IRB Process Flow Chart (can only occur prior to initiation of research)

IRB Coordinator

- IRB Review: Complete Protocol Required
  - Expedited (one reviewer)
  - Full (all reviewers)
  - Revisions or resubmits as requested by IRB
  - AVP Pam Stacks grants final approval
  - PI is notified of approval; valid for 1 year from approval date

- Exempt Registration: Complete Protocol Required
  - IRB coordinator
  - Revisions or resubmits as requested by IRB coordinator
  - AVP Pam Stacks grants final approval
  - PI is notified of approval; valid for 1 year from approval date

- Extensions and Addendums to Approved IRB Protocol:
  - IRB coordinator or IRB Reviewer
  - Revisions or resubmits as requested by IRB coordinator or IRB Reviewer
  - AVP Pam Stacks grants final approval
  - PI is notified of approval; valid for 1 year from approval date

Registration (acknowledgement that documents were received):
IRB coordinator

- Pending grant. Submit Intent to Conduct Human Subjects Research Form. Standard screening for IRB review or exemption takes place once PI submits a complete IRB protocol. **SJSU approval required** prior to initiation of research.

- IRB approval obtained from outside institution for involvement of SJSU investigator. Submit a copy of the IRB approval, a complete copy of the approved protocol, and the Intent to Conduct Human Subjects Research Form. SJSU IRB approval not required.

- IRB approval obtained from outside institution for outside investigator conducting research at SJSU. Submit a copy of the IRB approval, a complete copy of the approved protocol, and the Intent to Conduct Human Subjects Research Form. SJSU IRB approval not required.

Notifications of registration are issued by the IRB coordinator; such notifications are **not** an indication that the protocol has been reviewed or approved by the SJSU IRB or that the protocol qualifies for exemption.
Flowchart Used by IRB Coordinator for Determining Type of Review

- **Are the activities research?** Research is a systematic investigation designed to develop or contribute to generalizable knowledge, including the dissemination of research findings beyond the boundaries of the institution (e.g., publication - including a thesis or dissertation - or presentation or use outside the specific instructional setting)

- **Do the activities involve human subjects?** Research is considered to involve human subjects if it involves individuals about whom an investigator obtains data through intervention or interaction, or if an investigator obtains identifiable, private information about an individual through a third party.

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**Yes to both:**
- Does the research pose only minimal risk to participants?
- Does the research involve subjects that are **not** considered a vulnerable group (minors, prisoners, pregnant women, human fetuses, individuals who are cognitively impaired)?
- Does the research fit into at least one of the categories of exemption? *

**No to either:**
Submission of an IRB protocol is not required. SJSU IRB approval or registration of activities with the Office of Research is not required.

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**Yes to all of the above:**
A complete IRB protocol is required, but is not reviewed by the IRB. The protocol is registered as “exempt” by the AVP of the Office of Research. The investigator must wait for confirmation of exempt status before involving human subjects in research.

**No to any one of the above:**
A complete IRB protocol is required, and is sent to the IRB for review and approval. The investigator must obtain IRB approval before involving human subjects in research.
* Categories of Exempt Research:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, including research on regular and special education instructional packages and comparisons among instructional techniques.

(2) Research involving the use of educational tests, survey procedures, or observation of public behavior, unless: information obtained is recorded in such a fashion that individuals can be identified and disclosure of the human subjects' responses outside the research could place the subjects at risk of criminal/civil liability and/or damage subjects' financial standing, employability, or reputation.

(3) (i) Research involving public officials or (ii) collection of personally identifiable information for which federal statutes require permanent confidentiality.

(4) Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if: these data sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

(5) Research and demonstration projects approved by public agency heads and designed to study, evaluate, or otherwise examine public benefit or service programs.

(6) Taste or food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or all ingredients are at or below safe levels set by the FDA.