The Clinical Research Support Program
Policies and Procedures

SERVICES
The Clinical Research Program (CRSP) is funded by the department of medicine in the university of louisville school of medicine to provide research support to investigators in the department. We provide telephone, email, and in person consultations and are also available for collaboration on research projects. Our main focus is providing research support in the areas of data collection, data management and statistical analysis. However, based on need, members of our team can provide consultation in all other areas of the research process as needed. We host a research support clinic in which we provide consultations in 30 minute blocks per appointment.

CONSULTING CLINIC
A free consulting clinic is offered on Wednesdays by appointment from 2-4pm EST. Please submit a request at http://louisville.edu/research-support/clinic, call 852-1770, or email kim.buckner@louisville.edu to set up an appointment. In the event the investigator is late to the consulting clinic, the appointment will be canceled. The consulting clinic is operating in MedCenter One. The exact room will be indicated upon scheduling and may change from week to week.

SUPPORT REQUESTS
Support requests can be sent through the online support request form located here: http://louisville.edu/research-support/clinic. Once the form is submitted, members of the CRSP will discuss the project at their weekly meeting (Friday 10am). The investigator should expect to hear back from the team no later than Wednesday of the following week. Email will be used for all communication, additional requests and discussions in order to ensure appropriate documentation of all time spent on the project.

PUBLICATION
Publication is the primary way investigators and analysts get credit for their work. It is especially important to the members of CRSP and to the Department of Medicine which supports time for CRSP projects and collaborations. Authorship on an abstract, poster, or manuscript will depend on the actual work provided by CRSP team members. Authorship must meet the ethical criteria for scientific authors, which includes:

1. Substantial contributions to conception or design, or (b) acquisition of data, or (c) analysis and interpretation of the data
2. drafting the article, or (b) revising it critically for important intellectual detail
3. Final approval of the version to be published.
In the event that the investigator requests work on protocol design, hypothesis development, data collection, database development, data analysis, or manuscript writing, the CRSP requires as part of the consulting agreement that they assist in critical revision and final approval of the manuscript and are granted authorship on the publication. Any team member working on the project must be allowed to review and approve the manuscript and must be granted authorship.

**GRANT FUNDING**
Depending on the nature of the work a minimum of 10% effort of any supporting consultants will need to be added to available grant funding.

**LIMITATIONS AND LIABILITY**
The investigator may ask the CRSP for services in which the CRSP team may not agree with the methods or procedures. In this case, the CRSP reserves the right to reject the project or may provide the requested services without endorsement.

It is up to the investigator to use any information provided by the CRSP appropriately and ethically. It is the investigator’s duty to prevent any doctoring of the results or misrepresentation of the interpretation provided by the CRSP.

Any changes to any part of any services provided by members of the CRSP must have the prior consent of the team member working on the project or the CRSP Director in the event the team member is not available.

**TERMINATION OF SERVICES**
Members of the CRSP reserve the right to terminate services at any time. Upon termination of services, all existing data and analyses or other information will be transferred to the investigator. Termination may occur for many reasons, including situations where the team members feel they can no longer be of benefit to the project.

**ETHICAL ISSUES**
Members of the CRSP are obliged to maintain ethical principles of research including the ethical codes of the University of Louisville, and the rules established by the Human Subjects Protection Program Office at the University of Louisville. Members of the CRSP will report any unethical behaviors. This includes any accidental or intentional misrepresentation of services performed by our team.

**PRIVACY ISSUES**
All members of CRSP have up to date training for the management of patient identifiable information. In the event that the data set for a CRSP project contains patient identifiable information, one of the following is necessary:
1) the members of the CRSP team working on the project must be added to the study protocol as study personnel OR
2) only de-identified data is sent to CRSP team members

If data is being hosted by the CRSP team in a HIPAA compliant REDCap instance, all data access is secure and logged and data management staff do not need to be added to the study protocol.

IRB
Investigators are responsible for conducting human subjects research in accordance with all applicable Federal and state regulations, and UofL IRB policies and procedures. During the conduct of the study, changes may become necessary. If changes are required to a study, an amendment must be submitted for review utilizing the IRB Amendment Form in IRIS. The amendment and any required modifications to the protocol, consent or other study documentation are submitted at the same time. The investigator is responsible for adding all members of the CRSP team to the study within IRIS within appropriate categories and providing CRSP with the IRB number.

The federal regulations specifically require the IRB to review proposed changes in a research activity, and to ensure that such changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject [45CFR46.103(b)(4)(iii) and 21CFR56.108(a)(4)]. Research activity includes all aspects of the conduct of the research study, e.g., recruitment methods, consent process, procedures used to protect privacy and confidentiality, etc. Noncompliance with these regulations, or UofL IRB policies and procedures, during the conduct of a research study results in a protocol violation, and as such must be reported to the IRB by using the IRB Deviation/Violation/Misc. form.

If approved research is changed to eliminate an apparent immediate hazard(s) to the subject, the investigator is required to notify the IRB of the change(s) promptly (within five (5) business days). The IRB will review at the next convened meeting to determine if the change(s) instituted were consistent with the subject’s continued welfare.

Regulations permit the use of expedited procedures for review of minor changes to previously approved research during the period for which the approval is authorized. Modifications that alter the risk/benefit ratio are assigned to a primary reviewer and presented to the full committee at a convened meeting. Amendments submitted to the IRB, along with supporting correspondence, are entered into the IRIS system and stored in the study file.

Investigators are notified by e-mail and through the IRIS software of the decision of the IRB and of any changes required. Approval is not granted until all required changes have been made and submitted for review and approval. Once approved, the investigator is sent through the IRIS software an approval letter. The IRB may only approve modifications through the current approval expiration period. Upon receipt of the approval for the amendment, the investigator may initiate the modification.
Studies that meet the definition of Human Subject Research (HSR) must be submitted to the IRB and must receive IRB approval before any study activities take place. *This document may assist you in determining whether your study meets the definition.* For additional information on certain student projects, pilot studies, oral history projects, or quality assessment/quality improvement projects, see:

- HSPP Policy Manual, Chapter 7
- Approved Sources of Public Use Data
- FAQs about Quality Assessment & Quality Improvement (QA/QI)

For help in determining whether your project requires HSR approval, call the HSPPO at 502-852-5188.

Please visit [http://louisville.edu/research/humansubjects/lifecycle/initial-submissions](http://louisville.edu/research/humansubjects/lifecycle/initial-submissions) for further details on protocol submission, pilot studies, consent and IRB forms.