ROSEMAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

September 2022

CERTIFICATION ANNOUNCEMENT

Ms. Colleen Takahashi

- Ms. Takahashi recently took the exam and has obtained the distinguished CIP credential!

- The Certified IRB Professional (CIP®) credential was developed in 1999 to promote ethical research practices and programs by ensuring that professionals charged with their administration have demonstrated an advanced level of knowledge, understanding, and experience. The CIP credential validates an individual's professional experience and mastery of the body of knowledge determined by national experts to be essential for competent HRPP (Human Research Protection Program) and IRB practices.

- Congratulations Ms. Takahashi, you make us Roseman proud!

Dr. Rachel Novak

- Dr. Novak is a Faculty member and Investigator with the College of Dental Medicine.

- Dr. Novak is the first Investigator at Roseman to earn the title of Certified Human Subjects Research Specialist in Exempt Category II.

- In order to earn this certificate, Dr. Novak met all qualifications (see below) required for an Investigator at Roseman University of Health Sciences.

- Way to represent that Roadrunner spirit, Dr. Novak!

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CERTIFIED HSR SPECIALIST REQUIREMENTS

- Receive approval or an exempt determination on three protocols during academic year 2022-23 in which the Roseman IRB is the IRB of record
- Receive approval or an exempt determination with less than two revisions on one of the above discussed protocols
- Attend one of the Investigator Training seminars during 2022-23 academic year
- Successfully pass 2 IRB Bulletin Quizzes

DEFINITION OVERVIEW

Non-HSR (Non-Human Subjects Research)

- Some studies meet the definition of 'research' according to federal regulations but they don't meet the definition of 'human subjects' according to federal regulations.
- Other studies meet the definition of 'human subjects' but not 'research' (Ex: quality improvement projects)
- These studies are determined to be non-HSR and DO NOT fall under the purview of the IRB.
- Investigators may not make the determination that their study is non-HSR; many journals require that the IRB make this determination.
- If the IRB determines a study is non-HSR, the research team SHOULD NOT use any IRB documents in their research (consent cover letter, recruitment materials, etc.)

Exempt determination

- Although not intuitive, if the IRB determines that a study is 'Exempt', that study DOES meet the definition of HSR.
- The Exempt determination means the study is low risk or 'less than minimal risk' and certain requirements of HSR (like 2 reviews of the protocol) are waived. This allows for a faster review to be completed by the IRB.
- If the IRB determines a study to be 'Exempt', the research team SHOULD use IRB approved documents in their research.

Visit our FAQ page for more information at: https://research.roseman.edu/irb/institutional-review-board-faq/