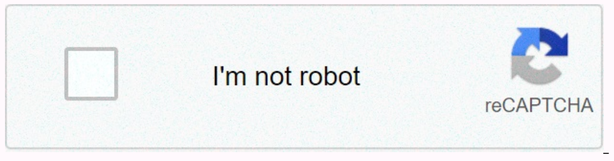

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Your rights protected. Your well-being is assured. I appreciate how quickly the IRB health sciences reviewed and approved our amendment to a large federally funded COVID-19 ECHO program with all nursing homes across the country. Effective HRPO support helps us meet a very aggressive schedule and, even better, be able to serve nursing homes better. — Nancy Hood, PhD, MPH, Director of Research and Evaluation, ECHO Institute, UNM Health Sciences 1000+ Active Studies Two weeks average time for IRB 2005 approval accredited by AAHRPP All human research conducted by UNM Health Sciences Faculty, students, and staff must be reviewed by the UNM Health Sciences Institutional Review Board – IRB (aka Human Research Review Committee – HRRC) and approved to comply with regulatory and ethical requirements before it can be undertaken (unless the IRB determines that activity is excluded from IRB review review). Principal Investigator Study Member Group Required Training PI Eligibility To serve as principal investigator (PI) in a human research study submitted to the Human Research Examination Committee (HRRC) should be a contract (paid) UNM HSC faculty member who is: .50 FTE or longer track term or non-term piece Researcher, clinical educator or lecturer Examples of positions that are not eligible to serve as Principal Investigator at UNM HSC: Complementary School Visit School Volunteer Professors Postdoctoral Students without an academic title letter In special cases (not mentioned above) and with support from the dean or chair of the department, other members of the HSC community may seek approval to serve as Principal Investigator with the support of a dean or department chair. PI must complete the PI eligibility application form. The completed request should be sent to HRPO@salud.unm.edu reviewed by the Vice-Chancellor for Research. Hrrc identifies a principal investigator for each project. The principal investigator is ultimately responsible for ensuring that the conduct of the study complies with all UNM HMRC HRC policies and procedures for the protection of human beings. Where the principal investigator for clinical studies involving medical/clinical interventions or research agents does not have a medical degree, there must be at least one co-investigator in the project who is a qualified, licensed healthcare provider. Responsibilities Design and implementation of ethical research, in accordance with the three ethical principles outlined in the Belmont report. Comply with all applicable federal regulations affecting the human beings. Make sure that all investigations involving human subjects are submitted and approved by the relevant HRRC. Comply with all applicable HRRC policies, procedures, decisions, terms and requirements. Implementation of the survey as approved and obtaining HRRC approval for Obtain informed consent and assent in accordance with federal regulations and as approved by hrrc. Document with informed consent and assent in accordance with federal regulations and as approved by hrrc. Report the progress of the approved hrrc investigation as often as and in the manner specified by hrrc. Report to HRRC any injuries, side effects or other unforeseen problems that pose risks to individuals and others. Keep signed HRRC consent documents and research records for at least three years after completion of the research activity. The HHS regulations in 45 CFR part 46 use the term researcher to refer to an individual performing various tasks related to conducting human-related research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of HHS regulations, OHRP interprets a researcher to be any individual involved in conducting human-related research studies. This participation will include: obtaining information on living persons by intervening or interacting with them for research purposes; obtaining identifiable private information on living persons for research purposes; obtaining voluntary informed consent of the persons to be investigated; and the study, interpretation or analysis of identifiable private information or data for research purposes. Researchers can include doctors, scientists, nurses, administrative staff, teachers and students, among others. Some research studies are conducted by more than one researcher, and usually a researcher is designated the principal investigator with overall responsibilities for the study. In each human research study, researchers have certain responsibilities regarding the moral treatment of human beings. CITI Training THE UNM HSC requires initial and continuous training (every 3 years) to protect participants in human research for individuals involved in conducting or supervising human research. UNM HSC endorses the Collaborative Institutional Training Initiative (CITI) established and managed by the University of Miami for Human Protection Education. All members of the research team involved in the design, conduct or reporting of the survey must complete the training. Members of the research team who have not completed training in the protection of human research may not participate in aspects of human research. For each new survey submission received, verification will be carried out during hrrc & Pre-Review that the applicable educational requirements have been met and are current for all staff members of the research study. If the educational requirements are incomplete or do not exist for any member of the study staff, the submission will be returned and must be resubmitted as soon as the requirements are met. HRRC approval will not be granted for proposed research in which researchers have not completed training to protect human research. Step 1. Create an account in citiprogram.org and link your account to the University of New Mexico Center for Health Sciences. Step 2. Choose one of the following groups: Group 1 Biomedical Research Researcher or Group 2 Social & Behavioral Research Researchers Step 3. Complete the course View a list of people who have completed CITI training to train the Huron IRB system and the IRB account request To access the Huron IRB submission system, you must complete the self-directed training and submit an IRB account request. You can access the training and account request at UNM LearningCentral, HSC 115-001 or use the following links: If you report as a principal investigator in a study and meet the criteria to be a PI in UNM Health Sciences, contact HRPO to request the Principal Investigator role to be added to your account. Allow 1-2 working days to be processed for your account request. An IRB account administrator will send you an email containing your login information, website address, and instructions. COI Training and COI Account Request Two courses must be completed in order to activate a COI account click: Electronic Research Administration: COI Notification (HSC 001) HSC Financial Conflict of Interest Training (HSC 104-002) Must be renewed every 4 years Courses are located: UNSC (HSC, main campus, UNMH & AMP; UNMMG) faculty, staff and students take courses at Learning Central Non-UNM unveiling and those who do not have a learning central account receive the courses in moodle as part of the course category, financial conflicts of interest of the EIA. View list of people who have completed FCOI training (HSC 104-002) IRB submissions IRB review and determination pay levels review committee Rapid Exempt Decisions Approved Approved Deferred Suspension/Termination The fees HRPO charges for reviewing the investigation unless the PI is a member of the UNM HSC staff and any of the following apply: The project receives no monetary support from any external entity. The project is supported by a federal or state grant or contract awarded directly to UNM HSC and the grant or contract includes facilities and management costs (FandA). The project is a sub-assignment to THE UNM HSC and the sub-assignment includes the flow of facilities and administration costs (F& A) by a federal or state agency. The project receives financial support from a non-profit organisation, such as an institution, and receives no other form of industry support. The project receives support from an industry sponsor limited to providing a drug or device (without monetary support). Researchers must complete the IRB fee identification form with each submission. This will guide the researcher in determining whether the fees are due. New study review: $2,500 Continuous Review: $1000 Amendment: $500 IRB Fees for Pharmaceutical Clinical Trials In an effort to reduce the time it takes to process IRB payments and improve efficiency in IRB payment collections, UNMHSC is establishing a new policy on the pricing of IRB fees for pharmaceutical clinical trials. From 1 January 2018 , all budgets for pharmaceutical clinical trials must include all applicable IRB fees in their direct costs. Read Note Review Fees for Non-UNM HSC Research The UNM Health Sciences IRB does not typically provide IRB review for studies conducted by non-UNM HSC entities or researchers. In some cases, the UNM Health Sciences IRB will serve as the IRB for a non-UNM HSC project when there is a clear cooperation agreement with UNM HSC, involving a UNM HSC staff member and the study is conducted in accordance with the investigator's manual – serving as the IRB for an unrelated entity. Review fees for non-UNM HSC studies/researchers follow the fee schedule listed above. Exemption from fees for the review In some cases UNM Health Science IRB will waive the required fees. To request discharge, attach the following to your submission (new study or ongoing review): Memorandum requesting resignation - in the memorandum specify why you are requesting resignation. Detailed budget that provides support to your reminder that there are no funds available for review fees. Please be aware that it is the investigator's responsibility to include IRB review fees in their budget when requesting money from a Any questions about fees can be addressed to HRPO. Please have the name of the PI, the title of the study and the IRB number, if it has been created. Refund of review fees If you submit a study that requires a fee and is withdrawn by PI or sponsor: If the submission has gone through the pre-review process we can only refund 50% ($1,000 ($1,000) remuneration). Once the IRB approval is issued, no refunds will be granted. Huron IRB submission system UNM Heath Sciences uses Huron IRB to process applications for IRB review (e.g., new studies, modifications, continuous revisions, and reported new information). Review of Huron IRB 8.2 self-directed education for researchers: Overview of Huron IRB in the core activities of UNM Health Sciences, Navigation and Workplaces Walk-through a new study submitting IRB submission assistance and Huron IRB support Levels review committee Rapid Exempt Identified Modifications Required Deferred Rejection/Termination HRPO fees charge for reviewing the survey unless the PI is a member of the UNM HSC staff and any of the following apply: The project receives no monetary support from any external entity. The project is supported by a federal or state grant or contract awarded directly to UNM HSC and the grant or contract includes facilities and management costs (FandA). 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