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Chaminade IRB Frequently Asked Questions:

What is an IRB? IRB is the acronym for Institutional Review Board for Human Participants. Any institution that receives federal funding to conduct research with human participants, such as Chaminade University, is required to establish an IRB to review all research that directly or indirectly involves human participants, and to set forth institutional policy governing such research. The Chaminade IRB has the authority to review, approve, disapprove or require changes in research or related activities involving human participants. Research reviewed by the IRB may also be subject to other review and approval or disapproval by officials at Chaminade University. However, those officials may not approve research that has not been approved by the IRB for Human Participants. The IRB primary role is to ensure the protection of human participants as subjects of research at Chaminade University.

How do I know if I am conducting research with human participants? Research is defined as *"…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."* Activities which meet this definition constitute research for this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Human subjects are *"…living individuals about whom an investigator (whether professional or student) conducting research obtains*

- *data through intervention or interaction with the individual,*
- *identifiable private information."*

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g, providing stimuli to gauge reaction and response). Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews). 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
Private information must be individually identifiable (i.e., the identity of a participant is associated with the information or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

Please see the IRB Decision Tree to help review requirements. If you are unsure if your project involves research with human subjects, please consult with IRB staff who can provide guidance in making this determination.

When am I required to submit a proposal involving research with human participants to the IRB? All research projects that will involve human participants must be submitted for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any

advertising or other recruitment procedures. You can also get more information determining when a research activity needs IRB review in the Decision Tree/

I am just doing a simple survey; do I need to submit my proposal to the IRB? Yes, if the study meets the definition for research with human participants, as explained above. Chaminade's University's Federal-wide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review? Yes, if your research project involves active data collection. Federal regulations and Chaminade University IRB require that ALL research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the research study. However, if your research project involves use of existing information collected from human participants (e.g., secondary datasets, existing biological samples), but there are not any identifiers linking individuals to the data/samples, then the activity may not require IRB review. Please see the IRB's Decision Tree.

Do research projects conducted by Chaminade students need IRB approval? Yes. Projects conducted by Chaminade undergraduate and graduate students need IRB approval, if the project fits the definitions of "research" and "human participants" as described above. If the project is to be used in classroom setting only to teach research methods, the project may not constitute human participant research. However, this means that at no point during or after the conclusion of the course can the results or the data be used for publication, presentation or other research purposes. Therefore, students should discuss these limitations with their instructor or faculty advisor so that they can determine whether IRB review is necessary.

Can researchers be subjects in their own studies? Does self-experimentation require IRB review? Yes, researchers can be subjects in their own studies. However, Chaminade policy regards this type of research (investigator self-experimentation) as research with human participants, and generally requires the same review and approval as research that recruits other people as subjects.

What is meant by "exempt" protocol? What are the requirements? Under certain circumstances, human participant research activities may be granted exempt status. Technically, exemption means that all the research activities fall under one or more of the exemption categories specified by the federal regulations. The criteria and processes for determining "exemption" from IRB review are outlined in the IRB Flowcharts and Form I and II.

The significance of exempt status is that the research activity is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct.

If my research qualifies as exempt, does this mean that I don't have to submit a protocol

for review? No. The Federal Regulations do make certain categories of research exempt from IRB review. However, Chaminade University IRB does not allow investigators to self-exempt their human participant research projects. Instead, determining if a project is exempt from IRB review is an administrative review process handled by the IRB staff. Fill out Form I or II.

I will be collaborating with another institution. Do I need to submit to Chaminade's IRB and the other institution? If you are a member of the Chaminade University faculty or staff, or a Chaminade University student, and you are the person responsible for the conduct of the study (PI), you must get Chaminade IRB approval to conduct your research regardless of where the research takes place. Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; however, in order to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB to review and approve the research.

I have an IRB approval through another institution – what do I do? If you are a member of the Chaminade University faculty or staff, or a Chaminade University student, and you are the person responsible for the conduct of the study (PI), you must get Chaminade IRB approval to conduct your research regardless of where the research takes place. Provide the Chaminade IRB with your approved protocol within 1 month of approval and the IRB will provide an approval notice.

I want to conduct a study that involves the use of deception. Is this allowed? What do I need to consider? The use of deception in research is not prohibited by either the federal regulations or Chaminade. However, because at some level the use of deception in research violates the trust that the participant puts in the researcher, this method should be considered carefully. Please refer to the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct for further guidance.

I am planning to do an oral history project; do I need to submit my proposal to the IRB? Some research involving the collection and use of oral histories or life histories meets the federal definition of 'human subjects research' and requires an application to the IRB office, while other research using the same methods does not.

I am developing case studies; do I need to submit my proposal to the IRB? Studies that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, meets the federal definition of 'human subjects research' and requires review by the IRB office.

Does journalism require IRB review? The reporting of current events, trends, newsworthy issues or stories about people or events generally does not meet the federal definition of 'human subjects research' and therefore requires no application to the IRB office

When may I begin data collection for my study? You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

How long will it take for me to obtain approval to do my study? That depends on the nature of your study and the characteristics of the people you intend to recruit. See Cover Letter for target review times.

Can the IRB approve a project "retroactively?" No.

What does the IRB look for in an application? Are there standard criteria for evaluation? The IRB evaluates every research protocol according to the ethical principles described in the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). Basically, this means the IRB considers whether the risks and benefits of a study are acceptable and managed appropriately, and whether individuals being asked to participate are adequately informed about the research and its possible risks. Considered another way, investigators could look at their plans from the point of view of a subject, or an observer concerned about responsible research. Who are the subjects and how are they recruited? Could they be lured or coerced to participate? Is it through an institution that may have responsibilities toward them (e.g., a school or hospital) and should be consulted? Do they understand, in advance, what they are agreeing to participate in and give their consent willingly? What will they actually do, and what is done to them, during the study? Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful? Might there be long-term consequences? Could the subject be endangered, compromised or embarrassed if information collected leaked out? There are many possible considerations, but they should not be difficult to understand if one assumes the subject's perspective. The IRB's role is to look at the study from this perspective and to ensure that proper precautions are taken to protect individuals when they agree to participate in research.

What does "informed consent" mean? What are its essential components? Fully informing participants of the risks, benefits, and procedures involved in a study is a standard requirement in research with human participants. Ethically and legally, consent is not considered to be "informed" unless the investigator discloses all the facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate in a research protocol. This applies to ALL types of research including surveys, interviews, and observations in which participants are identified, and other experiments, such as diet, drug and exercise studies.

Are there different types of informed consent? What are they? The informed consent process can take on various forms:

- Signed informed consent is the standard expectation in research with human participants. This is in the form of a document with the elements of informed consent, signed and dated by the participant and kept as a record by the researcher.
- In research with children (individuals under 18 years old), assent of the child and parental permission are standard requirements.
- In some circumstances, investigators can seek alternatives to standard informed consent procedures, such as:
    - A waiver of using a signed consent form (e.g., giving participants an information sheet but not collecting signatures)
    - A waiver of written consent (e.g., using oral consent procedures)
    - A waiver of some or all of the elements of informed consent (e.g., in research that involves deception)

Do I always have to obtain written permission from parents for children to participate?
No. There are two sets of circumstances where the IRB may waive the requirement for parental permission:
The first involves research or demonstration projects that

- Are conducted by or subject to the approval of state or local government officials and are 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
- Could not practicably be carried out without the waiver or

alteration. The second involves research that

- Poses no more than minimal risk to the children;
- Would not adversely affect the rights and welfare of children if the IRB approved a waiver or alteration of the requirement for parental permission;
- Could not be carried out without the waiver or alteration; and
- Whenever appropriate, would provide the children with additional pertinent information after participation.

I am not collecting any identifying information. Do I still need an informed consent form?
Yes. If the proposed study is truly "anonymous" - no coding for identifiers (e.g., names, social security numbers, drivers license numbers, etc.), a modified informed consent form (often called an information sheet) may be used. That is, all of the elements of consent must be documented for the participant, but the signature line is replaced with a statement informing the participant that completion and return of the survey is considered implied consent.

How is the consent process handled for Internet-Based research? For Internet-based surveys, it is sometimes appropriate to use implied informed consent. Participants would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey. If, for study design purposes, the researcher needs to keep track of who participated or if the IRB determines that some sort of documented consent is required, instead of "signed" informed consent, the researcher may email the consent form to participants who may then type their name and the date into the spaces provided on the consent form, and return it to the researcher via email. This process may be appropriate for data collected via email, chat rooms, online interviews, etc. Alternatively, some Internet-based survey vendors and/or software packages provide a means to record whether a respondent has consented to participate before beginning a survey (e.g., a date/time stamp feature).

What are the IRB requirements for training? At Chaminade University, all investigators and research staff much successfully complete the CITI Program for training in the ethical conduct of research with human participants and update it at least once every five years. Additionally, investigators and research staff must be qualified by training and experience for the research they will be conducting. It is important to understand that the responsibility for the welfare of participants lies with the principal investigator, even when participants have given consent. Investigators and research staff must have the necessary training and expertise to

- Ensure the rights, welfare and safety of participants are protected

- Comply with regulations concerning IRB review and approval, including
- Informed consent requirements
- Reporting requirements
- Maintenance and retention of records (keep complete files during and 5 years after research ends)
- Supervise research conduct
- Apply relevant professional standards that are applicable to the research

Who is required to complete the human participants training? All faculty, students, and staff proposing to use human participants in research under the auspices of Chaminade University are required to complete the human participants training.

How can I take the required training? Online, consult the IRB Chair for details.

When should a modification (amendment) to an approved research study be submitted? Any and all changes to an approved research study must be submitted for review and approval prior to implementing the change(s) into the research study. Investigators with approved projects must submit an Amendment application if there are significant changes involving any of the study protocols, study design, informed consent procedures, or principal investigator team. The administrator and chair of IRB review all amendment applications, and assign them to either expedited or full committee review.

Does approval of an amendment to an approved research study extend the original approval date? No. The expiration date of the original approval is not changed by the review and approval of an amendment.

After my approved protocol has passed the one year expiration date what do I do? If IRB approval of the human research expires, all study procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information. Continuing human research procedures is a violation of federal regulations. You need to receive continued approval from the IRB in order to continue research.

How do I obtain continued approval (renewal) for my research study? It is the responsibility of the principal investigator (PI) to ensure continued approval of his or her human participant research study.

In the case of a potential unanticipated problem involving risks to participants or others, when is the principal investigator expected to report this occurrence to the IRB? Serious adverse events must be reported to the IRB immediately, with a written report by the PI following within 24 hours of the PI's becoming aware of the event. Serious adverse events are (1) death of a research participant; or (2) serious injury to a research participant. All other non-serious unanticipated problems should be reported to the IRB within 2 weeks of the first awareness of the problem by the Protocol PI or another researcher.

Can the IRB temporarily or permanently discontinue a research project as result of an unanticipated problem involving risks to participants or others Yes. If an unanticipated

problem poses a risk(s) to the participants or others, the IRB may temporarily discontinue a research project until a thorough investigation has been conducted.

Can the IRB request revisions to the approved research study and the informed consent form as a result of an unanticipated problem Yes. As a result of the IRB's investigation of the unanticipated problem, revisions to the approved research study and the informed consent form may be requested.

Does Your Project Constitute Human Subjects Research? Decision Tree

Will you, a member of your research team or a collaborator observe, interact with, or intervene with individuals to gather information that will be used for research? Examples:

- Surveys, questionnaires, focus groups, interviews
- Games, experiments in physical or in electronic environments
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures
- Diet, nutrition studies, taste tests
- Studies examining effectiveness of educational tools or curricula
- Use of instruments or devices, including phones, to collect data or monitor or influence behavior
- Passive observation of public behavior (in physical or online environments, including social media)
- Studies examining individuals' responses to manipulation of their physical or online environment
- Another activity that involves observation of, or interaction with, individuals to gather information for research

NO, research will use only existing data

YES

Is the information being collected 'about' individuals?

NO

The focus of the project is only on products, methods, policies, procedures, organizations: e.g., interviewing transportation staff and officials about parking or transportation policies and procedures.

Consult with IRB chair, see next page

YES

The focus of the project is on people or their opinions, perceptions, choices, decisions regarding themselves or how methods, policies, procedures, organizations etc. affect them or their environment.

Not human participant research.IRB will issue a determination letter

YES

Is this a **class project**?

YES

Is the sole intent of the project to meet course requirements, with **no intention to use the results for something other than the course assignment?**

NO

The project ma lead to use of t results outside the course (e.g., a publication presentation, the or dissertation

NO

Is the project an **oral history, ethnographic, or journalistic piece**?

YES

Does the project involve stories that will or may draw broad conclusions about the population, cultures, norms and practices; even if no research hypothesis is being tested or validated?

NO

Published materials will be limited to only documenting or reporting on events, situations, policies, institutions or systems without the intent to form hypotheses, draw conclusions, or generalize findings.

Not human participant research. IRB will issue a determination letter

NO

Is this a **quality assurance/quality improvement/organizational effectiveness study**? I.e. to assess, improve, or develop programs or services for an organization?

YES

Will outcomes be generalized for other organizations, programs or services?

NO

Outcomes will remain specific to the organization, programs or services, although other organizations may use the results for their own programs.

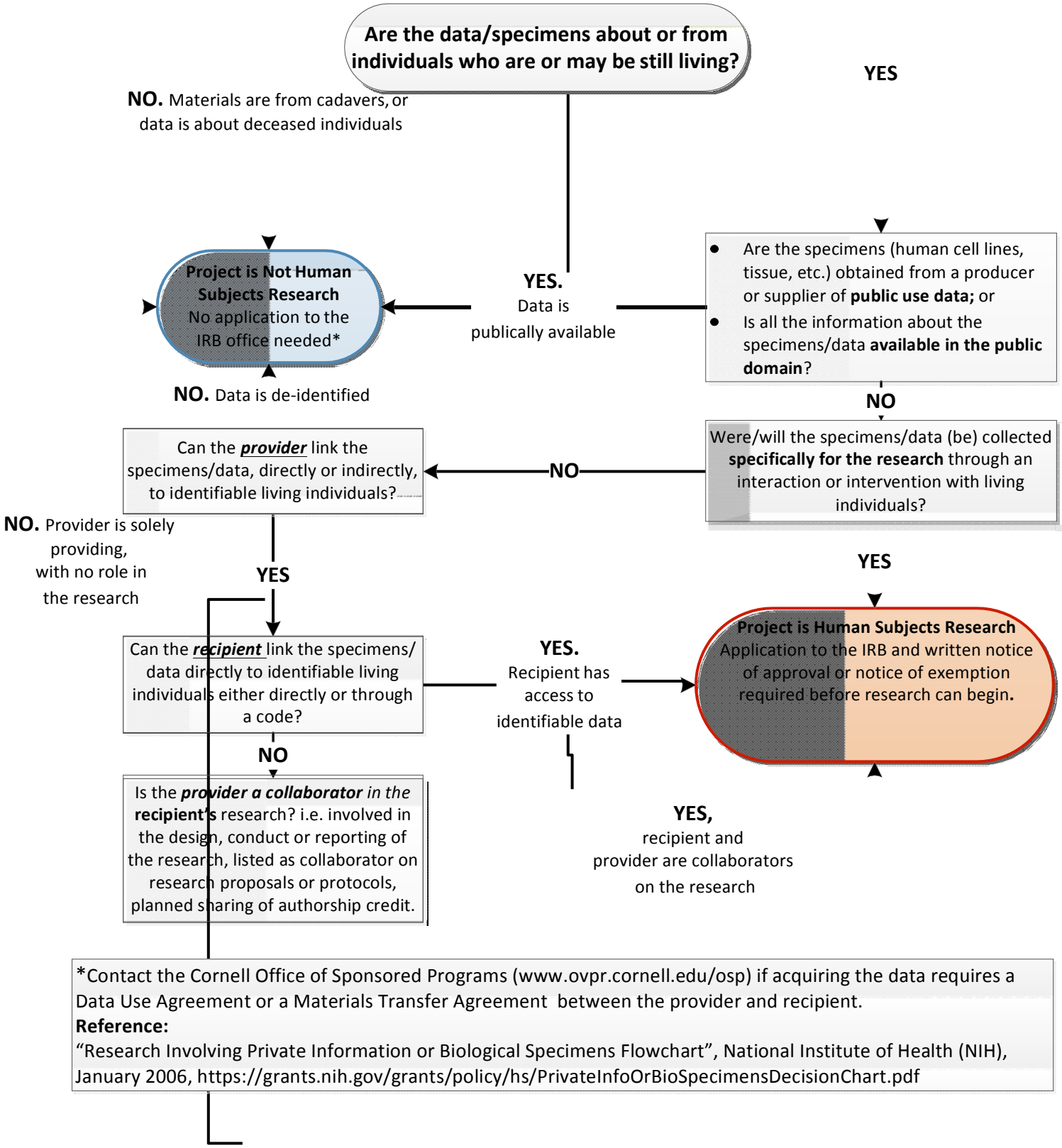
YES

YES

NO

Project is research with human subjects.
An application to the IRB and written notice of approval required before the study can begin.

Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require Review by the IRB ?



*Contact the Cornell Office of Sponsored Programs (www.ovpr.cornell.edu/osp) if acquiring the data requires a Data Use Agreement or a Materials Transfer Agreement between the provider and recipient.

Reference:

"Research Involving Private Information or Biological Specimens Flowchart", National Institute of Health (NIH), January 2006, https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf