VALENCIA COLLEGE

Human Research Protection (HRP) Institutional Review Board (IRB)

The Valencia IRB Overview and Application Package for Researchers – Primary Investigators (PIs)

The following overview provides information and resources that you should review before you proceed with your online application to receive an IRB determination. After reading through this document if you have questions please contact the IRB Chair at irb@valenciacollege.edu

Document Title	Pages	Purpose
Responsibilities and Related Policies	2-7	Overview of investigator / researcher responsibilities along with the applicable college policies that should be followed.
Participant Informed Consent Forms	8-14	Guidance for developing a compliant informed consent document to be included with your IRB application.
Common Definitions	15-23	List of common IRB-related definitions
A copy of the online application form.	24-30	Review this copy of the online application form and please gather all of the items you need before applying online.

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Investigator Responsibilities

Investigators must comply with all Valencia policies and procedures as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research. Within this, researchers must obtain IRB approval prior to involving any human subjects (including their data) in research studies and they are expected to:

1. Ensure that only qualified personnel conduct the study according to the approved protocol, and in compliance with each individual's scope of practice.

2. Ensure the rights and welfare of each research participant; the participant's rights and welfare must take precedence over the goals and requirements of the research.

3. Implementing no changes in the approved protocol or Participant Informed Consent Form without prior IRB approval, except in an emergency, if necessary to safeguard the well-being of human subjects. Changes must be submitted to the IRB in advance using the Addendum/Modifications Request Form; emergency changes must be submitted to the IRB within five (5) working days of occurrence.

4. Ensuring that anyone obtaining informed consent has read the protocol and has sufficient knowledge of all information provided in the informed consent document.

5. Obtaining legally effective informed consent from human participants or their legally responsible representative before any research-related screening or intervention commences and using only the currently approved Participant Informed Consent Form.

6. Providing each participant enrolled in the study a copy of the IRB-approved informed consent document at the time of the consent, unless the IRB has specifically waived this requirement.

7. Unless specified otherwise, retaining all signed informed consents and other research-related documents (including but not limited to paperwork submitted to and approved by the IRB) throughout the study and for an additional three years after the study is completed/closed with the IRB.

8. Promptly reporting any injuries or unanticipated problems to the IRB in writing within five (5) working days of occurrence or discovery of occurrence using the Adverse Event Form.

9. Reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once per year. This includes submitting a Continuing Review/Termination Form to the IRB prior to expiration and also when the research is completed.

10. Completing at least one of the following training options prior to participant recruitment: Training must have been completed less than three years prior to the start of participant recruitment and must continue to be completed at least once every three years; copies of completion certificates must be submitted to the IRB Chair to be placed in the IRB records as proof of completion. The IRB will consider accepting alternate HRP training on a case-by-case basis if requested by the PI or Co-PI, beyond the training offered by Harvard University, Collaborative Institutional Training Initiative - CITI, or the Protecting Human Research Participants (PHRP) Online Training.

    All investigators should review and be familiar with The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, and the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46. Valencia policies and procedures are applicable to human subjects protection and research and should be followed, including but not limited to:

    - 6Hx28:5-03 Public Contact with Students, Faculty, and Staff;
    - 6Hx28:7B-01 Preservation and Disposal of Records;
    - 6Hx28:10-02 Trespass;
    - 6Hx28:9-06 Grant Funding;
    - 6Hx28:1-10 Policy Against Improper Activities; Whistleblower Protection
    - 6Hx28:3E-05.2 Ethical Conduct and Performance
    - 6Hx28:2-01 Discrimination, Harassment, and Related Conduct;
    - 6Hx28:4-03 Research by Faculty; and
    - 6Hx28:7B-02 Student Records.

11. If unavailable to conduct or direct this research personally for a period exceeding fourteen (14) calendar days (as when on sabbatical, leave, or vacation), notifying the IRB Chair in writing in advance of the absence, indicating arrangements made for a Co-PI to assume research-related responsibilities in the researcher's absence.

12. In the event that employment with Valencia is discontinued, completing one of the following with each approved/active protocol (steps that were reviewed and are being followed in the study) prior to the last day of employment: (1) transferring the study to a new PI; or (2) closing the project. These changes must be sent in writing to the IRB Chair by submitting either an Addendum/ Modifications Request Form or a Continuing Review/Termination Form. This notification must be submitted at least two (2) weeks prior to the end of employment.

Exemption from Valencia IRB review does not exempt the PI or Co-PI from compliance with all applicable institutional, Federal, State, and local rules, regulations, policies, and procedures.

Because Valencia does not typically conduct medical research, this list of responsibilities does not include any references to medical or health-related research activities. Such research projects require special IRB review because they are subject to additional requirements above and beyond those addressed in the standard Valencia IRB process, therefore investigators must contact the IRB Chair to seek approval for protocols related to medical research.

If you have any remaining questions about Valencia's IRB process, contact the IRB chair at irb@valenciacollege.edu .

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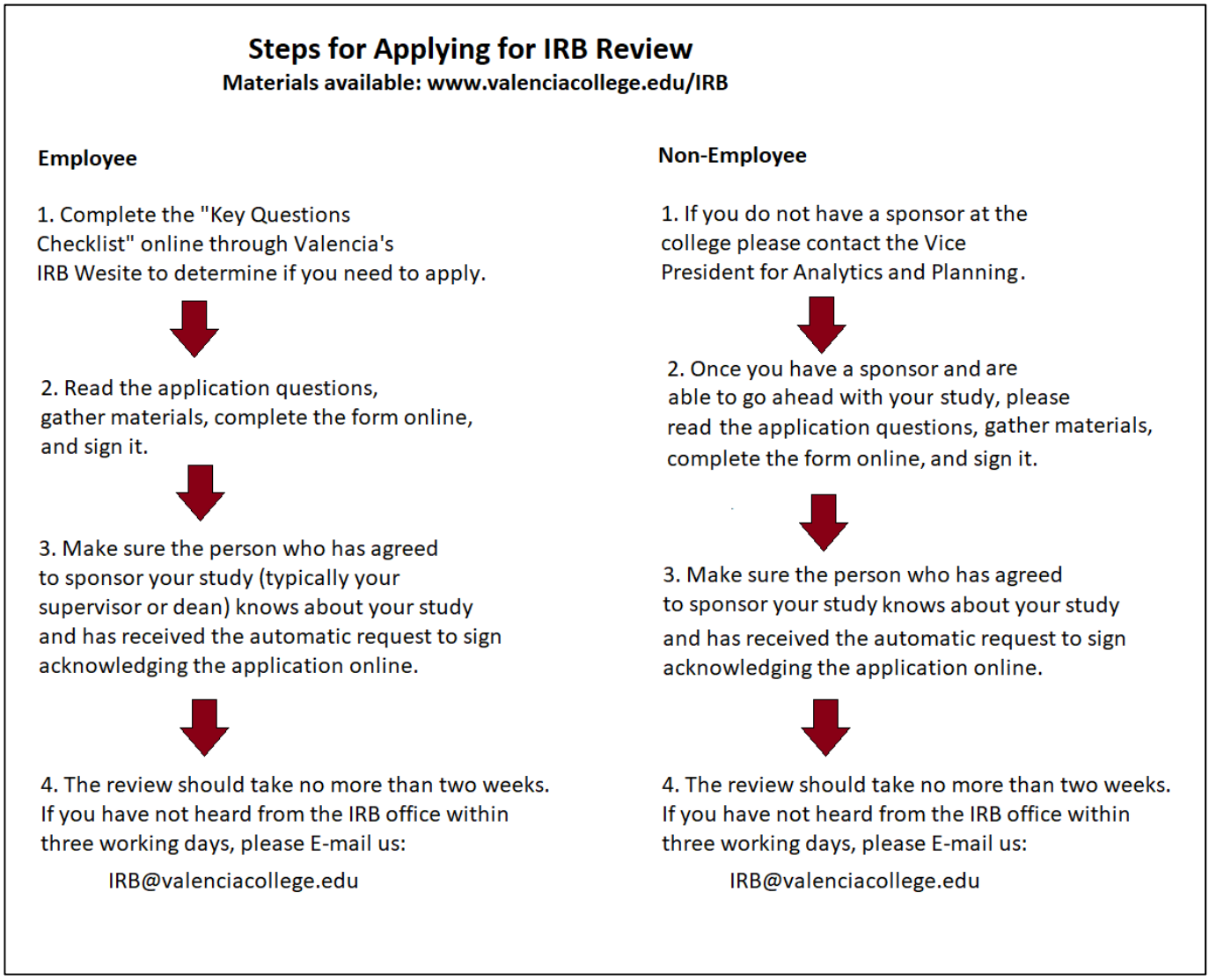
IRB Protocol (Steps that will be Followed in the Study) - Initial Submission Form

Four Submission Steps…



Begin the Process…

- Please read this document so you understand the expectations and process before you complete the online application and follow the steps shown in the graphic above. Review the questions asked in the online form (see below) and gather your application documents in PDF format (e.g., your informed consent forms, recruitment flyers, survey questions, pre- and post-tests).

- Complete the application online, upload your documents, and sign the form. When you enter the e-mail of the person who has agreed to sign and sponsor the study (for example a dean) that person should get an automatic message with a link asking them to sign. You will want to e-mail that person separately to make sure they received the invitation to sign.

- Once we have your completed application we will contact you. The review should take no more than two weeks. If you have not heard from us within three working days or if you have questions, please contact us at: irb@valenciacollege.edu.

Keep in Mind…

- Non-employees should have a Valencia College administrator who sponsoring the work sign as the person responsible. This might be a dean or a director who is familiar with your proposed study and agrees to be responsible. If there is no sponsor for the proposed study at the college, then have a conversation with the Vice President for Analytics and Planning. If the research study is approved and an administrator has agreed to sponsor the work, then apply for IRB review.

- Employees should have their supervisors read and sign the application on the page indicating they agree to be the responsible administrators.

- In order to prepare your application, please review the questions asked (see below) and gather your application documents in PDF format (e.g., informed consent forms, recruitment flyers, survey questions, pre- and post-tests) to upload into the online form.

- If the protocol involves having non-investigators such as college class instructors, staff, or students disseminate or administer documents or services in classes or other settings, you must include a description of how you will train these individuals in the research protocol, copies of scripts that the individuals will read to their subjects, and a confirmation that the individuals have agreed to participate in this manner.

- If the research is for a dissertation, please apply for IRB review at the institution of study before submitting an application to Valencia.

- If research activities are being conducted by Valencia students within a course, including Honors, the faculty members teaching the course are responsible and should work within the Undergraduate Research initiative in order to take steps to ensure ethical research practices. Undergraduate student research activities are not required to undergo IRB review.

Once your application is complete…

Submissions will be processed as quickly as possible after they are received and the application is complete, however please allow a minimum of two weeks for the review and approval process.

Once the outline of steps to be taken in the research (protocol) is submitted online and reviewed and determined to be exempt, or is reviewed under the guidelines for expedited or full review, the Researcher / Principal Investigator (PI) will receive an IRB Determination document detailing the IRB's findings. If the research protocol is approved under expedited or full review, the IRB Determination Form will be part of a larger IRB Determination Package that includes additional documents for review and completion by the investigators involved in the protocol. An IRB Determination Form will be sent to the researcher (principle investigator) indicating one of the following determinations:

1. The research is exempt from IRB review.
2. The research is eligible for expedited review but requires modifications and re-submission.
3. The research is eligible for expedited review which has been granted.
4. The research is subject to full review and will be discussed at the next scheduled IRB meeting.
5. The research protocol (steps that will be followed) - has undergone full review and accepted.
6. The research has been subjected to full review and has been rejected.

Research activities that are not accepted may be re-considered for review, subject to submission of re-design changes that are responsive to the findings of the IRB. If you have any remaining questions about Valencia's IRB process, please contact the IRB Chair at irb@valenciacollege.edu.

Required attachments – supporting materials:

- A sample of the informed consent form or statement to be used for this research project must be submitted with this application. Please refer to the Participant Informed Consent Form for more detailed information and guidance.

- Other documents (e.g., recruitment materials, statements to be read to the subjects, questionnaires, tests, or other instruments) should be attached as appropriate.

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Participant Informed Consent Form (for Internal and External Investigators)

Informed consent means that research participants need to have sufficient information about the project in which they are being asked to become involved so that they have a general understanding of the research before they volunteer to participate. **The information given to prospective participants (and/or their representatives) must be in language they can understand.**

The information contained in your Participant Informed Consent Form should provide sufficient details about what the participant will be asked to do and must match what you have stated in your IRB Protocol Initial Submission Form (or, if applicable, reflect modifications as described in your IRB Continuing Review/Termination Form or IRB Addendum/Modification Form). The following suggestions are offered as guidelines; the exact language of the informed consent form is the decision of the researcher and should be age and language-appropriate.

SECTION 1 - SAMPLE INFORMED CONSENT FORM:

The following sample Participant Informed Consent Form includes a side-by-side table that lists the required components of informed consent along with some suggested wording.

SAMPLE PARTICIPANT INFORMED CONSENT FORM

[Date]

Dear [Student/Parent/Sir/Madam]:

Required Components of Informed Consent	Sample Wording
1. Statement of purpose of the study.	We are conducting a study to determine _____.
2. Short description of methodology and duration of participant involvement.	In this study, [you/your child] will be asked to _____. Participation should take about ___ minutes/hours/days/weeks/months].
3. Statement of risks/benefits to the participants (including remuneration, if applicable).	There are no risks to [you/your child]. *OR* The only risks to [you/your child] include _____.

Required Components of Informed Consent	Sample Wording
4. Statement of data confidentiality. (Note: "confidential" means that the researchers will know the names of the participants, whereas "anonymous" means that the researchers will not know the names of the participants.)	All information will be handled in a strictly confidential manner, subject to the disclosure requirements of Florida Sunshine Laws, so that no one will be able to identify [you/your child] when the results are recorded/reported. *OR* All information will be submitted anonymously, so that no one will be able to identify [you/your child] when the results are recorded/reported. *AND* All information is subject to the Family Educational Rights and Privacy Act (FERPA) of 1974, which is designed to protect the privacy of educational records.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.	[Your/your child's] participation in this study is totally voluntary and you may withdraw at any time without negative consequences. To withdraw at any time during the study, simply contact [name, title of Principal Investigator] at [phone number, email address], or [mailing address]
6. An offer to answer any questions the participant may have.	Please feel free to contact [name(s), title(s) of all investigators] at [phone number(s)] if you have any questions about the study.
7. Contact information for Valencia's IRB.	Or, for other questions, contact the Chair of Valencia's Institutional Review Board at irb@valenciacollege.edu.

Required Components of Informed Consent	Sample Wording
8. Line for signature of participants and/or parents or legal guardian, and statement that participant is 18 years of age or older unless parent or legal guardian has given consent	*If the participant is of age (18 years old or older), use:* I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate. _____ Signature of Participant Date ***OR*** *If the participant is not of age so parent/guardian will be signing, use:* I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child to participate with his/her assent when possible. _____ Signature of Parent/Guardian Date ***AND*** *ASSENT format (see Section 4):* I understand what I must do in this study and I want to take part in the study. _____ Signature of Child Date ***OR*** *If the research is minimal risk and anonymous and you are requesting a waiver of documentation of consent (see Section 2), use:* I am at least 18 years of age and completing this [survey] constitutes my informed consent.

A copy of the Participant Informed Consent Form must be given to the signatory, along with copies of any research materials that are provided to the participants and/or their parents/guardians (e.g., recruitment materials, description of the research, lists of questions).

If you will only be seeking participants who are 18 years of age or older, it is recommended that you include the statement "You must be 18 years of age or older to participate in this research" at the top of your Participant Informed Consent Form so that it is clearly visible.

SECTION 2 - WAIVER OF DOCUMENTATION OF CONSENT:

You may request a waiver of documentation of consent (just state this in Section 4 of your IRB Protocol Initial Submission Form) if your research is minimal risk, truly anonymous, and you do not need to know who completed which survey. By using the waiver of documentation of consent, you must still provide participants with a consent form/letter, but participants do not have to sign the form. You may convert the sample consent form above to a waiver of documentation of consent by removing the signature lines and removing any reference to signing. The title of the form should remain "Participant Informed Consent Form."

Federal regulations provide for seven (7) "minimal risk" categories, and four (4) of those categories are related to medical research. Because Valencia does not typically conduct medical research, only the three (3) non-medical-related minimal risk categories are described below. If your activity is related to medical research, please contact the IRB Chair. The three (3) non-medical-related minimal risk categories are:

(1) research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

(2) collection of data from voice, video, digital, or image recordings made for research purposes.

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

SECTION 3 - DECEPTION:

In situations where participants will be **intentionally deceived as part of the research process**, items 1 and 2 of the sample informed consent in Section 1 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and a debriefing document must be signed by the participants "after the fact" in order to guarantee informed consent. If deception is part of your research, the following is suggested debriefing format:

SAMPLE DEBRIEFING DOCUMENT FOR DECEPTION RESEARCH

Thank you for your participation in this experiment. As you may have gathered from the activity, we are interested in _____. The research activity that you participated in was designed to _____. We will be combining your results with the results of others to determine _____.

If you do not wish for your results to be part of this study, please inform the experimenter at this time. If you have any questions, comments, or concerns, or would like a copy of the final results, contact _____.

_____ _____ _____

Participant's Signature (or Parent/Guardian) | Participant's Printed Name | Date

SECTION 4 – CHILDREN:

For participants less than 18 years of age, the researcher must obtain the informed consent of a parent or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study. Documentation of this assent must be signed by the child (or the parent/guardian if the child is too young to sign) and a witness (not the person obtaining the assent).

If your participants will be children of elementary age or younger, you should consider obtaining the child's assent by reading the informed consent information to prospective participants instead of presenting only a written document.

SAMPLE CHILD'S ASSENT SCRIPT

My name is _____ and I am _____ at Valencia College. I am interested in how students like you ____ and I would like to ask you some questions. You may stop at any time and you will not have to answer any questions you do not want to answer. If you don't want to do this, it is OK and your [parent/teacher] will find something else for you to do. Would you like to do this?

If the child is old enough to sign his/her name, have your script printed out on a piece of paper with the following:

I want to participate in _____'s research project.

_____	_____	_____
Student's Signature (or Parent/Legal Guardian)	Student's Printed Name	Date

_____	_____
Witness' Signature	Witness' Printed Name

If the child is not old enough to sign his/her name, the child must clearly say "Yes" and you must document in writing on the assent form that the child said "Yes." A witness should sign this written documentation. A nod of the head or other physical gesture alone is NOT acceptable as evidence of assent.

SECTION 5 – VERBAL RESEARCH:

If your methodology involves verbal questioning (such as telephone surveys) where obtaining written consent is difficult, here is some suggested wording:

SAMPLE ADULT VERBAL CONSENT SCRIPT

(Telephone survey sample)

Hi, my name is _____. I am a _____ at Valencia College and we are doing a survey for _____. The survey is really short and only takes about 5 minutes. I can only interview people who are 18 years of age or older. Are you at least 18? (If yes, continue; if no, May I please speak to anyone in the household who is at least 18)

(Add as necessary to assure respondent) Let me stress that your participation in this survey is completely voluntary and confidential, subject to the disclosure requirements of Florida Sunshine Laws. Do you have any questions you want to ask about the survey? You will not be identified by name in any document we produce. We are interviewing approximately ____ people and your answers will be combined with everyone else's. You have the right to refuse to answer any question you want. You may also terminate the interview at any time.

Proceed with survey questions approved by the IRB.

SECTION 6 – ONLINE RESEARCH:

If the research process involves an online survey, the survey should open up with a consent letter being displayed first and instructions for the participant to click the accept button if they want to participate. An https-type secured site is preferred for confidentiality purposes (subject to the disclosure requirements of Florida Sunshine Laws).

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Common Definitions
(Relevant selections from the
U.S. Department of Health and Human Services Office of Research Protection Glossary)

ADVERSE EFFECT An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g.*, headache following spinal tap or intestinal bleeding associated with aspirin therapy).

ASSENT Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.

ASSURANCE A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy §___.103].

AUTHORIZED INSTITUTIONAL OFFICIAL An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

AUTONOMY Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

BELMONT REPORT A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

BENEFICENCE An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFIT A valued or desired outcome; an advantage.

CASE-CONTROL STUDY A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (*See also: Retrospective Studies*.)

CHILDREN Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

COGNITIVELY IMPAIRED Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (*e.g.*, mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly

diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

COHORT A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

COMPENSATION Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (*Compare: Remuneration*.)

COMPETENCE Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Incompetence, Incapacity*.)

CONFIDENTIALITY Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

CONSENT *See: Informed Consent*.

CONTRACT An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant. (*Compare: Grant*.)

CONTROL (SUBJECTS) or CONTROLS Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

CONTRAINDICATED Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (*e.g.*, a drug may be contraindicated for pregnant women and persons with high blood pressure).

CORRELATION COEFFICIENT A statistical index of the degree of relationship between two variables. Values of correlation coefficients range from -1.00 through zero to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching -1.00 or +1.00 indicate strong relationships between the variables. However, causal inferences about the relationship between two variables can never be made on the basis of correlation coefficients, no matter how strong a relationship is indicated.

CROSS-OVER DESIGN A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

DATA AND SAFETY MONITORING BOARD A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

DEBRIEFING Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

DECLARATION OF HELSINKI A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

DEPENDENT VARIABLES The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

DESCRIPTIVE STUDY Any study that is not truly experimental (*e.g.*, quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

DOUBLE-MASKED DESIGN A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind."

EMANCIPATED MINOR A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (*See also: Mature Minor*.)

EQUITABLE Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed [Federal Policy §___.111(a)(3)].

ETHICS ADVISORY BOARD An interdisciplinary group that advises the Secretary, HHS, on general policy matters and on research proposals (or classes of proposals) that pose ethical problems.

ETHNOGRAPHIC RESEARCH Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (*See also: Fieldwork*.)

EXPEDITED REVIEW Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy §___.110].

EXPERIMENTAL Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (*See also: Research*.)

EXPERIMENTAL STUDY A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (*See also: Quasi-Experimental Study*).

FALSE NEGATIVE When a test wrongly shows an effect or condition to be absent (*e.g.*, that a woman is not pregnant when, in fact, she is).

FALSE POSITIVE When a test wrongly shows an effect or condition to be present (*e.g.* that is woman is pregnant when, in fact, she is not).

FEDERAL POLICY (THE) The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the "Common Rule.")

FIELDWORK Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (*See also: Ethnographic Research*.)

FULL BOARD REVIEW Review of proposed research at a convened meeting at which a majority of the membership of the IRB 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 [Federal Policy §___.108].

GENERAL ASSURANCE Obsolete term, previously used to denote an institutional assurance covering multiple research projects. (*See also: Assurance*.)

GRANT Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract*.)

GUARDIAN An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

HELSINKI DECLARATION *See: Declaration of Helsinki*.

HISTORICAL CONTROLS Control subjects (followed at some time in the past or for whom data are available through records) who are used for comparison with subjects being treated concurrently. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.

HUMAN SUBJECTS Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy §___.102(f)].

INCAPACITY Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (*See also: Incompetence*.)

INCOMPETENCE Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (*See also: Incapacity*.)

INDEPENDENT VARIABLES The conditions of an experiment that are systematically manipulated by the investigator.

INFORMED CONSENT A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

INSTITUTION (1) Any public or private entity or agency (including federal, state, and local agencies) [Federal Policy §___.102(b)].

INSTITUTIONAL REVIEW BOARD A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy §§___.102(g), ___.108, ___.109].

INVESTIGATOR In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (*e.g.*, drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (*See also: Principal Investigator*.)

IRB *See: Institutional Review Board*.

JUSTICE An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

LEGALLY AUTHORIZED REPRESENTATIVE A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, 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 [Federal Policy §___.102(c)].

LONGITUDINAL STUDY A study designed to follow subjects forward through time.

MASKED STUDY DESIGNS Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. Sometimes called "blind" study designs. (*See also: Double-Masked Design; Single-Masked Design*.)

MATURE MINOR Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (*e.g.*, consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (*See also: Emancipated Minor*.)

MENTALLY DISABLED *See: Cognitively Impaired*.

MINIMAL RISK A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [Federal Policy §___.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [*See 45 CFR 46.303(d) and Guidebook Chapter 6, Section E, "Prisoners."*]

MONITORING The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

NATIONAL COMMISSION National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.

NONAFFILIATED MEMBER Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher, homemaker).

NORMAL VOLUNTEERS Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have

the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

NULL HYPOTHESIS The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.

NUREMBERG CODE A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR) The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

OPEN DESIGN An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.

OPRR *See: Office for Protection from Research Risks*.

PATERNALISM Making decisions for others against or apart from their wishes with the intent of doing them good.

PERMISSION The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].

PRESIDENT'S COMMISSION President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. An interdisciplinary advisory group, established by congressional legislation in 1978, which was in existence until 1983, and which issued reports on ethical problems in health care and in research involving human subjects.

PRINCIPAL INVESTIGATOR The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

PRIVACY Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

PROSPECTIVE STUDIES Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

QUASI-EXPERIMENTAL STUDY A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups. (*See also: Experimental Study*.)

RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (*e.g.*, as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

REMUNERATION Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) (*Compare: Compensation*.)

RESEARCH A systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge [Federal Policy §___.102(d)].

RESPECT FOR PERSONS An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES Research conducted by reviewing records from the past (*e.g.*, birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

REVIEW (OF RESEARCH) The concurrent oversight of research on a periodic basis by an IRB. Annual reviews are mandated by the federal regulations, however reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy §___.108(e)].

RISK The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (*See also: Minimal Risk*.)

SECRETARY A U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.

SINGLE-MASKED DESIGN Typically, a study design in which the investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the investigator, knows the assignment. Sometimes called "single-blind design."

SITE VISIT A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

SOCIAL EXPERIMENTATION Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

STATISTICAL SIGNIFICANCE A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. [*See McLarty (1987), p. 2.*] If the probability is less than or equal to a predetermined value (*e.g.*, 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

SURVEYS Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

VARIABLE (NOUN) An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

VOLUNTARY Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Overview and Contact

Welcome to Valencia College's Human Research Protection (HRP) Institutional Review Board (IRB) Application

Please complete this form only when you have all materials ready to submit. Read the application overview and the related expectations and responsibilities outlined for researchers posted here. The overview also includes sample forms that you can tailor for your own study as appropriate. It also includes a list of the items you need to have gathered before you use this form.

This is the online form where you will apply for IRB review and upload supporting documents (e.g., your informed consent forms, recruitment flyers, survey questions, pre- and post-tests). You will also need to enter the name and e-mail address of the person who has agreed to sponsor your study. Make sure that person has agreed and is familiar with your study as this step in the form will trigger an e-mail that will be sent to that person requesting their signature approximately five hours after you submit this.

If you are an employee you will want to first complete the Key Questions Checklist to determine whether or not you should be completing an IRB application for review if you are uncertain.

After reading through this application if you have questions please contact the IRB Chair at irb@valenciacollege.edu.

Please let us know the title of your study and how to contact you...

Title of your study	
Your first name	
Your last name	
Your current position / title	
Department / program	
Mail Code (if applicable)	
Campus (if applicable)	
Phone number (xxx-xxx-xxxx)	
Address first line	
Address second line	
City	
State	
Zip code	

Let us know your planned start date:

Month

Day

Year

Let us know your planned ending date:

Note: The IRB determination spans one year and researchers are able to apply to extend approval.

Month

Day

Year

Which best describes you?

- ◯ I am a Valencia College employee
- ◯ I am not a Valencia College employee

I have read the application overview and the related expectations and responsibilities outlined for researchers, which describes the federal policies that are applicable as well as the college policies that the investigators (researchers) must follow, accessible here.

- ◯ Yes, I have read this and agree to abide by the policies and procedures as described.
- ◯ No, I have not read this.

External Connections

Is this for a graduate dissertation or thesis?

If so please obtain IRB approval from your institution first, as they may ask for changes to your study.

- ◯ Yes
- ◯ No

What is your source of funding for this research?

- ◯ External funding (please specify the source, for example Title III, NSF)
- ◯ Funding from the college
- ◯ No funding (independent research)

Other

Will individuals outside of Valencia be collaborating on your study?

- Yes
- No

Please let us know more about that person.

First Name	
Last Name	
Organization	
Title / role:	
E-mail	

Please describe this person's role:

Human Protection of Subjects Training Completion

Principal Investigator (PI) Lead Researcher

IRB - Protecting Human Research Participants (PHRP) Training Completed

Training must have been completed less than three years prior to the start of participant recruitment and must be completed at least once every three years; please upload copies of completion certificates at the end of this application in PDF format. The Valencia college workshop regarding principles of good practice in research is not applicable as Protecting Human Research Participants (PHRP) Training.

- Completed CITI training
- Completed Harvard's non-affiliate training
- Completed Protecting Human Research Participants (PHRP) training
- Completed training elsewhere

Will you share the responsibilities for this study with a co-Principal Investigator (co-PI) - a second lead researcher?

- ◯ Yes
- ◯ No

Co-Principal Investigator (PI) Second Lead Researcher (if applicable)

IRB - Protecting Human Research Participants (PHRP) Training Completed

Training must have been completed less than three years prior to the start of participant recruitment and must be completed at least once every three years.

- ◯ Completed CITI training
- ◯ Completed Harvard's non-affiliate training
- ◯ Completed Protecting Human Research Participants (PHRP) Training
- ◯ Completed training elsewhere
- ◯ I am not sure

Please let us know the name and affiliation of this person.

First name	
Last name	
Title / Role	
Organization / Department / Office	

Please enter the E-mail address of your co-PI - collaborating Principal Investigator.

(Please double-check it, as a copy of this application will be sent to this address.)

Research Methodology

Briefly describe your project's research methodology in non-scientific language.

Your research design (including measures and observations to be taken, location)

Procedures to be used for data collection

Plans for:

(1) data confidentiality (the researchers will know the names of the participants but have a plan to control the process so the names will not be revealed to others) or data anonymity (the researchers will not know the names of the participants and have a plan to control the process so the names will not be tied to the data);

(2) limited data access (the researchers have a plan to limit those who have access to the data to ensure security); and

(3) data disposition (the researchers have a plan to ensure the safe and complete destruction of data after the data is no longer needed for research purposes).

Specifically what will be done with or to the research participants

Expected outcome of research / how research findings will be used

Other (e.g., request for waiver of documentation of informed consent)

Age of participants

- ◯ Younger than 18
- ◯ 18 or older
- ◯ Both

Number of participants to be recruited

Special populations to be targeted (select all that apply)

- ☐ Economically disadvantaged
- ☐ Racial / ethnic minority
- ☐ Other
- ☐ Does not apply

Recruitment Process (including steps to ensure that participation is voluntary and any renumeration):

Please let us know the review category that best applies to your research study. If you would like to read more about these designations, please click here.

- ◯ I request that this research be considered exempt from IRB review.
- ◯ I request that this research be considered for expedited IRB review.
- ◯ I believe this research is subject to full IRB review.
- ◯ I am not sure.

Supervisor / Sponsor Sign-off

Please enter the e-mail address for your Valencia College supervisor / accountable administrator. This should be the person with whom you have already discussed your study and this person should have agreed to permit / sponsor the study. Please double-check this E-mail address as you type it. Once you have submitted this application an E-mail will be sent to that person including a summary of your study. They will be asked to login and provide an online signature.

Note for non-employees: Researchers seeking IRB review must have an administrator at the college who has agreed to be accountable for the research. The IRB office does not facilitate or coordinate research projects and does not connect researchers with administrators. Please exit this application and contact the office of the Vice President for Analytics and Planning if you do not have a sponsor at the college for your research - here are the steps you need to take.

First Name	
Last Name	
Title / Role	
Department / Office	
E-mail	

Request and Final Signatures and Agreement

Please upload your complete application materials, This should include your supporting documents (e.g., your informed consent forms, recruitment flyers, survey questions, pre- and post-tests) and Human Subjects Protection training certification. These should be combined as one PDF document. Please name the document file using your last name, first name, and the date you are uploading it (for example, 5-28-2020).

Enter your E-mail address - please double-check it as this is where your confirmation will be sent.

Please read and sign before submitting...

I certify that the protocol and method of obtaining informed consent as approved by the Valencia IRB will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

× SIGN HERE

clear

With your next click you will be submitting your application and you should receive an acknowledgement e-mail message within the next five hours (please check your spam folder). Approximately five hours after you submit this, please contact the person who has agreed to sponsor your study and ask if they received the link to the signature page. Make sure that the notification did not go to that person's spam folder.

If you have questions please contact the IRB Chair at irb@valenciacollege.edu.
