communicates the IRB's findings and actions to the investigator and to the Vice President for Analytics and Planning as well as to the full Board. The proposals are made accessible online and discussed at the Fall and Spring IRB meetings. The Chairperson communicates any modifications or clarifications required by the IRB to the investigator as a condition of approval. Due to the nature of the research that is conducted at our college, most proposals are designated as exempt or expedited under the definitions provided under the federal policy; they do not require full IRB review.

III. What should the researcher expect in the process of review?

g. How the office handles the application: We aim to turn the forms around within two weeks of the receipt of the completed, signed paper application. We only begin the review once all parts of the application have been received. Review for expedited and exempt

designations take the same amount of time and require the same forms. Applications that receive exempt designations do not require follow-up by the researcher.

Applications that receive expedited designations require follow-up from the researcher after one year, and - as appropriate - they require follow-up by the investigators (researchers) with the IRB in the case of adverse impact on subjects or when substantial changes are made to the study. Other researcher reporting requirements and forms are included in the "determination packet," which is sent electronically and by mail once a determination is made (as having received exempt, expedited, full review).

h. The termination or suspension of IRB approval: This is reported by the Chair to the Vice President of Analytics and planning and other administrators as appropriate, including the office of the General Counsel. In accordance with the federal policy, researchers found to have put participants at risk may have their IRB approval suspended or terminated. https://www.ecfr.gov/cgi-bin/text-idx?SID=c164f9086669bb546a4dab96940957c8&mc=true&node=se45.1.46_1113&rgn=div8
Violations to the rights of participants that were to be upheld as described in the policy, as well as the failure to adhere to the terms of the IRB application which had undergone IRB review, are taken into account when the chair makes the determination. College policies and practices are also taken into consideration, for example 6Hx28:1-10 Valencia College's policy against Improper Activities and 6Hx28:7B-02 our policy related to Student Records. The Chair will consult with the Vice President for Analytics and Planning and, as appropriate, General Counsel and also inform the Board of Trustees of actions taken, if the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1123

i. How we document and make the application review process open and accessible:
Researchers are told in advance to expect to have their applications shared with others at the college with the possibility of posting online within the college system for more transparent sharing of applications with faculty and staff members in the process of review. As of Nov. 1, 2020 IRB members will be notified of each application and provided the option of reading the proposals. IRB members are expected to actively review proposals that require full Board review. They will have on-going access to all reviewed proposals through Sharepoint and access for others can be added upon request. Electronic files are stored indefinitely on a password-protected shared drive online.

IV. Who serves on the IRB and What are Its Responsibilities?

j. The composition of the IRB and terms of service: At Valencia all aspects of the IRB including the composition of the Board are carried out according to the steps required in the federal law. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_11 07 While the policy recommends a minimum of five members, Valencia's Board will have no fewer than eight members. The members serve two-year terms, beginning in December of 2020. Up to four seats may be filled by faculty members as determined based on recommendations from the Faculty Association. The other members typically include non-faculty representation from the Instructional Affairs Committee (IAC) and other areas, such as Analytics and Planning, Student Affairs, and divisions that conduct human subject research most subject to risk. The board comprises a mix of members with research experience with projects that need IRB approval in the sciences, outside of the sciences, while also including community representation. The Chair of the IRB and the Vice President for Analytics and Planning will send out invitations for two-year terms to non-faculty members to serve two-year terms. IRB members are expected to have completed the nationally recognized trainings that are required of researchers (principal investigators) (such as CITI) and member certification must have been acquired / renewed before assuming the position. Administrative support staff are trained individually and through a one hour workshop offered to all staff and faculty members at the college.

k. The IRB and its members – other activities: Overall Board communications and related documentation (e.g. minutes) are maintained in an accessible online space. In addition to gathering for any full reviews of an application (see procedures described prior) the Board gathers in person and via video conference at the end of the Fall and the Spring semesters. The purpose of the gathering is for an overview of all applications submitted and their determinations as well as any full reviews of applications and other discussions as determined by a collaborative agenda organized by the Chair of the IRB focused on items specific to the work of the IRB. This time frame will be evaluated after the first cycle to determine if additional (or fewer) meeting times are needed.
There is an overview of all applications processed that semester. The applications with completed determination packets will be available online no later than one week prior to the meeting. Applications processed within a week of the meeting will be presented in the following semester. Documents routinely distributed to all IRB members include the agenda and minutes of meetings. Board access to all approved applications in Sharepoint is updated at the end of the fall and spring semesters.

l. The IRB Chair – additional responsibilities: The Chairperson ensures that researchers promptly report proposed changes to research activity to the IRB and that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without review and approval except where necessary to eliminate apparent

immediate hazards to the human subjects. Steps are in place ensuring prompt reporting of adverse effects on research participants and these are outlined in the packet that is provided to the researcher upon the designation of expedited review. The Chairperson maintains records as described in the federal policy https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1115 and also maintains and renews the registration of Valencia's IRB with the Dept. of Health and Human Services OPHR https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.e5.1 renewing it every three years. It is also updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The registration information is posted on Valencia's IRB Website.
The Chair of the IRB carries out the policy and procedures approved by the Board of Trustees, maintains the "Key Questions Checklist" online, and updates this document— the IRB's Written Procedures – as needed, and provides professional development opportunities on a regular basis. The IRB Chair visits classrooms upon request to explain the role of the IRB and also provides materials for faculty members to incorporate in their classes (including slides, videos, and role play simulations). The IRB Chair also customizes workshops for specific groups, collaboratively developing goals and outcomes that meet the needs of the faculty and staff members.

m. Scope and authority: The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties, is outlined in the college policy as approved by Valencia College's Board of Trustees. The office of the Vice President for Analytics and Planning upholds the independence of the IRB Board by serving as a gatekeeper for researchers outside of the college. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected are described in The Belmont Report (1976) created as a result of the National Research Act of 1974 and identifying basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects.

n. How these procedures fulfill federal requirements: This list of written procedures will be reviewed by the Chairperson and Board annually along with an assessment of whether the IRB-approved informed consent form requires revision. These procedures are in compliance with the federal policies that guide the protection of human subjects in research, including the following regulatory requirements outlined in the recently revised policies (2018):

- Each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]

- Each IRB must follow written procedures for determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material

changes have occurred since previous IRB review [45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2)]

- Each IRB must follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects [45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4)]

- Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials or others as needed, and the requirements or determinations of the IRB, and any suspension or termination of IRB approval [45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b)] The college policies that are upheld within our IRB process are outlined in the IRB application which all researchers complete (for example 6Hx28:1-10 our policy against Improper Activities and 6Hx28:7B-02 our policy related to Student Records).

- Please see the Frequently Asked Questions (FAQs) for definitions of the three categories of review (exempt, expedited, or full review) and the Valencia College - IRB - Revised Common Rule Checklist, which is used when reviewing applications based on the revised Common Rule regulations that structure this process. Links to the materials referenced in this document (such as the college policy regarding the IRB approved by the Board of Trustees) are accessible on the Valencia College IRB Website www.valenciacollege.edu/IRB.

Appendix I. Additional Details about the "Guidance for Institutions and IRBs" from HHS / OHRP

The "Guidance for Institutions and IRBs" https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#2085 (2018), which informs our written procedures, was developed by the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP)

HHS regulations allow flexibility in both format and content of written procedures, which gives IRBs the ability to establish procedures best suited to their own operations. Written procedures may be maintained electronically or may be paper-based and formatted in a style that conforms to the needs of the institution. Institutions/IRBs may choose to create written procedures that focus solely on the regulatory responsibilities of the IRB, or they may choose to also incorporate institutional policies and procedures that are a function of the institution's Human Research Protections Program (HRPP). Detailed administrative procedures for the IRB support staff (e.g., how and where to track study approvals for calculating continuing review) may be included, or may be managed through other locally written policies and procedures (e.g., work instructions, standard operating procedures (SOPs), or a staff operations manual). Institutions and IRBs should use the flexibility afforded by the regulations to adopt written procedures that are suitable for their organizations.

Institutions/IRBs may decide to make their written procedures available to ensure that others (e.g., investigators, sponsors) are aware of the IRB's requirements, and to facilitate compliance. Some institutions/ IRBs post their written procedures on a website to provide broad access. Written procedures should be reviewed on a regular basis and updated as necessary to ensure they reflect the institution's/IRB's current processes. Although the IRB must follow written procedures for functions and operations specifically described at 45 CFR 46.103(b)(4) and (5), and/or 21 CFR 56.108(a) and (b), there are other IRB activities that require findings and determinations for which the underlying regulations do not explicitly require the IRB to follow a written procedure.

As previously stated, institutions and IRBs have flexibility in how they choose to format their written procedures and how much detail to include. For example, topics listed in the Checklist may not be applicable to all institutions/IRBs. On the other hand, the institution/IRB may determine that additional topics not found in the Checklist should be included (e.g., written procedures related to how the IRB interacts with an Institutional Biosafety Committee or a Radioactive Drug Research Committee). In addition, institutions/IRBs may choose to combine items in the Checklist as needed to avoid redundancy, or use a different order than that presented in the Checklist. OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes OHRP's and FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Appendix II. Definitions Related to Human Subjects Research

Additional definitions related to research are provided in the IRB application.

(1) **Human subject** means a living individual about whom an investigator (lead researcher
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) **Principal Investigator (PI)** The lead researcher for the project named on the IRB application who has signed the form as PI.

(3) **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(4) **Interaction** includes communication or interpersonal contact between investigator and subject.

(5) **Private information** includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(6) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(7) **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(8) **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).

(9) **IRB** means an institutional review board established in accord with and for the purposes expressed in the Health and Human Services (HHS) regulations for the protection of human subjects in research (45 CFR 46), the Common Rule (45 CFR 46 Subpart A).

(10) **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(11) **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for

providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(12) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(13) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities and there is a list of activities that are deemed not to be research. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104

(14) Applications that receive expedited designations require follow-up from the researcher after one year, and - as appropriate - they require follow-up by the investigators (researchers) with the IRB in the case of adverse impact on subjects or when substantial changes are made to the study.

(15) Other reporting requirements for researchers are included in the “determination packet” (the packet of materials sent by the IRB Board to researchers after they receive an expedited or full review).