CTSC Request for Resources Form

Thank you for your interest in the UNMHSC Clinical & Translational Science Center (CTSC). The Clinical Research Unit (CRU) is an institutional resource for multidisciplinary human research. The CRU is funded by the Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH) for the purpose of providing specialized facilities for clinical research into the cause, prevention, control and cure of human disease.

All the protocols including Industry sponsored and Multi-Center NIH funded protocols will receive an administrative review regarding resource availability and allocation. These services and resources are available to all HSC researchers and collaborators, and will be offered through CTSC at discounted user fees and cost sharing mechanisms. All protocols must be fully IRB approved prior to subjects being seen at the CRU.

Please complete this application and submit to CTSCResearchConcierge@salud.unm.edu. You will be contacted by the Research Concierge to schedule a FREE consult/intake meeting.

NOTE: If your study does not involve human subjects, DO NOT complete this form. Please email CTSCResearchConcierge@salud.unm.edu to discuss support options.

For questions regarding this form, please contact Danielle Trujillo DaTrujillo@salud.unm.edu

I. RESOURCE REQUIREMENTS

A. INVESTIGATOR & PROTOCOL INFORMATION

1) Title:

2) Principal Investigator(s):
*If PI is not an MD, please provide a designated physician for your study.

3) Study Coordinator:

4) eRA Commons Name:

5) Protocol number, if one has been assigned: ☐ Not assigned yet

6) Expected duration of research project (i.e. how long will you need CTSC resources):

B. RESEARCH SUBJECTS

Does this study involve research subjects: ☐ Yes ☐ No If no, skip to section II

1) Expected total number of study participants consented:

2) Anticipated Date Study to Begin (1st patient) / / 

3) Anticipated End date / /

4) Age range of participants:
C. INPATIENT VISITS

CTSC 5-East Unit ☐ Other UNMH Inpatient Unit ☐ Specify:

1) How will study visits be charged?
   - All study visits charged to sponsor ☐ (i.e. research related visits/research related procedures)
   - Some study visits charged to sponsor, other visits charged to patient/ 3rd party payer ☐
   - Some research related, some standard of care ☐

3) How many participants will require an inpatient stay:

4) How many inpatient admissions per participant:

5) How many days per inpatient admission:

6) Total number of inpatient **days** (for all enrolled participants):

D. OUTPATIENT VISITS

1) How many total visits do you anticipate (including screening visits) for all participants:

2) Approximate number of screening visits (including screen failures):

3) How many study participants qualify and complete study related procedures:

4) How many outpatient visits per participant:

5) Expected duration of:
   - Consent/Screening visit:
   - Outpatient visit:

6) Where will visits occur?
   - ☐ CTSC clinic  ☐ UNM hospital clinic  ☐ Home  ☐ School  ☐ Other, Specify:

**SUMMARY:**

<table>
<thead>
<tr>
<th>Study Visits</th>
<th>Number of Subjects</th>
<th>Number per subject</th>
<th>Total Number of Visits (Multiply # of subjects by the # per subject)</th>
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<tbody>
<tr>
<td>Screening Visit(s)</td>
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<td>Inpatient Visit(s)</td>
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<td>Outpatient Visit(s)</td>
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II. FUNDING INFORMATION

A. FUNDING SOURCES

*Check all that apply; comment as needed*

☐ NIH submitted, not yet funded  ☐ NIH, funded  ☐ Other Federal:

☐ Foundation: ☐ Department Funded:

☐ Investigator-Initiated Industry Supported  ☐ Industry-Initiated Industry Sponsored:
1) Check here if no funding sources support this protocol: ☐

2) List all forms of support from grants or other agencies.
   **IMPORTANT:** If this is a pilot or other CTSC award project, please enter the RFA category you are applying to under the “Name of Grant/Agency”.

<table>
<thead>
<tr>
<th>NAME OF GRANT/AGENCY</th>
<th>GRANT #/Preward #</th>
<th>BILLING/GUARANTOR #</th>
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<td>(i.e. Innovation)</td>
<td>Unknown</td>
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**B. CLINICAL LABORATORY SERVICES**

Does this study involve clinical laboratory services: ☐ Yes ☐ No If no, skip to section II.C.

☐ Meet with the Science Research Manager, Amy Overby 272-8033, to determine testing feasibility within CTSC Clinical Laboratory or shared resources and associated fees

1) Please detail below all lab tests that your protocol requires.
   **IMPORTANT:** If you have already arranged for a lab other than CTSC to perform the test, or if other funding has been arranged, please note that in the comments column.

<table>
<thead>
<tr>
<th>LAB TEST</th>
<th># SUBJECTS</th>
<th># PER SUBJECT</th>
<th>TOTAL # REQUESTED</th>
<th>LOCATION (Screening/Outpt/Inpt)</th>
<th>COMMENTS</th>
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**C. ANCILLARY SERVICES**

Does this study involve ancillary services: ☐ Yes ☐ No If no, skip to section III

1) Please list all tests and supplies required for the protocol; if other funding has been arranged, please note that in the comments column.
NOTE: Some protocols require services or supplies that are not provided by the CTSC, but can be ordered by the CTSC; these are considered “ancillary” services. Examples are MRI, ultrasound, medications, etc. The CTSC does not cover the cost associated with these services. PI is responsible for completing required UNMH billing forms and obtaining a guarantor number, if necessary.

### III. RESEARCH NURSING/COORDINATOR REQUIREMENTS

Does this study involve require CTSC research nursing/coordinator services: □ Yes □ No If no, skip to section IV

#### A. INPATIENT UNIT (CTSC 5-East Unit or Other UNMH Unit)

1) Does this study require the services of the CTSC 5-East Inpatient Unit: □ Yes □ No
2) Does this study require the services of the CTSC nursing/coordinator staff on another UNMH unit, other than CTSC’s 5-East Unit: □ Yes □ No

2) Please indicate which inpatient unit services will be utilized for this protocol:

- □ Nursing Assessment (i.e. vital signs, height, weight), Specify:
- □ Nursing Procedures (i.e. ECG, bronchoscopy), Specify:
- □ Single venipuncture for blood samples, Specify:
- □ IV start, Specify:
- □ Multiple/Timed blood samples or infusion, Specify:
- □ Specimen collection(s) (i.e. urine, saliva, stool), Specify:
- □ Questionnaire administration/Data collection, Specify:
- □ Administer study medication/pill, Specify:
- □ Monitoring of subject (i.e. frequent vitals), Specify:
- □ Nursing services between 5 pm-8 am, Specify:
- □ Processing of specimens between 5 pm-8 am, Specify:
- □ Other, Specify:

#### B. OUTPATIENT CLINIC

1) Does this study require the services of the CTSC Outpatient Clinic: □ Yes □ No

2) Please indicate which outpatient clinic services will be utilized for this protocol:

- □ Room space for informed consent or other interview
- □ CTSC Pulmonary Function Lab
- □ Nursing Assessment (i.e. vital signs, height, weight), Specify:
- □ History & Physical Exam by CTSC physician
- □ 12-Lead ECG
- □ Exercise test
- □ Single venipuncture for blood samples, Specify:
- □ IV start, Specify:

### TEST/SUPPLY

<table>
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<tr>
<th>TEST/SUPPLY</th>
<th># SUBJECTS</th>
<th># PER SUBJECT</th>
<th>TOTAL # REQUESTED</th>
<th>LOCATION (Inpt/Outpt)</th>
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<td>Research Pharmacy (Contact Nancy Morgan 272-2515)</td>
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</table>
Multiple/Timed blood samples or infusion (includes pharmacokinetic sampling), Specify:
Specimen collection(s) (i.e. urine, saliva, stool), Specify:
Questionnaire administration/Data collection, Specify:
Administer study medication/pill
Monitoring of subject, Specify:
Other, Specify:

IV. RESEARCH BIONUTRITION REQUIREMENTS

Does this study require CTSC Bionutrition Unit services: □ Yes □ No
If yes, please contact Diana Gonzales-Pacheco to discuss feasibility (272-5501) and complete relevant section below. If no, skip to section V.

A. NUTRITION TESTS

1) Please indicate which body composition tests will be utilized for this protocol:
   □ Bioelectrical Impedance Analysis (BIA)
   □ Skinfold Measurement
   □ Anthropometry (Circumferences)
   □ Dual Energy X-Ray Absorptiometry (DEXA)
   □ Exercise Testing / Monitoring
   □ Other, specify:

2) Please indicate which metabolic gas measurements will be utilized for this protocol:
   □ Metabolic Cart
   □ MedGem
   □ Other, Specify:

B. NUTRITION SERVICES

1) Please indicate which nutrition services will be utilized for this protocol:
   □ Nutrition Assessment
   □ Diet History
   □ 24 hour recall
   □ Food Diaries (kept by subject)
   □ Food Frequency Questionnaire
   □ Diet Instruction
   □ Computer Analysis of Intake
   □ Computer Analysis of Body Comp.
   □ Calorie Count (in house)
   □ Activity Instruction
   □ Questionnaire Administration, Specify:
   □ Other, Specify:

C. RESEARCH MEAL SERVICES

1) Please indicate which research meal services will be utilized for this protocol:
   □ Regular Meals
   □ Regular Snacks
   □ American Diabetes Association Meals
   □ American Diabetes Association Snacks
   □ Caffeine Restriction
   □ Specialized Meals
   □ Other, Specify:
2) If requesting specialized meals, please describe (i.e. timed meals, weighed meals, regulated fluid intake, defined meals, nutrient controlled, enteral formulas, etc.):

3) Are there any other special considerations that the bionutrition staff should be aware of:

**V. OTHER CTSC RESOURCES**

Does this study involve other CTSC resources:  
☐ Yes  ☐ No  If no, skip to Signature Page

**A. RESEARCH PARTICIPANT ADVOCATE**

All protocols that are greater than minimal risk as determined by the Human Protections Office Require a Data & Safety Monitoring Plan.  
([http://hsc.unm.edu/research/ctsc/Docs/RPADocs/CTSC%20DSMP%20Template.doc](http://hsc.unm.edu/research/ctsc/Docs/RPADocs/CTSC%20DSMP%20Template.doc))

1) Submit DSMP with CTSC application to CTSC Research Participant Advocate

☐ Copy of DSMP has been included with CTSC application packet

**B. PATIENT RECRUITMENT**

1) If requesting the **Patient Recruitment Service (Honest Broker/Contactor)**, you must complete the following steps.

☐ Develop a recruitment/ screening script to use when calling interested patients. Copy of proposed script with CTSC and/or HRPO Application

☐ Meet with the Research Participant Advocate, Heather Savage, 272-0407, to determine study feasibility and associated fee

2) Use of the Online **Clinical Research Volunteer Registry** (HRRC#06-412)  
([https://ctsctrials.health.unm.edu/redcap/surveys/?s=VAbh7G](https://ctsctrials.health.unm.edu/redcap/surveys/?s=VAbh7G))

☐ Submit a copy of your HRPO approval letter to utilize the registry to the Research Participant Advocate. Please reference HRRC#06-412 in your application to the HRPO.

**C. REGULATORY SUPPORT**

1) Use of Regulatory Support Unit

☐ IRB Submission and Regulatory maintenance

☐ Federal Regulatory submissions/support

**D. TRANSLATIONAL TECHNOLOGIES AND RESOURCES**

1) Use of T1 Laboratory

☐ Meet with the Science Research Manager, Amy Overby 272-8033, to determine study feasibility, assay/protocol development, T1 Lab services and associated fees

☐ Wet-Laboratory space for T1 research

☐ T1 Laboratory testing or technical assistance

☐ Laboratory space for development and testing of prototype equipment being built as a result of CTSC Biodesign Initiative

Please indicate which equipment will be utilized for this protocol

☐ Arcturus XT Laser Capture Microdissection System

☐ Applied Biosystems Viia7 Real-Time PCR

☐ Beckman Coulter Z2 Cell Counter Analyzer
Bio-Rad BioPlex 200 multiplex array system with HTF and BioPlex Pro II Wash Station
Labconco FreeZone Plus Cascade Freeze Dry System
Molecular Devices SpectraMax Plus384 Absorbance Microplate Reader
ThermoScientific NanoDrop Spectrophotometer

2) Use of Shared Resources
☐ Meet with the Science Research Manager, Amy Overby 272-8033, to determine utilization of shared resources and associated fees
☐ Coordinating sample collection and assays within the CTSC shared resources and provide links to other core facilities to support CTSC research

E. COMMUNITY RESEARCH SPECIALIST

If you are planning on conducting any research with a community engagement component and/or the CTSC community research specialist is involved in your research plan, specify level of need:

F. BIOSTATISTICS

Each HSC Faculty investigator is entitled to 15 free hours of statistical support per calendar year; this includes face to face meetings as well as time spent by the statisticians working on your protocol outside of those face to face meetings.

1) Please indicate which biostatistical services will be utilized for this study:
☐ Determine statistical study design
☐ Calculate sample size and power
☐ Review the design of questionnaire/data collection form(s)

2) Meet with a CTSC biostatistician prior to submitting CTSC application (recommended). Please email CTSCBiostats@salud.unm.edu to set up an initial consultation.
☐ Meeting with biostatistician has been completed (prior to CTSC application submission)

G. BIOMEDICAL INFORMATICS (COMPUTER SUPPORT)

1) Please indicate which biomedical informatics services will be utilized for this study:
☐ Coordination of database design (i.e. RedCap/ RedCap Survey)
☐ Data Warehouse (i.e chart review (de-identified) & feasibility counts)

H. INVESTIGATIONAL DRUG PHARMACY

1) Please list which medication(s) are needed for this study:

2) Where will medication(s) be administered: ☐ Outpatient ☐ Inpatient ☐ Other:

3) Required documents given to research pharmacist (Nancy Morgan at namorgan@salud.unm.edu):
☐ Copy of IRB application. Attachment 3 and Study Protocol
☐ N/A (WIRB Application)

I. OTHER CTSC RESOURCES

☐ Other:
SIGNATURE PAGE

By submitting this document, the PI agrees to the following:

- **Consenting**: The PI assures that the consenting process will be conducted properly and will conform to the IRB regulations for human investigation.
- **Data collection/study conduct**: The PI assures that the actual conduct of the study, record keeping, data collection and processing by research personnel will be monitored during the study.
- **Research training**: The PI affirms that key research personnel associated with the study have completed the UNM Human Subjects Protection Certification (“CITI Course”).
- **Reporting**: The PI affirms that adverse events, unanticipated problems, and protocol amendments will be reported to the CRU, IRB, and other appropriate institutions.
- **Notification of Changes**: The PI affirms that all protocol amendments and changes to the informed consent document will be reported to the CRU, IRB, and other appropriate institutions.
- **FDA & Sponsor Paperwork**: The PI affirms that the RSA will receive copies of all correspondence between the research team and the FDA, as well as the Sponsor. Such correspondence includes the topics of safety, protocol changes, holds, and overall study conduct.

**NOTE: this is not a Memorandum of Understanding and in no way commits the Clinical Research Unit to the services requested until further notice.**

______________________________  ______________________
Signature of Principal Investigator  Date

The CTSC Representative acknowledges this study proposal and the request to utilize CTSC Resources.

______________________________  ______________________
Signature of CTSC Representative  Date