



COMPLIANCE TIP

Do you need to make a protocol change on a study that's currently ongoing? Many researchers know that submitting ARIA's protocol modification form to the IRB is part of the protocol amendment process. However, that form alone is not all that's needed. If you're changing your protocol, you must update the actual protocol document as well. Submit the updated protocol, with the changes marked, to the IRB along with the PI signed protocol modification form in order to trigger IRB review. If your protocol changes affect your informed consent form,

remember to upload a new consent form with the changes marked as well. Lastly, remember that the IRB must approve all protocol changes before they're implemented, so get IRB approval before you change your study activities. The only exception to that is a change that eliminates an apparent immediate hazard to subjects. That type of change can be implemented without prior IRB approval, but the IRB must be notified about it immediately. For more information, call the Research Compliance office at 686-8062 or 526-6270.

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The following job ad for a Clinical Research Coordinator position may be satirically exaggerated, but only slightly. In fact, CRCs routinely perform 99% of these tasks during a regular workday.

The Human Research Education Program in the Office of Research Compliance is here to help. We can't bend the space-time continuum, but we can give you the tools and information you need to be an effective CRC.

For more information, check out our website at <http://www.uams.edu/orc/home.htm>, or call the Research Education Manager, Kate Henning PhD, at 526-6879.

Study Coordinator Wanted

A challenging position is open for a qualified study coordinator.

Do not miss this opportunity!

Applicants must possess the following personal attributes: accurate, active, adaptable, agreeable, alert, analytical, articulate, assertive, attentive, aware, broadminded, businesslike, calm, capable, careful, cheerful, clear-thinking, compassionate, confident, conscientious, considerate, consistent, constructive, cooperative, creative, credulous, curious, decisive, dedicated, deliberate, dependable, desperate, detail-oriented, determined, diligent, discreet, efficient, empathetic, energetic, ethical, fair-minded, flexible, focused, foolhardy, friendly, good-natured, hallucinatory, hard-working, healthy, helpful, honest, illusory, imaginative, independent, industrious, intelligent, intuitive, inventive, kind, knowledgeable, level-headed, likable, logical, meticulous, motivated, observant, openminded, optimistic, organized, outgoing, patient, perseverant, personable, persuasive, pleasant, poised, polite, practical, precise, principled, productive, professional, proficient, prudent, punctual, rational, realistic, reflective, reliable, resilient, resourceful, respectful, responsible, responsive, self-directed, sensible, sensitive, serious, sincere, sociable, stable, supportive, sympathetic, tactful, team player, tenacious, thorough, thoughtful, tolerant, trustworthy, unaffected, understanding, unhinged, versatile, warm, well-connected, and well-informed. In addition, applicants must be a good listener, a problem solver, a quick learner, able to multitask (preferably in two or more places at once), accepting of constructive criticism, concerned for others, a critical thinker, able to handle conflicts well, hold self to high standards, negotiate effectively, take initiative, and possess integrity, a good sense of humor, common sense, fluency in local Unanga language, and excellent communication, interpersonal and mind-reading skills.

Applicants must be experienced in clinical research, with expert knowledge of good clinical practice, including current governmental regulations and guidances, International Conference on Harmonization (ICH) guidelines, and the Shen-nung Pen Ts'ao Ching.

Applicants must have physician, nurse and/or allied health professional credentials.

Required certifications include CCRC (Certified Clinical Research Coordinator), CCRP (Certified Clinical Research Professional), RAC (Regulatory Affairs Certification), and SPC (Shamanic Practitioner Certification).

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In addition, CPR, first aid, phlebotomy, hazardous materials handling, universal precautions, and site SOP certifications are required. Applicants must have experience conducting clinical trials in the therapeutic areas of cardiology, dermatology, endocrinology, gastroenterology, gynecology, hematology, hepatology, immunology, infectious disease, neurology, oncology, ophthalmology, orthopedics, psychiatry, pulmonology, reanimation, rheumatology and urology.

Applicants must be proficient in the following responsibilities:

- Ensure the safety and welfare of study subjects.
- Conduct clinical studies according to governmental regulations and guidelines, International Conference on Harmonization (ICH) regulations, GCP guidelines, and site SOPs and other policies and procedures.
- Read, understand and implement protocols, informed consent forms, investigator's brochures, and other study instructions.
- Prepare IRB submission materials.
- Attend investigator meetings.
- Document special requirements for the study, e.g., manner of measuring blood pressure or entering data in source documents.
- Train other site personnel and other medical staff in understanding and implementing protocols.
- Develop and implement plan to recruit subjects for the study.
- Materialize subjects from air at sea level with high humidity.
- Screen and enroll subjects according the protocol's eligibility criteria.
- Obtain informed consent from study subjects, with participation of Principal Investigator. Ensure that the original signed and dated informed consent form for each subject is filed correctly.
- Maintain a recruitment log detailing who was contacted for enrollment and why people declined to participate.
- Liaise between subjects and Principal Investigator.
- Develop and implement plan to retain subjects in the study.
- Ascertain the reason for premature withdrawal from the study by any subject.
- For subjects who drop out, (a) document their reason(s), if available, (b) record attempted contacts, and (c) obtain all follow-up information or document subject as "lost to follow-up."
- Ensure that Principal Investigator is available during study visits to perform required tasks.
- Maintain a screening & enrollment log.
- Maintain all other required documentation.
- Assign study numbers and randomize subjects.
- Schedule and conduct study visits.
- Document any deviations from the protocol.

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- Dispense medications and devices, educating subjects on their use.
- Maintain complete and accurate source documentation (any document, form or record where subject's data is first recorded).
- Maintain a complete and accurate CRF for each subject that records all observations and data during the study.
- Record and report all adverse events and serious adverse events to the Principal Investigator, sponsor and IRB, as appropriate.
- After obtaining written authorization from the subject, inform the subject's primary physician about the subject's enrollment and completion in the study, and any significant events.
- Document and explain any premature unblinding of the study drug.
- Maintain complete and accurate records of the receipt, dispensing, retrieval and return of all clinical supplies. Identify and document any discrepancies.
- Ensure that Principal Investigator reviews and signs required documents.
- Keep the Principal Investigator informed of study activities and any issues that may arise.
- Document substantive study-related conversations.
- Communicate with sponsor's representatives regarding study activities.
- Prepare for and host site selection, initiation, monitoring and close-out visits.
- Respond to data queries on a timely basis.
- Anticipate amendments to protocol.
- After close-out, inventory, organize and pack study materials for long-term storage. Destroy study materials properly, when appropriate.
- Supervise preparation for site visits from regulatory agencies by collecting and organizing all subject data pertinent to the inspection.

Attractive compensation based on local standards and benefits, including fresh salmon (seasonal) and subsidized kerosene. We are an equal opportunity employer.

Serious applicants meeting the above requirements are invited to apply in person by April 1, 2009 at:
Aleutian Institute of Clinical Research
1 Shipwreck Cove
Cape Wrangell, AK 99659

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IRB Submission Deadline Guidance

In order to ensure that the IRB meets the highest possible quality standards for the protection of the rights and welfare of all research subjects, strict review standards are in place for all submissions. To meet this objective the IRB has a standard turn-around processing time for all submissions it receives. All submissions, including full-board, expedited, exempt, determinations, modifications, adverse events, etc... have the same processing turn-around schedule. There are no rush categories and expedited does not mean faster turn-around. The deadline for submission is each Monday at 4:00 p.m. CST. The IRB Administrative staff has until Thursday at 4:00 p.m. CST to review the submission and issue a pre-review contingency letter if necessary. All pre-review contingencies must be addressed by the PI before the submission will be placed on an IRB agenda (lack of response to pre-review contingencies will delay turn-around time). Once the pre-review contingencies have been met or none exist, the submission will be assigned to an IRB reviewer and placed on the IRB agenda. The agenda is distributed to the IRB Committee on Monday and the reviewer will confirm their acceptance for the review by the next day. The reviewers have one week to review the submissions for the meeting to be prepared to discuss your submission on the following Tuesday. A letter from the IRB Chair or delegate will be sent to the PI and primary contact by the Friday following the meeting with one of the following decisions: approved, not yet approved major revisions required, not yet approved minor revisions required, Administrative Hold, or Declined.

Submission Example:

EVENT	DATE
Submission Received	Monday, May 4, 2009
Administrative Staff Review	Thursday, May 7, 2009
Administrative Staff assign reviewers	Friday, May 8, 2009
Distribute the agenda to the reviewers	Monday, May 11, 2009
Reviewers confirm the agenda and begin the review process	Tuesday, May 12, 2009
The IRB Meeting convenes	Tuesday, May 19, 2009
Letters from the IRB Chair or Delegate are sent to the PI and the Study Contact	Friday, May 22, 2009

This processing schedule does not in any way guarantee an approval by the IRB committee within a certain time frame. All contingencies must be met and a final approval letter received before the research study can begin.

In the event this is an emergency use exemption request, please follow the procedures outlined in IRB policy 18.3 for a drug or biologic and 18.4 for an unapproved medical device. These policies are located on the IRB website at http://www.uams.edu/irb/IRB_Policies.asp.

For the status of any of these submissions, please email irb@uams.edu and one of our IRB Administrators will respond to your request within one business day.

RESEARCH EDUCATION CLASSES

Validation of Processes and Procedures

Thursday, May 7, 2009 9:00 am-11 am

ED2 Building, 8th Floor, Room 121

Presented by Raymond Anderson, PhD

Associated Director UAMS Research Support Center

Research Education CRS 2 Contact Hours

Extreme Informed Consent Audio Conference: Eight Novel Ways to Improve the Process

Wednesday, May 13, 2009 1:00 pm-2:30 pm

CPH Building, Room G232

Audio Conference Presented By Thompson Interactive

Research Education CRS 2 Contact Hours

Bring your lunch, drinks will be provided

Writing Standard Operating Procedures (SOPs)

Wednesday, June 17, 2009 9:00 am-11 am

CPH Building, Room G232

Presented by Raymond Anderson, PhD

Associated Director UAMS RSC

Research Education CRS 2 Contact Hours



You can register for these course through [Training Tracker](#)
Call Kate Henning, PhD at 501-526-6879 for more information

New Video Clips of the Continuing Review Process in ARIA

On February 19, 2009 Jennifer Sharp Esq., the director of the Office of Research Compliance at the University of Arkansas for Medical Sciences (UAMS) presented "**Submitting Your Continuing Review in ARIA**". This presentation described the 13 steps of the Continuing Review submission process to the UAMS Institutional Review Board (IRB) via their software system ARIA. In order to make this program available to the researchers and staff on the ACH/ACHRI/UAMS campuses, the presentation was video-taped. This videotape was then broken down into smaller more "user-friendly" clips of no more than 10 minutes each.

See these video clips on the new ACHRI webpage at: <http://achri.archildrens.org/guidebook/ARIACRR.html>