



**Participant Clinical Interactive Resources
University of New Mexico
Health Sciences Center**

**PCIR
INVESTIGATOR'S
MANUAL**



**National Center for
Research Resources**

Credit on Publications: All publications that result from utilization of any of the PCIR resources should cite the grant as a contributing source of support and indicate the GCRC/PCIR grant number, HHS/PHS/NIH/NCRR/GCRC “Grant #5M01 RR000997”

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I. Mission Statement

The mission of the Participant Clinical Interactive Resources (PCIR) at the University of New Mexico Health Sciences Center is to provide an optimal setting for biomedical investigators to conduct safe, controlled, state-of-the-art clinical research in adults and children.

The PCIR is funded by the National Institutes of Health, specifically, the National Center for Research Resources, to facilitate scientific advances from the laboratory to patient care and ultimately to practice in the community. We are here to serve our volunteer research subjects, investigators, and the public. Providing infrastructure and resources to investigators, PCIR supports career development opportunities. Goals of the center are:

- Ensuring that PCIR research participants are treated safely and with respect and gratitude for their contributions.
- Facilitating medical advances through our diverse support services.
- Increasing the number of quality publications that are made available to the medical community with the outcome of better treatment standards
- Development of junior faculty to perform clinical research by providing them with mentorship

II. General Information

The PCIR facilitates the conduct of clinical research to help understand human physiology, translate basic research into patient care, and develop new therapies, ultimately to improve healthcare outcomes. This is accomplished through core support for the design, implementation, and analysis of clinical studies. Core support includes inpatient and outpatient research space, research nursing services, laboratory services, bionutrition services, informatics & biostatistics services, Research Participant Advocate (RPA), and funding support. The PCIR is committed to providing an environment that ensures state of the art training and mentorship for the next generation of clinical investigators through support of fellows, residents, and medical students. PCIR resources are available to all UNMHSC faculty, staff, and students.

a. *What types of studies can be done at PCIR?*

- Clinical and translational research are supported
- NIH funded research and pilot studies that may lead to future NIH or other sources of peer-reviewed clinical research grant support.
- IRB approved research [UNM HSC Human Research Review Committee](#)
- Those utilizing Biostatistical (data analysis) support only

b. *Who can be a PCIR principal investigator?*

- Must meet [HRRC criteria](#) to be a PI
- All biomedical research must include a UNM physician as one of the research team members

III. PCIR committees

a. *Administrative Committee*

The PCIR *Administrative Committee* consists of the program director, associate directors, and the PCIR administrative team members. This committee meets the second (2nd) Wednesday of each month to review

new studies and addendums to current research studies. The role of the PCIR administrative committee is to focus on the feasibility and resource utilization requests of the proposed research. Correspondence will be sent to the PI outlining approved PCIR resources. If there are any outstanding issues raised in this meeting, the management team will work with the investigator to resolve them prior to advisory committee review. The administrative committee also approves policies and procedures for the PCIR.

b. Advisory Committee

The **PCIR Advisory Committee (PAC)** supervises and reviews all operations of the PCIR. All research utilizing PCIR resources must have a data and safety monitoring plan (DSMP) and undergo PAC review. The PAC consists of 17 voting members, appointed by director of the CTSC Grant. This committee is responsible to the PCIR director. The advisory committee is composed of UNMHSC faculty members, who have a wide range of diverse expertise. They meet on the fourth (4th) Friday of each month and review new proposals as well as ongoing activity of current studies. New proposals are assigned to two primary reviewers who provide an in-depth written review, and also receive a review by the full advisory committee. During the advisory meeting, proposals are numerically scored on the basis of their scientific merit utilizing the NIH review process. Applications to the PAC are judged primarily on the quality of their science (delegating the feasibility and need for PCIR resources to the administrative committee). In all cases, NIH-funded clinical research is given preference. The investigator is responsible for presenting his/her proposed study to the committee with a power-point presentation addressing the purpose, background, methods, and request for PCIR resources (in a 5 to 7 minute presentation). Feedback from the committee is provided immediately to the investigator which is then followed up in writing in order to strengthen the research design in terms of validity and credibility. If the PAC has recommended revisions (as conditional to approval) to a proposal, the revision(s) must be submitted and approved by either the PAC chairman or one of the primary reviewers prior to approval of the research. In addition to reviewing new research projects, the PAC also reviews reports of activities of currently approved research (amendments, progress reports, and unanticipated problems involving risks to subjects or others).

IV. Services available at the PCIR

a. Inpatient Nursing Services

The inpatient nursing staff is trained to support projects through complex research observations and precise collections of specimen while providing exemplary subject care. The inpatient unit of the PCIR contains 4 beds (private or semi-private) and is located on 3 East and 5 East of the UNMH. One inpatient research room is equipped with a one-way mirror for observation. The nursing staff on the inpatient unit is trained in the special needs of caring for research participants. Some of the general nursing services available on the inpatient unit include:

- Initiation of new Protocols
 - Development of data collection forms
 - Development of standardized orders
- IV insertions
- Medication administration and infusions
- Capillary Blood Glucose/Glucose analyzer
- Single/Timed blood draws and other specimen collection
- Specimen processing and storage
- Performing EKG tracings and cardiac monitoring

- Pulse oximetry
- Continuous Pulse and BP Monitoring
- 24 hour nursing observation/monitoring/care
- Data collection and documentation

b. *Outpatient Nursing Services*

The outpatient nursing staff is trained to support projects through complex data and specimen collections while providing excellent participant care. The outpatient clinic of the PCIR is located just north of the 5 East inpatient unit of the UNMH. The clinic has conference room access, a private procedure area with 2 reclining chairs, limited exercise equipment, and 3 equipped exam rooms for conducting interviews, consenting participants, and performing any other research procedures requiring a private, quiet space. Some of the nursing services available in the outpatient clinic include:

- Initiation of new Protocols
 - Assistance with the development of data collection forms
 - Assistance with the development of standardized orders
- Assistance with recruitment and screening of participants
- Medication administration including infusions
 - Single/Timed blood draws and other specimen collections
 - Capillary Blood Glucose/Glucose analyzer
 - Pulse Oximetry
 - Performing EKG Tracings
 - Data collection and documentation
 - Offsite research activity

c. *Scatterbed – Neonatal/Pediatric Nursing services*

The scatterbed nursing staff is trained to support projects through complex data and specimen collections while providing excellent participant care. The neonatal/pediatric scatterbed nurses are experienced research nurses both with federally funded and industry sponsored clinical trials. Their offices are located on the 3rd floor of the Bill and Barbara Richardson Pavillion department of pediatrics. Some of the services provided through the PCIR scatterbed unit include:

- Initiation of new Protocols
 - Assistance with the development of data collection forms
 - Assistance with the development of standardized orders
- Assistance with recruitment and screening of participants
- Medication administration including infusions
- Single/Timed blood draws and other specimen collection
- Data collection and documentation
- Offsite research activity
- Assistance with regulatory documentation and submissions
- Providing study related information and education to parents and staff

d. *Laboratory*

The primary function of the University of New Mexico Clinical Translational Science Center Core Laboratory is to support peer-reviewed clinical investigation by providing the highest quality laboratory results and making these results available to investigators in a timely manner and in an interpretable format. The laboratory performs complex procedures to provide reliable, reproducible, and accurate analysis of research specimens for PCIR approved projects. The assay lab has been certified by the College of American Pathologists since 1983. The PCIR lab not only performs many [assays](#) on site, but also negotiates for competitive pricing of assays with outside laboratories for investigators.

The PCIR lab has the capability to develop or validate new laboratory analysis methods when 3 or more investigators are interested in utilizing the same assay. This should be discussed with the PCIR lab director and manager. Some of the services provided through the PCIR core laboratory include:

- *Specimen Processing Satellite Laboratory*

The specimen processing lab is located on 5 East in the UNMH which allows for rapid, efficient processing of bio-specimens that are collected on the inpatient unit and the outpatient clinic. Bio-specimen collection, processing, and storage procedures are determined in collaboration with investigators, based on the protocol requirements.

It is the responsibility of the PCIR Core Lab to ensure that a) sufficient quantities of blood are collected for the protocol assays, b) blood samples are collected in the correct tubes types, c) test tubes are correctly labeled with unique identifiers to maintain participant confidentiality, d) samples are properly inventoried in the PCIR Core Lab's computerized database, and e) samples are appropriately shipped to the correct outside laboratory when applicable.

The Core Laboratory can perform simple to complex specimen processing. Among the services we perform are blood, serum, plasma or urine aliquots and DNA and RNA isolation.

Bio-specimen processing includes several steps, including centrifugation, aliquoting, and ambient or cold storage (-20°C and -70°C). All CTSC laboratory refrigerators and freezers are equipped with centrally monitored alarm systems for accurate temperature control. The lab also has the capability to ship ambient or frozen specimens to outside laboratories if this has been approved by the PCIR advisory committee. The Core Lab does not provide long-term storage of samples once study closure has occurred.

The hours of operation for the processing lab are 7:00am to 4:00pm. Processing during off hours is arranged based on the specific requirements of the protocol.

- *Radioimmunoassay (RIA)/Special Chemistry/ELISA*

The PCIR core laboratory has developed over 30 different assays for investigators convenience. The factors impacting the selection of an assay not only include cost effectiveness, but also the availability of tests through send-outs to other laboratories.

- *Gas Chromatography/Mass Spectrometry Section*

Mass Spectrometry and Gas Chromatography are powerful and versatile analytical techniques that are currently used in the PCIR laboratory to analyze stable isotopes in tracer studies of metabolism. They may also be used to detect trace compounds in bio-specimens. By specializing in gas chromatography and mass spectroscopy, PCIR Core Laboratory encourages investigators to utilize stable isotopes as alternatives to radioactive tracers. These tracer techniques are non-radioactive and safe for clinical investigation, thereby facilitating IRB approval of protocols and reducing radioactive waste.

PCIR provides analysis of blood, urine, or sputum samples if at least one of the following criteria are met: a) the assay is not commercially available, e.g., d2-Glucose/d5-Glycerol, b) the cost of a commercial laboratory per sample is prohibitive and would prevent the investigator from pursuing his

or her investigation, e.g., stable isotopic tracers; and c) the assay requires specific manipulation of the sample not available commercially, e.g., immediate polyethylene glycol treatment to measure free insulin.

Core Lab Policies

Labeling Specimens - Bio-specimens must be received by the laboratory in an organized and understandable manner. All samples must be clearly labeled, accompanied by a spreadsheet or requisition listing the ample identification. It is the responsibility of the principal investigator to ensure that a HIPAA compliant unique identifier system is in place to assign study code numbers to individual participants. [REDCap](#) is one option for creating a unique identifier.

Inventory – It is the responsibility of the investigator or their research staff to provide the laboratory with a requisition or spreadsheet when delivering any specimens to the laboratory. Any samples that do not match the requisition/spreadsheet will be returned to the investigator.

Planning a new Study - Investigators requesting core laboratory resources are strongly encouraged to discuss experimental details with the laboratory manager prior to the beginning of a study to ensure that the PCIR Core Laboratory can meet study needs appropriately. Once a study has been fully approved and is ready to be initiated, it is imperative that the investigator meet with the laboratory to ensure that all details of specimen collection (i.e. what tubes are necessary for each assay) and processing have been communicated and are clearly understood.

Closing a Study – It is the responsibility of each investigator to check with the laboratory staff to ensure that all assays have been performed **prior to** closure of their protocol. Laboratory will be notified when each protocol has been officially closed with HRRC and CTSC. Once a study is officially closed, no further testing can take place and therefore, all biological specimens for that study will be discarded per laboratory procedure.

For Open Studies - As a courtesy, investigators will be notified by email that their specimens that have already been assayed are no longer viable and will be scheduled for disposal. PI will have 2 weeks from the time of the email to respond and if no response, it will be assumed by the lab, that specimens may be disposed of.

e. *Bionutrition*

The PCIR bionutrition area has both a metabolic kitchen and clinical nutrition staff providing scientifically controlled dietary regimens needed for inpatient, outpatient, and field settings. The bionutrition area is located on the 5 East inpatient unit in UNMH, and the kitchen is staffed seven days a week. All PCIR meals are prepared by the metabolic kitchen staff, independent of the UNMH kitchen.

The PCIR dietitians perform a variety of clinical nutrition services as well as body composition testing and indirect calorimetry measurements. Assistance is available to help set up the nutrition component of PCIR protocols, and to analyze nutrition/body composition data for publication. Some of the services available through the bionutrition unit include:

Metabolic Kitchen Services

- Regular meals and snacks
- Timed meals
- Nutrient-controlled diets and therapeutic diets (ADA, renal, etc.)
- In-house calorie counts
- Weighed diets (Ohaus electronic balances)
- Preparation of specialized foods/formulas
- Inpatient, outpatient and off-site meal service

Clinical Nutrition Services

- [Nutrition assessments](#)
- Diet instruction
- Exercise instruction
- Questionnaire Administration (i.e. activity questionnaires)
- Dietary and body composition analysis with transfer to spreadsheets/REDCAP
- [Nutrient intake assessment](#) (24 hr recall, food frequency, diet history, subject- kept food diaries)
- Computer analysis of intake
 - [FIAS Millennium 1.0 \(Food Intake Analysis System\)](#)
 - [Nutrition Data System for Research \(NDSR\)](#)
- Design of special diets for Metabolic Kitchen
- Dietary Supplement Data Collection
- Design nutrition component of protocols
- [Indirect Calorimetry](#)
- Anthropometric measurements/body composition (skinfold measurements, hip-waist ratio, others)
- [Bioelectrical impedance analysis](#)
- Exercise Testing/Monitoring
- Accelerometers
- [Dual Energy X-ray Absorptiometry \(DEXA\)](#)
 - [Patient Radiation Dose Exposure](#)

Important things to know

- For any research involving a dietary component, it is strongly recommended that the investigator consults with a bionutritionist for ways to strengthen the protocol design.
- It is important to remember that any dietary restrictions must be clearly stated in the procedure section of the consent form. Participants have been known to withdraw from a study because they were unaware of dietary restrictions imposed by the protocol.

f. *Biostatistics*

Biostatistical support is available to assist with protocol development, statistical design, protocol monitoring, statistical analysis, and publication of PCIR approved biomedical research projects. Statistical assistance should begin before protocol submission to the HRRC and the CTSC, but may also begin at other times in the research project. An investigator may also request Biostatistics Only assistance from the PCIR. Approval of such projects depends on the available resources, and a review of the science by the PCIR Advisory Committee. NIH sponsored protocols will be given priority in utilizing PCIR biostatistics resources.

The biostatistician offices are located on the first floor of the UNMHSC Multidisciplinary Research Facility (MRF) at 2307 Frontier N.E. Investigators utilizing the PCIR/CTSC biostatistical services may schedule an appointment by calling the administrative offices at 272-2366, making an appointment on [Groupwise](#), or stopping by and signing up on the biostatistician's clipboard for an appointment. Some of the services provided by the biostatisticians include:

- Statistical design of experiments (prospective or survey)
- Power analysis/determination of sample size
- Teaching/training in statistics
- Delineation of primary study objectives and specific research questions
- Assistance with methodology section of proposals and papers

- Assistance with randomization
- Proper statistical analysis of data
- Mathematical modeling
- Advice on presentation of data
- Assistance with results section of manuscripts
- Assistance with responses to reviewers
- Collaboration

It is best to consult with a biostatistician as early as possible in the process of protocol development. Statistician input facilitates study reliability and validity to help ensure appropriate outcome measures. This in turn enhances the probability of obtaining quality research results for publication.

g. *Bioinformatics*

The PCIR bioinformatics unit provides computer support, database design, and data management assistance in order to facilitate quality data collection. They implement the use of current technologies for optimal design of data management tools and methodologies. The bioinformatics offices are located on the first floor of the UNMHSC Multidisciplinary Research Facility (MRF) at 2307 Frontier N.E. Specific services they provide include:

- Design of databases
- Design of data entry and retrieval
- Teaching/training in computer applications
- Resource for PC hardware/software decisions
- Data conversions from a variety of computer platforms/software
- Computer connectivity to and from the GCRC
- Custom Application Development – creating computer programs to aid in data processing and data collection (i.e. create a form to determine eligibility by entering a height/weight and the program automatically calculates a BMI, after entering age the program can then look at percentiles, etc.).
- Assist with slide/poster presentation of results
- Assistance with powerpoint slides in preparation for initial PAC presentation ([Slide Guidelines](#))
- General resource for computing issues
- REDCAP – (Research Electronic Data CAPture) – web-based data management system (database)
 - *REDCAP Link Set-up* – strongly recommended tool to create your study link. Subject information is entered into the database by the PI, and a unique identifier code is automatically assigned to each subject. This tool allows for all involved PCIR staff to access the link which enables them to correctly label any data and specimens associated with each subject in the study. This tool facilitates appropriate and HIPAA compliant handling of subject data and specimens.
 - *REDCAP Data Management system* – This web-based database is used to house and manage the investigator’s research data. Data may be entered or downloaded from remote locations. This database provides access control, an audit trail, the ability to do blind double data entry, as well as other features. Investigator/Research team members enter data and a statistician can then transfer coded data into the appropriate statistical program for analysis.
- PCIR Website Posting Research – This is another tool to facilitate recruitment. All actively recruiting studies may be posted on the PCIR website (area where potential participants can search for enrolling research studies). The information that will be posted will be determined with the PI but may include:
 - HRRC Number

- Study Title
- Disease Condition
- Brief Description of study purpose/procedures
- Eligibility requirements
- Whether study is compensating
- PI's Name
- Contact Person
- Contact's Information (phone, email, etc.)

h. *Research Pharmacy*

The PCIR investigational drug pharmacy follows standardized procedures for the use of investigational drugs in humans that is in compliance with all applicable regulations governing the custody and distribution of investigational drugs. All research protocols utilizing drugs, biologics, or isotopes are under the oversight of UNMHSC Pharmacy Department. Working together with the research pharmacist helps to pro-actively avoid errors that may create safety issues, waste time, and waste resources. Points to keep in mind when using the PCIR research pharmacy are:

- First and foremost, it is the principal investigator's responsibility to meet with the research pharmacist to determine the details of how each protocol will be handled. To ensure that all drug-dispensing details are addressed, the research pharmacy should become involved early in the protocol planning process.
- Pharmacy charges do apply when medications are involved in the research, and funding should be requested in the initial PCIR budget worksheet. Charges that apply are:
 - Study Management Fee – this is a one time study start-up fee
 - Dispensing charge
 - Blinding/Compounding charge
 - Study medication(s) charges – investigators receive medications at the UNMH cost if the drug is not being obtained or provided by an outside source.
- If a study involves randomization, the research pharmacist will work with a biostatistician to create a randomization plan then ensure proper administration of the randomization plan.
- Prior to scheduling the first participant, it is the responsibility of the PI to:
 - Contact the research pharmacist in order to ensure that study drug is available.
 - Create a set of physician orders which clearly state all treatments that are to be administered during the research visit. The details of these orders should be developed (or at least reviewed) with the research pharmacist.
- Research participants should be instructed to bring in their routine medications from home to ensure uninterrupted therapy and to assess for any potential interactions with the research interventions or procedures.

i. *Research Participant Advocate (RPA)*

Under the guidance of the National Institutes of Health National Center for Research Resources (NCRR), this office is responsible for ensuring the safety and welfare of research participants during all phases of research activity including participant recruitment/enrollment, research intervention, follow-up, and data collection.

The RPA Office is staffed by professionals who have specialized training in bioethics, human subject research, and research subject safety. Accordingly, the RPA plays a lead role in the protection of human subjects at the University of New Mexico Health Sciences Center (UNMHSC) PCIR. The RPA Office works closely with the Human Research Protections Office (HRPO) to establish common rules that protect the safety of subjects participating in research at PCIR. The principal investigator is responsible for working with the RPA to develop a data safety monitoring plan (DSMP). The DSMP addresses the risk level of the research, appropriate level of monitoring, and proper reporting mechanisms for unanticipated problems involving risks to subjects or others.

The RPA office is responsible for:

- Reviewing all protocols prior to PCIR approval (to include an assessment of any COI that are present/perceived)
- Assisting the PI with [classifying risk level](#) of the research and determining the appropriate level of monitoring
- Guiding and advising PI in the development of a [Data Safety Monitoring Plan \(DSMP\)](#) and assistance with the set-up of a Data and Safety Monitoring Board (DSMB), when required. If required, a [DSMB Charter](#) must be submitted with the DSMP for review.
- Reviewing each DSMP for accuracy and completeness, and making recommendations to the PAC on the appropriateness of the DSMP.
- Performing audits of research when indicated, to ensure that the DSMP is fully complied with. The audit process helps to ensure compliance with all applicable regulations, and to identify any safety or documented data concerns. This activity may also include observation of the consent process.
- Working closely with the PAC, PCIR administration, and investigators to examine and resolve questions and problems as they arise during the conduct of the research.
- Maintaining up-to-date forms and links related to data safety monitoring on the PCIR website.
- Educating and training investigators and research staff in human subject research, good clinical practice (GCP), and utilization of the PCIR.
- Reviewing all unanticipated problems involving risks to subjects or others and making recommendations when necessary.

PCIR Recruitment Database – This tool was developed to facilitate recruitment in to PCIR research studies, and is fully compliant with the federal regulations. It is maintained by the RPA office. Once HRPO approval to use this method of recruitment is obtained by the PI, a written request (by memo or email), should be submitted to the RPA office, outlining what criteria the query should contain (e.g. healthy volunteers, Type II DM, age parameters, etc.). A written list of potential participants with their contact information will then be provided to the investigator.

Please contact the RPA office for assistance with:

- Development of a DSMP
- Identifying an appropriate independent monitor for your research
- Creating a DSMB for your research
- Questions about the submission process (new studies, progress reports, amendments, unanticipated problems, etc.) to the HRRC or the PCIR
- Accessing the PCIR recruitment database for a list of potential research participants
- Creating a regulatory binder or participant study binders for your PCIR study
- Learning how to set up tracking systems to work within good clinical research practices

j. *PCIR Administration*

The PCIR administrative office is located on the 5th floor of the UNMH, across from the service elevators close to the in-patient/out-patient units. Grant management for the PCIR is supported by the Program Director and the Program Manager. Administrative assistance for PCIR protocols includes:

- Investigator assistance with PCIR application process
- Budget development and administrative review of PCIR application
- Education of billing procedures, billing review, and adjustments when necessary
- Assistance with submission of addendums
- Facilitating smooth admission of inpatients when applicable

V. Resources Available at PCIR

a. *PCIR Equipment*

- 2 Mass Spectroscopy Instruments
- ACE – Chemistry Analyzer
- Bioelectrical Impedance Analyzer RJL Systems Quantum II
- Blood gas and metabolite/electrolyte analysis (ABL 735)
- Body Plethysmograph
- Centrifuges
- Chemiluminescent Instrument (Immulate)
- Crash Cart
- Cycle Ergometer (can use in conjunction with Metabolic Cart for exercise testing) Sensormedics
- DEXA GE Lunar DPX-NT
- Dietary Scales (weighs to the nearest 0.1Gm)
- EKG Monitor
- ELISA Plate Reader
- Flexible bronchoscopy
- Flexible endoscopy
- Freezers (-20°C, -80°C)
- Fume hood
- Harvard Dual Infusion Pump
- Heart rate monitors (for exercise testing)
- Metabolic Cart (for indirect calorimetry) Sensormedics VMax 29
- Pediatric/Adult Sphygmomanometer
- Pulmonary Function with Body Box
- Pulse Oximetry
- RT3 Accelerometers
- Telemetry
- Treadmill

b. *Ancillary Tests/Procedures*

Ancillary tests and procedures are defined as those that are not provided directly by the PCIR but are routinely available through UNMH and may still be considered for funding by the PCIR (i.e. MRI, U/S, medications). The PCIR supports some ancillary tests and procedures that are necessary for research purposes but which are outside of those provided by PCIR. PCIR support is not available for services covered by other grant funding, professional fees, lab work performed in the investigator's lab, or

experimental tests done in a research laboratory outside of the PCIR Core Lab. For more information on what ancillary tests are covered by PCIR, please contact the PCIR director or program manager.

c. *PCIR space for conducting research*

- Four (4) Inpatient Beds – private or semi-private
 - One room equipped with 1 way mirror for research requiring continuous observation
- Outpatient clinic
 - 3 Exam rooms equipped with examining tables
 - Procedure area with 2 reclining chairs
 - Conference room for consenting participants
 - Procedure room with DEXA scanner and Hood for Methacholine challenges
- Scatterbed facilities provided by the department of pediatrics in the hospital pavilion
 - Office space with locked storage/computers
 - Lab facility for minor processing with a phlebotomy chair

VI. Research Categories

The NCCR guidelines require that all PCIR research be classified into one of three categories. A general description of each category is given below, with the billing method used. Questions regarding these categories should be directed to the Program Director or the Program Manager.

Research Patients - Category 'A'

Research inpatient days or outpatient visits in investigator-initiated studies that are utilized solely for research purposes. All patient care costs are the responsibility of the CTSC grant and the investigator's research funds, with the exception of some Medicare Qualifying Clinical Trials (MQCT) that bill routine care charges.

Research Service Patients - Category 'B'

Research inpatient days or outpatient visits that involve patients admitted for diagnosis or treatment based on established standards of care. The PCIR and investigator are responsible for research-related charges, while non-research care is billed to a third party carrier or the patient. Billed by UNM to a third party payor or the patient, EXCEPT for research related charges, which are applied to the PCIR's or the investigator's research accounts before the bill is sent.

Industry-Sponsored Projects - Category 'D'

Inpatient days and outpatient visits utilized for an industry sponsored study. Charges are the responsibility of the investigator and the sponsor. PCIR approved resources are billed directly to the investigator's UNM research account for the industry supported study.

VII. Principal Investigator Responsibilities

a. *Submitting a New Study to PCIR*

- All forms and requirements for new submissions may be found on the [PCIR website](#)
- Prior to study submission, contact the administrative office to work out a proposed budget, the RPA office to develop a DSMP, and any other involved PCIR cores to help ensure a complete submission.

- All new proposals that are submitted to the PCIR will receive 2 reviews. First is an administrative review that looks at the resources requested and assesses feasibility. Second is the advisory review that looks at the scientific aims and design.
- A new study must be received by the last day of the month prior to the month it will be reviewed by the 2 committees. The study will be reviewed by the administrative committee on the 2nd Wednesday of the month, and if approved to move forward, will then be reviewed by the advisory committee on the 4th Friday of the month. For example, a study which is submitted by May 31 will be reviewed by the 2 PCIR committees in June.
- Applications may be submitted at any time during the IRB approval process. However, studies will not receive PCIR final approval until documentation of IRB approval is on file.
- Applications must be submitted by the last working day of the month in order to be reviewed by the two PCIR committees the following month.
- Completed application packets must be submitted electronically to gcr@salud.unm.edu
- Submit one paper copy of all documents that require a signature (i.e. PI, Pharmacist, etc.)
- Utilize the GCRC Application Submission Checklist to assure that the submission is complete. If the submission paperwork is incomplete, this could delay PCIR review.
- The administrative committee will notify the investigator in writing, once the proposal is reviewed by them. If the study is approved to go to advisory committee, the PI will be notified that they should prepare to present the proposal to the PAC at the end of the month. The [presentation guidelines](#) template will assist you with preparation of the presentation.

b. *Initiating a new study*

- Once all approval letters are obtained (i.e. HRRC, PCIR, etc.) a regulatory binder should be created if not done already. See section IXa for guidance.
- Create a [study link](#), order form(s) and data collection forms (it is recommended that investigators work with the bioinformatics staff to set these up in REDCAP).
- Investigators and their research team are encouraged to discuss protocol details with each core manager prior to the beginning of a study to ensure communication, that study needs can be met, and that all details of the protocol are clear.
- An investigator in-service is required - This is an extremely important step – PI must set up a meeting with all PCIR managers and staff who will be involved in the research and data collection. This process facilitates communication between staff, management, and investigators to ensure that all clarifications are made **prior to** the data collection process. This also provides an opportunity to discuss study procedures, lab techniques, supply needs, review orders and data collection forms for clarity, and to review procedures for labeling study data and specimens. The inservice should be scheduled by sending an email directly to all of the core managers of the departments involved (i.e. Inpatient unit director, Lab Manager, Bionutrition manager, Outpatient Manager).
- The PCIR has developed some preprinted [order sheet templates](#) to assist physicians in the admission process. The PI should prepare orders and a set of data collection forms (flow sheets) for the study. Orders should be written straight from the protocol and kept simple; outlining what is to be done by the staff (e.g. blood draws, frequency of vital signs, medication administration and physicians to be notified in case of emergency).
NOTE: If blood specimens are to be drawn, please include the type of tube in which the specimen should be drawn, and any special handling instructions. If special processing is needed,

- please provide specific instructions. Include which lab the specimens are to be sent to or will be picked up by PI or a designee. The Principal Investigator must sign a finalized copy of orders.
- Flow sheets can be created for studies when serial specimens are to be obtained, medications are to be given, or procedures are to be performed at very specific time points over the course of the patient's visit. A well-devised flow sheet will enable all staff to easily determine procedures at a glance. This minimizes the chance of errors and ensures that the study is run properly and clean data is collected.
 - New Study Start-up checklist
 - Create all data collection forms consistent with the protocol
 - Create order forms/[Outpatient Visit Log](#) consistent with the protocol
 - Create study participant aids – instruction sheets, calendars, and diaries consistent with the protocol
 - Create tracking logs (see [section IX d](#))
 - Create regulatory binder
 - Create study data binder(s)
 - Register study at clinicaltrials.gov (if applicable)

c. *Studies in progress*

- i. Study Continuations - It is the investigator's responsibility to see that all renewal paperwork is submitted to the PCIR electronic mailbox, gcr@salud.unm.edu prior to the study expiration date. Renewal documentation consists of:
 - HRRC/IRB Progress Report
 - HRRC/IRB Approval Letter
 - Approved consent form(s), assent form(s)
 - The version date should remain the same as the prior consent unless changes were made to the consent in which case the version date should be updated
 - The approved consent form(s) must have updated approval and expiration dates in the footer
 - Any monitoring reports that are required (DSMB, DSMC, or Independent Monitor reports [signed]) per the data and safety monitoring plan.
 - Any documents that were updated at the time of continuation (i.e. protocol, advertisements, changes to study investigators, etc.)
 - If the study was non-compliance closed, a reactivation report is also required
 - NOTE: If study is FDA regulated, an annual progress report must be submitted to FDA ([21CFR312.33](#))
- ii. Amendments – It is the investigator's responsibility to see that all amendments made to the research are submitted to the PCIR electronic mailbox, gcr@salud.unm.edu. Amendment documentation required is:
 - HRRC/IRB Amendment Request Form
 - HRRC/IRB Approval Letter
 - All documents that changes were made to with version dates updated (i.e. consent form, protocol, etc.)
 - NOTE: If study is FDA regulated, protocol amendments must be submitted to FDA ([21CFR312.30](#))
- iii. Addendums – It is the investigator's responsibility to complete an [addendum form](#) when making any changes to the requested resources from PCIR. Until formal documentation of

approval from PCIR is received by the PI, no changes may be made. If expedited approval is granted by the PCIR director prior to administrative committee review, the PI should have this in writing (email, memo, etc.) before change(s) is made.

iv. Reporting of Adverse Events and Unanticipated Problems – It is the investigator’s responsibility to submit reportable adverse events and unanticipated problems to gcr@salud.unm.edu and all appropriate entities according to their data and safety monitoring plan (DSMP). This may include reporting to one or more of the following:

- HRRC/IRB (See HRRC manual [section 8.2](#) for HRRC reporting criteria)
- FDA if a drug or device is involved ([21CFR312.32](#))
- Sponsor (pharmaceutical company, NIH, other funding organization)
- IHS or other tribal council
- VA Research Office
- Independent Monitor or DSMC/DSMB

d. *Closure of a PCIR study*

- If you are also closing the study at HRRC, submit your closure report and HRRC approval letter to close the study to gcr@salud.unm.edu
- If you are only closing the study at PCIR and are keeping the study open at HRRC, submit an email to gcr@salud.unm.edu explaining that PCIR resources are no longer needed.
- It is very important that the [NCR grant number](#) be acknowledged in your publication
- Record retention
 - 2 years post drug/device approval or study termination for FDA studies
 - 3 years after study closure for non-FDA studies
 - If sponsored study, must retain records per sponsor’s requirement.
 - For VA studies, records must be retained indefinitely. Contact VA research administration for further information.
- Study close out checklist
 - If using lab resources, contact the lab manager to determine disposition of any remaining specimens (prior to closure of study). If assays are still pending, they should be run prior to study closure.
 - All unused data collection forms and supplies should be discarded in a confidential manner
 - All study drug should be accounted for and returned (if applicable)
 - All data must be de-identified and the link to identifiers should be destroyed.
 - Study summary and closure report should be submitted to IRB (and sponsor if applicable).
 - All study documents should be archived in a secure location with provisions clearly stated for data storage (how and where records are being kept).
 - Ensure study is registered with PubMed

VIII. Research Study Visits

a. *Inpatient Study visits*

- 1) To schedule an inpatient study visit, submit the following to the PCIR administrative office at least 48 hours prior to the planned admission:
 - A completed [Request for Admission](#) form
 - A copy of the physician’s orders (dated with the date of admission)

- The data collection form (flow sheet)
 - A copy of the signed consent form
 - A copy of the signed HIPAA form
- 2) Contact the 5 East Charge Nurse at 272-2770 to check on space availability and to reserve an inpatient room. This will be documented by the charge nurse in the 5 East Black reservation book.
 - 3) The necessity for a private room is study specific (and not per participant preference). Please remind your study participants that a private room cannot be guaranteed. If the study does require a private room, be sure to communicate this to the charge nurse when scheduling the inpatient visit.
 - 4) Notify the PCIR administrative office and the 5 East Charge Nurse if you need to cancel the admission for any reason. This should be done ASAP to allow for room availability to other 5 East patients or research participants.
 - 5) Please note that admissions are scheduled on a first come, first serve basis. Admissions are scheduled based on resource availability (space, nursing, and lab or dietary personnel). When scheduling an admission, it's a good rule of thumb to have at least two dates in mind, in order to have some flexibility in scheduling inpatients for their admission.

Important Reminders for Inpatient admissions:

- **Prior Informed Consent** - Ensure that written informed consent was obtained prior to the 5 East admission
- **Medical History and Physical Exam** - All subjects admitted to the GCRC for participation in a research study should have documentation of a recent H & P on their *research chart* before the initiation of any research procedures. The H & P must have been obtained within 30 days prior to admission.
- **Physician Orders** - A set of study-specific research orders must be signed by the admitting physician and available on the chart before admission and before the initiation of any research procedures. Only an MD may admit participants to the PCIR inpatient unit.
- **Daily Visit Note** - All subjects must have a daily investigator visit note entered into the research chart for every 24 hours that they are on the PCIR inpatient unit. A note must be entered upon discharge describing the participant's response to any study drugs or tests administered, including a complete description of any adverse events and required treatments.
- **Inpatient Nurse's Responsibilities** - The inpatient nurse is responsible for:
 - Completing a Nursing Admission Assessment Form, medication record, and all other baseline documentation according to UNMH Nursing Policy, prior to initiation of any research study procedures
 - Document narrative observations on each research subject per physician's orders
 - Ensuring that all protocol-specific documents (i.e. study flow sheets/data collection forms) are labeled with the participant's study code number and completely and legibly filled out with black ink. Once the flow sheet(s) are completed, they are to be placed in the research drawer under the specific study folder for the investigator or research team to collect.
- **GCP Reference Binders** - There should be a set of the most current orders (with version date) available in the 5 East binder for each individual study using inpatient services. The RPA office creates these binders at study start-up and keeps them updated as changes occur. It is **imperative** that the PI send all updated documents to gcr@salud.unm.edu or the RPA office in order to ensure that the inpatient unit has the most current documents to work from. The binders contain a current protocol, all current consent documents, a current order form, and a current inpatient data collection form (flow sheet) for the nurse's reference.

- **Research Data** The de-identified research data must be collected by the investigator as soon as possible and locked up per protections put in place for confidentiality. This data should not be placed in the medical record unless it contains information that would be useful or helpful in future clinical care of the participant, it is entered onto a hospital approved form, AND it has been HRRC approved to be entered into the individual's medical record.
- **Participants with difficult IV access** The admitting physician may wish to write an order to specifically address the number of IV access attempts allowed if this number is no more than four (4). If no order is written with regard to the number of IV access attempts allowed, the nurse(s) will defer to the PCIR approved procedure when difficulty is encountered in establishing IV access. No more than 2 attempts by the same person and no more than a maximum of 4 needle sticks (by any combination of qualified healthcare professionals) will be made to establish IV access, assuming that the participant is in agreement with this. If four unsuccessful attempts have been made at establishing IV access, the PI will be notified for further guidance.

b. *Outpatient study visits*

Scheduling an outpatient visit

Participant visits are scheduled by contacting the outpatient group (nurses and administrative assistant) by email to [PCIR Outpatient Clinic](#) and providing the following information:

- HRRC Number
- Study Visit Number (i.e. screening, visit 4, etc.)
- Name of Participant
- Participant's Unique Identifier
- Date/Time that you are requesting to schedule the visit
- Completed [Outpatient Data Collection Sheet](#) (Demographic Form) at the time of the initial study visit. Please ensure all information is completely filled out (i.e. middle name, DOB, contact information).

Outpatient study visits are scheduled in the Groupwise shared calendar by the outpatient team. Please note that every effort is made to collaborate with investigators to accommodate their requests for specific times and space within the provisions of the outpatient staff.

Cancellations should be made by phone at 272-2451 or if no answer, please do not leave cancellation information on voice mail, but instead please email the [PCIR Outpatient Clinic](#) with the cancellation. To reschedule, please refer to the prior instructions.

Some studies (i.e. ICU studies, ER studies) may require immediate accessibility to the outpatient staff. In these situations, advance notice by the PI/research coordinator may not be feasible. In such cases, scheduling details should be arranged in advance with the Outpatient Clinic Manager; every effort will be made to accommodate the study visit contingent upon staff availability. These visits should be scheduled by calling 272-2451 and discussing with an outpatient staff member.

Research Records

In general, a study file is generated for each study participant. The study file includes a copy of the order form ([Outpatient Visit Log](#)). The investigator/research team is responsible for providing a copy of the current consent form and all applicable data collection forms for inclusion in the participant's study file. Please note

that an additional 3 copies of the consent form are required for each participant's study file (1 for participant, 1 for medical records, 1 for the PCIR, and the last copy is the investigator's copy).

A separate study folder for each investigator is also maintained in the Outpatient Clinic. Completed outpatient visit logs, data collection forms, and laboratory reports are filed in the investigator's study folder for pick-up at the PI's/Coordinator's convenience. All Investigators are responsible for maintaining their own research records. Please note that there is no storage space available in the PCIR outpatient clinic for investigator's data research files.

c. Scatterbed visits

Inpatient scatterbed visits are coordinated by the Scatterbed Nurse Manager on a daily basis as these participants are hospital inpatients. Daily screenings occur in order to identify potential participants for each PCIR study.

Outpatient and offsite scatterbed visits are scheduled directly through the study coordinator in collaboration with the PI and the site. Contact the study coordinator directly.

IX. Good Clinical Practice

a. Recordkeeping

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for conducting research. GCP standards are generally a requirement for pharmaceutical and federal cooperative group research. The Research Participant Advocate strongly encourages the use of GCP in all research that is performed at PCIR.

Organizing and filing of essential documents at your site can greatly assist you in the successful management of your research. The benefits to complying with GCP include but are not limited to:

- Producing "clean" data, thus increasing the likelihood of credible results
- Protecting subjects, the investigator, and UNMHSC
- Facilitating amendments and re-approvals of the research

All of the following documents may be subject to and should be available for audit by CTSC, HRRC, and all pertinent regulatory authorities.

1. ***Regulatory Document Binder*** - consists of the following documents, filed in reverse chronological order:

- i. All approved versions of the protocol or grant dated **with a version date**
- ii. All approved versions of the Data and Safety Monitoring Plan
- iii. All approved versions of the consent document(s)
- iv. The initial application and supporting documents (i.e. recruitment materials) with interim correspondence followed by HRRC approval letter
- v. All amendments with supporting documents and approval letters
- vi. All Progress/Closure Reports with approval letters
- vii. All Independent Monitor (IM) reports, Data and Safety Monitoring Board (DSMB)/Committee (DSMC) reports, or interim analysis reports.
- viii. All CTSC correspondence (initial approval, addendums, etc.)
- ix. Study Budget

- x. All signed agreements and correspondence with any sponsoring organizations (NIH, RAC, etc.)
- xi. Any other approvals that are required (IHS, tribal councils, HUS, COI committee, etc.)
- xii. All correspondence with regulatory authorities (i.e. IND/IDE documentation)
- xiii. All versions of the Investigator Brochure: (when applicable)
- xiv. A standard set of orders – all versions, if applicable (may be an appendix to the protocol)
- xv. A standard set of Data Collection Forms – all versions, if applicable (may be an appendix to the protocol)
- xvi. Miscellaneous – any other important documentation (i.e. FDA audit, publications that are pertinent to the research or that result from the research).
- xvii. Current CV's of all investigators and a record their of human subject protections training (optional).
- xviii. Investigational drug/device accountability logs (when applicable)

2. **Study data binder(s)** should also be created and may be separate for individual subjects or a complete binder for the entire study. This would depend on either the investigator's preference, or on the amount of data that is being collected from each subject. Data binders should consist of the following documents filed in reverse chronological order:

- i. Source documentation of eligibility criteria (unless it is available through powerchart)
- ii. Completed data collection forms labeled only with a study code number
- iii. Tracking log for non-reportable events showing assessment of all AE's that have occurred on the study. May have 1 for entire study or 1 in each subject's study file depending on risks involved.
- iv. All reportable Adverse Events and Unanticipated Problems. Should also have acknowledgement(s) from appropriate entities that you've reported them to.

3. **Keep separately** - Subject screening log including assigned study code numbers (link).
Signed consent forms and HIPAA authorizations (if applicable)

b. Creating order forms and data collection forms for the study

It is important when creating these forms to keep in mind several factors:

- Always work from the protocol when preparing these forms so that they are complete and consistent with what information needs to be collected
- All procedures that are ordered should be described or addressed in the consent form
- Always meet with the applicable PCIR staff first to ensure that your forms are clear, concise, and user-friendly. This step is very important to ensure communication between the investigator and staff occurs resulting in quality data collection for the investigator's research.

c. Creating a link

Creation and protection of a study link is an extremely important detail of the research project. This document helps the investigator to maintain confidentiality of the research data while at the same time, longitudinally keep track of each research participant. At the PCIR, the investigator has two options for creating a study link that is functional, regulatory compliant, and user-friendly:

1. Use the [subject enrollment log](#) that is part of the GCP program (GCP tool # 4) See section IX d. This form should be accessible to only those people on the research team who need to know the participant's name and study code number (i.e. someone collecting data) It must also be

adequately protected from anyone outside of the research team (i.e. password protected computer, locked up in research file cabinet).

2. Work with the Bioinformatics Core to [create a link in the REDCap](#) web-based database. This tool involves a 20 to 30 minute meeting with the systems analyst to set up the link specific to the investigator's study. Once the link is set up in REDCAP, the investigator specifies who may have access to it. Once a participant name is entered into the form, the program creates a unique study code number that is to be used to label all of that individual's specimens and data.

d. GCP Program

This is a program that is being implemented to assist investigators to set up their research for success from its inception. Once HRRC approval for a new study has been obtained, the investigator and research staff meets with an HRRC Human Protection Specialist or with the PCIR Research Participant Advocate to set up study records and tools to facilitate proper recordkeeping. The tools are meant to be revised and adapted to meet the needs of the investigative team. Those forms that are currently available are:

- 1) Tracking log for non-reportable events
- 2) Event Form for reportable events
- 3) Log for tracking reporting (to sponsor, IRB, FDA)
- 4) Subject Enrollment Log (link)
- 5) Tracking Log for Consent/Re-consent
- 6) Log of IRB approved documents
- 7) Log of Document Submissions (IRB, sponsor, FDA, etc.)
- 8) Standardized order form template
- 9) Data collection form template example
- 10) Investigational Drug/Device accountability log
- 11) Specimen storage log
- 12) Temperature logs for freezer/refrigerator (when storage of specimens or drugs are involved)
- 13) History and physical template
- 14) Regulatory Binder Checklist
- 15) Study calendar (this can also be made into a checklist for each study visit, checking off when each study procedure is completed)
- 16) Subject Demographic Form Template
- 17) Concomitant Medication Log
- 18) Randomization Table Example
- 19) Subject Payment Log
- 20) Subject Diary Template
- 21) Checklist for documentation of the consent process

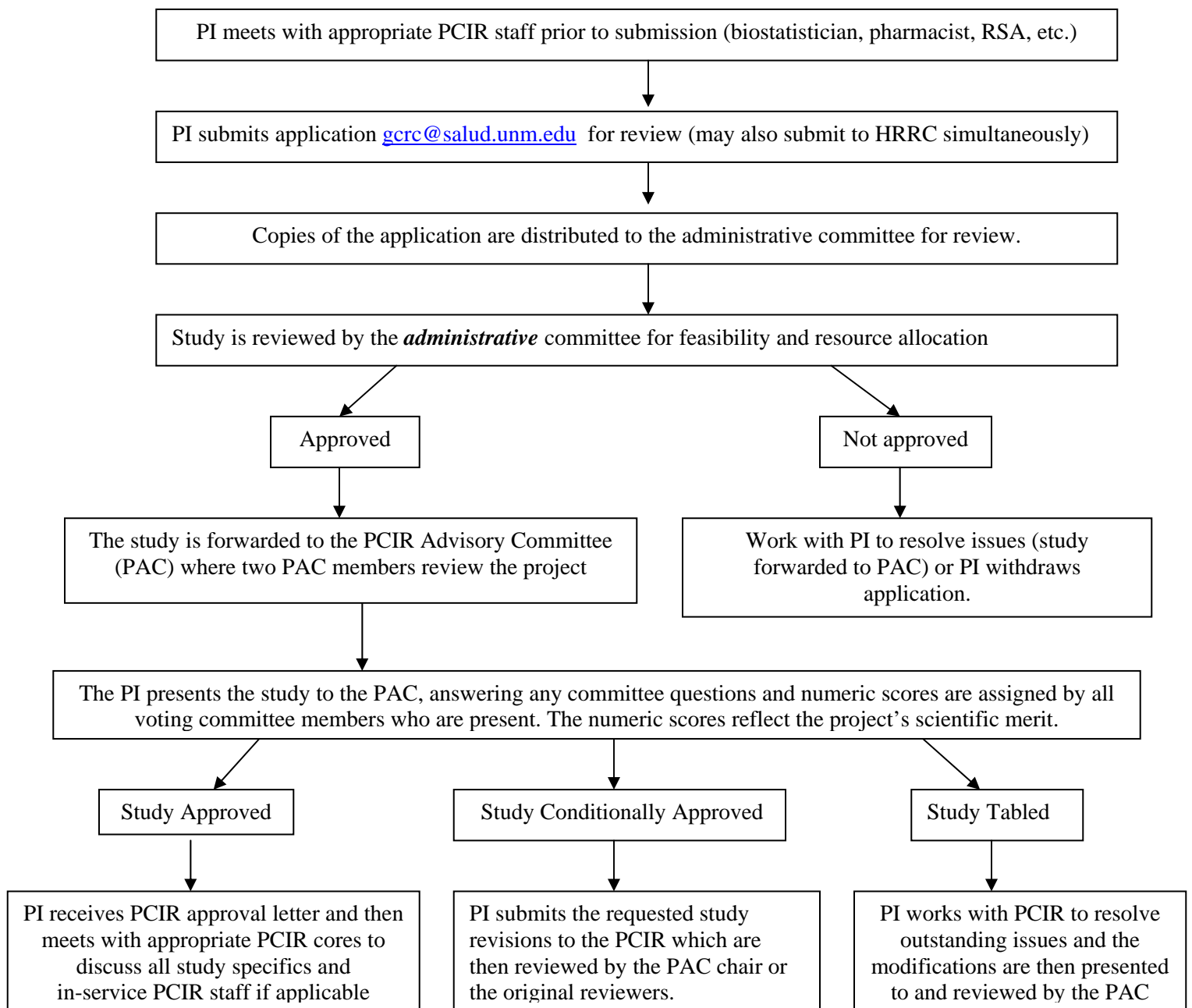
Proper Documentation in study participant files:

1. Provides a "verifiable audit trail"
2. Includes documentation of all eligibility criteria
3. All fields of data collection forms are completed
4. [Documentation of informed consent](#)
5. Documentation of all adverse events and unanticipated problems
6. Documentation may be in the form of medical history, hospital/clinic notes, lab results, progress notes, diagnostic test results, medication history, telephone logs, pharmacy records, correspondence, and data collection forms (if data are not collected for clinical care like questionnaires, rating scales, etc.).
7. Research data that is not pertinent to clinical care must only be placed in the research file and **NOT** in the subject's medical record
8. Study data are labeled with a unique code number and are **NOT** filed with the consent form or the link.

X. Annual Reporting to NIH

The PCIR is required to submit an Annual Report of scientific progress and an annual financial status report within 90 days after completion of the grant year. The grant year ends each year on November 30th. By February 28th of each year, patient census, financial reports, and future utilization must be submitted to NIH. The program manager and the informatics manager are primarily responsible for the submission of this report, with the assistance of each core contributing progress in their specific area. These reports are reviewed by NIH and are used for planning and evaluation. Through these reports, NIH is kept apprised of current research activities and accomplishments (i.e. publications) at the PCIR for Congressional reports and budget justifications and other reports.

XI. PCIR Operational Flow



Version Date: 09/10/09

XII. Contact Information

Administrative Office			
Name	Title	Telephone	E-Mail
Mark Burge, MD	Program Director	272-2366, 5 ACC 272-4658	mburge@salud.unm.edu
Mark Schuyler, MD	Associate Program Director	272-4658	mschuyler@salud.unm.edu
Robin Ohls MD	Pediatric Associate Program Director	272-6410	rohls@salud.unm.edu
Cindy Wootton	Program Manager	272-3183	cwootton@salud.unm.edu
Danette Peavy	Administrative Assistant	272-0195	dpeavy@salud.unm.edu
Research Subject Advocate's Office			
Name	Title	Telephone	E-Mail
Rebecca Rogers MD Anne Simpson MD	Research Subject Advocate, Director	272-6817	
Cheryl Reich RN,MSN,AOCN	Research Subject Advocate	272-6817	creich@salud.unm.edu
Christina Gallegos	Compliance Coordinator	272-6817	cmgallegos@salud.unm.edu
Bionutrition Research Area			
Name	Title	Telephone	E-Mail
Rosemary Wold, MS,RD,LD	Manager, Research Nutrition	272-5501	rwold@salud.unm.edu
Christine Calvin, MS,RD,LD	Senior Research Nutritionist	272-0196	ccalvin@salud.unm.edu
Karen Delgado	Coordinator, Dietary Services	272-2307	ktdelgado@salud.unm.edu
Rosalva Bustillos	Coordinator, Dietary Services	272-2307	robustillos@salud.unm.edu
Mickey VanVleet	Nutrition Tech	272-2307	mvanvleet@salud.unm.edu
Vanessa Garcia RT	DEXA Tech	272-0196	vygarcia@salud.unm.edu
Core Laboratory			
Name	Title	Telephone	E-Mail
David Schade, MD	Core Lab Director	272-4657	dschade@salud.unm.edu
Tony Brazfield	Lab Manager	272-3619	tbrazfield@salud.unm.edu
Chelsea Gregory	Research Tech 1	272-8854	cgregory@salud.unm.edu
Jeanette Mata	Research Tech 1	272-8854	jmata@salud.unm.edu
Susan Lee	Research Specialist	272-3619	srlee@salud.unm.edu
Outpatient Department			
Name	Title	Telephone	E-Mail
Patsy Lucero	Administrative Asst.	272-2451	plucero@salud.unm.edu
Mary (Pat) Leonard	Research Nurse/RN	272-0193	mleonard@salud.unm.edu
Meredith Somers	Research Nurse/RN	272-2451	msomers@salud.unm.edu
Linda Villegas	Research Nurse/RN	272-0193	lvillegas@salud.unm.edu
Scatterbed/Pediatric Department			
Name	Title	Telephone	E-Mail
Connie Backstrom Lacy	Supervisor	272-0367, pager 951-1275	cbackstrom@salud.unm.edu
Carol Hartenberger	Research Nurse	272-0916	chartenberger@unm.edu

		pager 951-1274	
Julie Rohr	Research Nurse	272-0363 pager 951-1265	jrohr@salud.unm.edu
5-East Nursing			
Name	Title	Telephone	E-Mail
Jessica Sanchez	Nurse Manager	272-1274 5E - 272-2770	jjsanchez@salud.unm.edu
Biostatistics and Informatics			
Name	Title	Telephone	E-Mail
Clifford Qualls, PhD	Biostatistician	272-2368	cqualls@salud.unm.edu
Ron Schrader, PhD	Biostatistician	272-2997	rschrader@salud.unm.edu
Lori Sloane	Informatics Core Mgr.	272-2523	lori@salud.unm.edu
Ron Sanders	Informatics Analyst	272-2533	RonSanders@salud.unm.edu

XIII. Miscellaneous

a. Hours of Operation

- The PCIR is closed during University observed holidays and winter break
- Administrative offices are open from 7:00 am to 4:00 pm weekdays
- The Outpatient Clinic and Bionutritionists are available from 7:00 am to 5:00 pm weekdays
- The Biostatisticians are available from 8:00 am to 5:00 pm Tuesday through Friday

b. Independent Monitors and Data and Safety Monitoring Boards

Independent review of research involving more than minimal risk is done by individuals unaffiliated with the research. This helps minimize the impact of any potential or perceived conflicts of interest. For research determined to involve lower risk(s), independent review may be expedited, and performed by an independent individual. An appropriate independent monitor (IM) will be a healthcare professional with relevant expertise in performing research as well as expertise in the specific field of the research. For research involving higher risk(s) or certain vulnerable populations, the independent review should be done by a full committee or board of individuals with a range of expertise who have the authority to approve, amend, or terminate the research.

When it is determined that a research study requires monitoring by an independent monitor, the person that is named for this role is asked to complete an [independent safety monitor conflict of interest \(ISM COI\) disclosure form](#) for submission to the Research Participant Advocate office.

When it is determined that a research study requires monitoring by a DSMB, the investigator is responsible for all aspects of managing the board, which can be summarized by completing a [DSMB Charter Template](#) that includes the role, responsibilities, membership, and procedures of the board.

The data and safety monitoring plan that is created at the time of initial submission will clarify what level of monitoring is required for the individual study – whether it can be done by the PI, an independent monitor, or by a DSMB.

c. Compensation of Participants in PCIR Research

Procedure for compensation of Non-VA Participants

When the PCIR advisory committee has approved compensation for participants in a research study, it is the PI's responsibility to complete a [participant reimbursement fee form](#) for each participant, when enrolled, and see that they have a current Banner ID number or if not, create one for the participant in the Banner system. The PCIR admin office will then provide an index number to the PI, who then generates a DPEZ form utilizing the Banner system. The PI signs and dates the DPEZ form and gets PCIR approval, then delivers it to the finance office. The PI may review the status of the compensation for each participant in the Banner system.

Procedure for compensation of VA Participants

- PI must obtain a [data use agreement](#) with VAMC
- PI is encouraged to specify in the data use agreement any provisions for use of subject information required for compensation (through the UNM Banner Finance system)
- If it is not specified in the data use agreement,
 - PI must obtain permission from Information Security Officer, VA privacy officer, or VA research office in writing that the VA subject's information may be entered into the UNMHSC Banner Finance System – for purposes of compensation.
 - Once permission is obtained in writing from one of the above VA entities, then the participant's name, address, and SSN must be provided directly by the participant to the PI.
- The VA requires that it be specified in the payment section of the consent form that personal information will be collected from the participant for the purpose of compensation. An example might be *“In order to provide you with compensation for participating in this study, the following information (name, social security number, and address) will be required for entry into the UNMHSC financial system. This information will be removed from the system...”*
- Once the prior procedures are in place, each participant should be given a [participant reimbursement fee form](#) to complete.
- The PI will be responsible for creating a Banner ID for the participant in the Banner system if none exists.
- The PCIR admin office will then provide an index number to the PI, who then generates a DPEZ form utilizing the Banner system.
- The PI signs and dates the DPEZ form and gets PCIR approval, then delivers it to the finance office.
- The PI may review the status of the compensation for each participant in the Banner system.