SW CACTI Pilot Project Application Instructions

Use these instructions to assist you with compiling the necessary items for your SW CACTI Pilot Application.

Applications are submitted through Camino: http://camino.health.unm.edu/

The Camino Application works best in Google Chrome or Firefox. If you are accessing the application off campus, you must have VPN access.

How to Apply

1. Log on to the SW CACTI Funding Opportunities website: http://hsc.unm.edu/research/SW CACTI/pilot-funding/current-opportunities/index.html
2. Click on the "Submit your application for a Pilot Award online" Link
3. Log In with your HSC Net Id and Password (same as your HSC workstation)
4. Click the "Go To >> Camino" Button
5. Once you are logged in, click on the "Start New Pilot Application Button"
6. You will need to input the title of your application – please contact the pilot administrator if you need to make a change to this title
7. Complete all application sections – a. through f. as listed below
8. Upload the required documents where advised – document descriptions listed in the "What to Upload" section below

Pilot Application Sections for completion

a. General Information

i. Resubmission Statement
ii. Select RFA you are applying to
iii. Supply Over Expenditure Index – used for pilot index creation and as backup for any spending overages if funded
iv. Input PI's Faculty Organization Code
v. List an accountant's contact name and email address from PI's department

b. Research Plan and Additional Information

i. Upload Summary *(Template)*
ii. Upload Research Plan – 5-page limit on all RFAs except the "Targeted Pilot Project Award in Autophagy" RFA has a 3 page limit. *(Template)*
    1. specific aims
    2. preliminary studies
    3. significance
    4. innovation
    5. approach

6. bibliography and references cited (not included in the page limit)

iii. Upload Letters of Support(Suggested/Optional)
iv. Upload DCI Reserve Funds Request *(SW CACTI/DCI RFA applicants only - Template)*
v. Describe Plan to Obtain Extramural Funding *(Text box in Camino is limited to 2500 characters, counting spaces, Template)*
vi. Describe how project meets the definition of Translational Research *(Text box in Camino is limited to 2500 characters, counting spaces, Template)*
vii. Describe how this project engages underrepresented or excluded groups *(Text box in Camino is limited to 2500 characters, counting spaces, Template)*
viii. Explain how the proposal may be generalizable *(Text box in Camino is limited to 2500 characters, counting spaces, Template)*

c. Go/No-Go Milestones

i. Two standard milestones are tracked, Funds Spent and Patient Enrollment. Please add two to three more Go/No Go milestones that can be used to track progress over the pilot award year. The SW CACTI Pilot Review Committee will review milestones bi-monthly for progress. Milestones should be quantifiable and realistic. Failure to reach stated milestones may result in reduction of award.

d. Human Subjects/Animal Research Files

i. Animal Research Determination
ii. Upload Animal Research Files *(Template)*
iii. Human Subjects Research Determination
iv. Clinical Trial Determination
v. Upload all Human Subjects Research Files
vi. Enter Planned Enrollment

e. Key Personnel/Biosketches

i. Add Key Personnel
ii. Upload Biosketch documents *(Template)*

f. Detailed Budget for Pilot Project

i. Select SW CACTI Services – sort services by selecting the specific department or by searching in the search box provided. Select services by dragging and dropping the service below the teal box – you will then be able to edit the Quantity of each selected item.
ii. Review selected SW CACTI services
iii. Add Non-SW CACTI Services
iv. Add Non-SW CACTI Personnel Salaries
v. Add Shared Facility Services
vi. Provide Budget Justification

What to Upload

Emphasis on concise communication of the relevant information will help to demonstrate effective proposal writing and communication skills, and the likelihood of success in developing the full, competitive proposals to follow these pilots. Uploaded documents must adhere to the following formatting specifications:

- 11-point Arial font
- Single-spaced
- ½ ” margins on all sides
- 8 ½” x 11” (i.e., standard size) paper
- Number all pages
- Headers identifying the Principal Investigator
- Footers identifying the document and page number (IRB-approval, Consent, Biosketch, etc.)

Attach the following documents as individual PDF files using the following naming convention:
UNM/AZ_PILastNameFirstInitial_ProtocolShortTitle_Document_YYYYMMDD.pdf
(e.g. UNM_AndersonC_PediatricAsthma_Biosketch_20170821.pdf)
No longer than 50 characters. Templates for some of these forms can be found within the SW CACTI Camino Pilot Application database once you have logged in and a new pilot project has been initiated.

The following document is required for all Pilot Project Submissions:

1. **Human Subjects Research Study Document** – download from inside the application database – this will be submitted to NIH for review

The following documents are required, along with the above, if the pilot is Minimal Risk Human Subjects Research or has an Exemption determination:

2. **Summary -** Provide a brief (< 500 words) summary of the specific aspects of the proposed study that will be supported and include a line item budget for each aspect (list supplies, services, and personnel costs) *(Template)*
3. **Research Plan -** Research Plan – 5-page limit on all RFAs except the “Targeted Pilot Project Award in Autophagy” RFA has a 3 page limit. *(Template)*
    a. specific aims
    b. preliminary studies
    c. significance
    d. innovation
    e. approach
    f. bibliography and references cited (not included in the page limit)
4. **Letters of Support** (Suggested/Optional)
5. **IACUC Approval Letter –** if conducting animal work
6. **Vertebrate Animals Section –** if conducting animal work *(Template)*
7. **IRB Approval Letter -** if Human Subjects research
8. **IRB Exemption Determination** – if exempt from federal regulations
9. **NIH Biosketch** – For the investigator, co-investigators and key personnel *(Template)*
10. **Human Subjects Training** - Certification that the PI, Co-I and key personnel have education in protection of human subjects *(Template)*

11. **SW CACTI GCP Training Certificate** - SW CACTI adheres to the NIH requirement that all investigators and research personnel complete the required Good Clinical Practice (GCP) training when conducting NIH-funded projects and/or NIH-related projects (NOT-OD-148; https://grants.nih.gov/grants/guide/notice-files/not-od-16-148.html). Please contact Regis Lacher (RLacher@salud.unm.edu) or visit the SW CACTI website to register for this training.
12. **Protocol** – IRB-approved pilot protocol
13. **Consent, Assent, Parental Permission, Waiver of Consent** – IRB approved consent documents
14. **Inclusion of Individuals Across the Lifespan -** Individuals of all ages are expected to be included in clinical research unless there are scientific or ethical reasons not to include them. *(Template)*
15. **Inclusion of Women and Minorities -** Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. *(Template)*
16. **Recruitment and Retention Plan -** Describe both planned recruitment activities as well as proposed engagement strategies for retention. *(Template)*
17. **Study Timeline -** Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates *(Template)*
18. **Protection of Human Subjects** *(Template)*
19. **Single IRB Plan** - if applicable *(Template)*

The following documents are required, along with 1-17 above, if the pilot is Greater than Minimal Risk Human Subjects Research OR Meets NIH Definition of a Clinical Trial:

20. **Data and Safety Monitoring Plan** (DSMP) - The overall framework for safety monitoring and what information will be monitored *(Template)*
21. **Overall Structure of the Study Team -** Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers *(Template)*
22. **Statistical Design and Power -** Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use *(Template)*
23. **Dissemination Plan -** Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met *(Template)*
24. **IND, IDE** - Documentation that an Investigational New Drug (IND) or Investigational Device Exemption(IDE) has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived
25. **Product Info** - Product information such as the clinical investigator brochure, package insert, or description of the device

On your Camino Home Page, you will be able to see the status of your Pilot Application

a. Draft
b. Submitted
c. Under Review
d. Administratively Denied
e. Pilot Funding Denied
f. Pilot Funding Awarded

Once you have reviewed the application for completeness, submit it to the SW CACTI for review by clicking the “Submit” button at the bottom of the page. The SW CACTI will offer a basic administrative review to those who have their applications submitted at least one week in advance of the due date. Please contact Daron Vigil-Scott (dvigilscott@salud.unm.edu) if you would like your pilot reviewed.