Recommendations for Research Review of

Institutional Review Board (IRB) Cañada College

July 2015

Request: The PRIE office to review current IRB and establish a formal IRB at Cañada College.

Recommendation: PRIE to improve the current IRB review process, including creating new IRB review application, clear guidelines on consent form requirements, and IRB review timeline. At this time, PRIE has determined that there is no immediate need to register our IRB or apply for Federalwide Assurance (FWA).

Rationale: PRIE has determined that all research currently conducted at Cañada or research submitted for grant funding have been in the exempt category under federal regulation 45 CFR 46.101(b). In this category, research studies are exempt from the full regulations and policies regarding Human Subjects Research (45 CFR 46).

Does Cañada have an immediate need to apply for Federalwide Assurance (FWA)?

PRIE does not see an immediate need to apply for FWA.

Rationale: In recent years, Cañada has only had exempt research studies. Only institutions engaged in non-exempt research studies are required to have an FWA number. The FWA number has been requested (as optional) on grant applications that we have applied for. As far as we know, we have not not received a grant because of not providing a FWA number. If the need arises for Cañada to have a FWA number, we can further explore whether it is feasible for us to have a full IRB internally or contract the service to an external organization with a fully registered IRB.

Does Cañada have an immediate need to have a fully compliant IRB?

PRIE does not see an immediate need to register our IRB.

Rationale: In recent years, Cañada has only had exempt research studies. According to Department of Health and Human Services (HHS), overseer of IRB policy and assurances, IRBs overseeing non-exempt research studies must be registered with OHRP. All other IRBs may register voluntarily. An IRB that is registered with OHRP does not mean that the IRB is in compliant in meeting all FWA requirement. But, a registered IRB associated with an FWA must be fully compliant with meeting all IRB and FWA regulations for exempt and non-exempt research studies.

Does Cañada's current IRB have capacity to fully review and determine exempt or non-exempt status of a research study and ensure those exempt research studies are in compliance?

Yes, current PRIE office is confident in determining the IRB exemption status of a research study. Exempt studies do not require review by full IRB committee. Federal guideline suggests that someone, other than the principal investigator, should make that determination. Currently, in addition to PRIE office's determination of a research study's exempt status, Jim Butterfield at the district office, has validated PRIE's determination on one occasion.

Federal Regulation:

Health & Human Services (HHS) "regulations at 45 CFR 46.103(a) require that each institution engaged in human subjects research that is supported or conducted by HHS provide the Office on Human Research Protections with a satisfactory Assurance of Compliance to comply with the regulations, unless the research is exempt under 45 CFR 46.101(b)." Sources: http://www.hhs.gov/ohrp/assurances/forms/index.html

IRB Options:

Internal IRB	Registering IRB with OHPR	Obtaining Federalwide Assurance (FWA)	Third Party IRB review services
• Dean of PRIE and the PRIE analyst review all IRB requests. • PRIE has documented all exempt research studies it has reviewed and approved since 2014.	• First step before FWA application • Registered IRB doesn't mean it is in compliance or meets standards of required IRB membership and education as an IRB with FWA approval. • IRBs reviewing clinical investigations regulated by FDA, must register with OHRP • Other IRBs may register voluntarily • IRBs that meet FWA requirement: 5 person committee with specified requirements (i.e., no conflict of interest, person from outside the institution, scientific and non-scientific backgrounds) • Members list must be registered and updated when changes occur. • Members must have knowledge of both exempt and non-exempt IRB policies and regulations.	• Institutions engaged in non-exempt research must have FWA assurance. • Institutions may use third party IRBs and show written agreement between the institution and outside approved IRB when applying for FWA. • For reference: UC Davis's internal IRB currently charges its programs for any non-exempt reviews. Cost for initial review is $3,400 and each annual review is $1,600.	• An alternative to establishing a full internal IRB, Cañada may contract with an external IRBs (e.g., Schulman Associates IRB) to obtain FWA approval. Cost is to be determined.

Current information on IRB at Cañada:

https://www.canadacollege.edu/inside/research/research_learning/Canada%20IRB%20Procedures.pdf

https://www.canadacollege.edu/inside/research/research_learning/IRB%20PROTOCOL%20REVIEW%20STANDARDS_V2.pdf