Instructions and definitions available here.
Frequently asked questions available here.

CLEAR FORM

New Study Checklist

Study Title: _____

Sponsor (if applicable): _____

Investigator: _____

CRA: _____

Coordinator: _____

Financial Manager: _____

IRB#: _____

Item	Yes	No	N/A	Date Received	Date Completed	Comments
STUDY ID / GENERAL INFORMATION						
Is your study industry or foundation sponsored*?						
Is your study government (NIH, DOD, CDD, etc.) sponsored?						
Is your study intramurally sponsored (Alliance, COM, Department, CCTS, etc.)?						
Center for Clinical and Translational Science (CCTS) (if applicable) *A service request form is required if utilizing CCTS services (http://www.ccts.uky.edu/ccts/ccts-service-request-forms). The CCTS will contact you and provide a budget estimate and letter of agreement. These must be executed prior to initiation of services.*						
Budget estimate and letter of agreement executed with CCTS?						
Cancer Patients (if applicable)						
Does the study involve enrolling cancer patients? If so, contact the Markey Cancer Center Research Network at (859) 218-4062.						
Has Markey Cancer Center approval been received?						

College of Medicine
Office of Research

Item	Yes	No	N/A	Date Received	Date Completed	Comments
SPACE / LABORATORIES / SITE INFORMATION						
Site Selection and Initiation*						
Has the site selection visit been completed?						
Has the site selection letter been received?						
Is UK Healthcare Ambulatory space being used to conduct research participant evaluations?						
If yes, are room fees applicable for the use of this space?						
If yes, have the room fees been included in the budget?						
Veteran's Affairs (VA) Patients (if applicable)						
Does the study involve enrolling patients from the VA? If so, contact the VA for additional information regarding research.						
Has VA approval been received?						
Laboratories						
Are UK Healthcare laboratories being used?						
Are any outside laboratories being used?						
Are all laboratories **CAP/CLIA certified?						
Will outside laboratory results be entered into Epic?						
If the study uses test results from a non-CLIA certified laboratory, do you agree that the results will not be used to guide clinical care?						
External Sites (if applicable) *This applies to research at an external facility that UK has a contract with but that UK does not own. Contact UK College of Medicine Office of Research with questions at (859) 218-4093 or medicineresearch@uky.edu.*						
Does your study involve an external site?						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
Does the external site's contract with UK allow research?						
Has indemnification of the external site been addressed?						
Will data be shared between the sites?						
Home Health Exemption (if applicable)						
Does the study involve going into a patient/participant's home? If so, you may need a home health exemption. Contact UK Office of Legal Counsel at ukofficeoflegalcounsel@uky.edu for assistance.						
Has a Home Health Exemption been received?						
COI / CDA / NDA / MTA / DUA						
Conflict of Interest (COI) *PIs are responsible for ensuring that significant financial interests and potential COIs are appropriately disclosed in IRB applications and any other required disclosure forms not vetted by the institution (e.g. FDA FCOI forms).*						
Has the Office of Sponsored Projects Administration (OSPA) been contacted for COI disclosures, https://www.research.uky.edu/office-sponsored-projects-administration/conflict-interest?						
Confidentiality Agreement (CDA/NDA)* *Most sponsors require a signed confidentiality agreement prior to sharing a protocol. PIs are not authorized to sign CDAs. The Office of Technology and Commercialization has sole signatory authority. Information on where to send draft CDAs can be found at https://www.research.uky.edu/office-technology-commercialization/transfer-agreements.*						
Fully executed CDA received?						
Clinical Trial Agreement (CTA)* *CTAs are negotiated by the Office of Sponsored Projects Administration (OSPA). PIs cannot sign CTAs. OSPA has sole signatory authority.*						
Fully executed CTA?						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
Non-Indemnification *It is the responsibility of the principal investigator to initiate the non-indemnification review process for all eligible clinical trials, as defined here. If an investigator does not forward a study for review that qualifies for Inclusion in the Indemnification Process and a problem occurs and a claim is made, the University is not obligated to defend the investigator. Contact (859) 218-6610 with any questions regarding the non-indemnification submission/review process.* *If your agreement is industry/externally sponsored, please contact OSPA if you have questions about whether your study qualifies for non-indemnification review.*						
Have you contacted UK Healthcare Risk Management Committee about non-indemnification review?						
Data/Material Sharing *Information can be found at https://www.research.uky.edu/office-technology-commercialization/transfer-agreements including appropriate contact information regarding data/material sharing.*						
Is the study sharing confidential information outside of UK and/or is UK receiving confidential information from outside UK?						
Material Transfer Agreement (MTA) *Information can be found at https://www.research.uky.edu/office-technology-commercialization/transfer-agreements including appropriate contact information regarding MTAs.*						
Will you be transferring materials (specimens, cell lines, mice, plants, etc.) outside of UK?						
If so, has an MTA been executed?						
Will you be transferring data (fully de-identified, a limited data set, or Protected Health Information (PHI)/Personally Identifiable Information (PII)) outside of the University?						
If yes, has a Data Use Agreement (DUA) been executed?						
If yes, did the DUA describe data destruction guidance?						
If no, is the data set a limited data set?						
If no, is the data set de-identified?						
Will the data be stored at UKHC?						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
If yes, has the request been reviewed by UKHC IT to determine if technology resources are required to support data storage?						
BUDGET / COVERAGE ANALYSIS / BILLING REVIEW						
Sponsor Budget Development/Negotiation* *Sponsors will typically send a budget template to guide budget negotiations. The budget should always be prepared using actual costs. Along with patient care costs, o PI effort, coordinator effort, regulatory support, grants management support, IDS, ancillary costs, patient stipend, long-term storage costs, IRB fees, pass-thru costs (protocol amendments, SAEs, IND safety reports, protocol violations, etc), and indirect costs need to be included.* *The F&A rate for indirect costs is determined by OSPA. Guidelines for F&A can be found here; any questions about the appropriate F&A rate should be directed to OSPA.*						
Sponsor budget approved?						
eIAF completed? https://www.research.uky.edu/uploads/instructions-completing-eiaf-myuk						
Coverage Analysis and Billing Review *Submit a service request form for coverage analysis at: https://cctsdata.uky.edu/membership/*						
Has the study been submitted to the CRSO MCA team for review?						
Did the MCA team determine if the study is qualifying?						
Billing Review: If a Clinical Research study contains items and services provided at any UKHC facility or by UKHC providers (i.e., Labs, Scans, Examinations), the research study is reviewed as well, and the CRSO will develop a financial calendar for charge segregation.						
A clinical research study (clinical trial or research with billable items) must be in the CTMS system and is send to the EHR (Epic) system after the billing review or CA has been completed.						
Do you have a designated staff member who reviews the billing in Epic and maintains the records in the CTMS system?						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
OnCore *All studies meeting the NIH definition of a clinical trial need to be built into Oncore regardless of the sponsor. To review the NIH definition of a clinical trial go to https://grants.nih.gov/policy/clinical-trials/definition.htm.*						
Does the study need to be built into OnCore? Please contact CRSOStudyAssist@uky.edu with any questions.						
Has the study been built in OnCore? Please submit studies at https://www.research.uky.edu/clinical-research-support-office						
Epic						
After the Billing review or CA process - Does the study have any services or procedures that will occur at a designated UKHC facility or provided by any UKHC provider? If so, the study must be included in Epic. If you have questions about this process please contact the CRSO at CRSOStudyAssist@uky.edu						
INVESTIGATIONAL DRUG / DEVICE AND RELATED SERVICES						
Investigational Drug Studies and IDS-related services (if applicable)						
Does the study use an investigational drug? If yes, contact IDS@uky.edu to request IDS support and agreement that support will be provided per the study protocol.						
If your study includes an investigational drug, have you obtained the FDA approval? A treatment could be a drug, medical device, or biologic, such as a vaccine, blood product, or gene therapy. Drug developers, or sponsors, must submit an Investigational New Drug (IND) application to FDA before beginning clinical research.						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
Do you need an IND based on the FDA rules? There are three IND types: An Investigator IND, Emergency Use IND (21CFR, Sec. 312.23 or Sec. 312.20), AND Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions. There are two IND categories: Commercial & Research (non-commercial)						
If your study is exempt, please document it as set forth by the FDA regulations: To be exempt [21 CFR 312.2(b)], 1) the drug must be lawfully marketed in the US, 2) the study cannot be intended to support a new indication or other significant change in product labeling, 3) the study cannot be intended to support a significant change in advertising for the drug or be used to promote the drug. During the billing review and study submission to the CRSO please indicate if your study is IND exempt.						
Is IDS providing support for your study?						
Device Studies (if applicable)						
Does your study involve a device? If so, you may need to go through the Celerian Group Company (CGS) device notification process. Contact renee.hensley@uky.edu (Please note this will require annual reapproval)						
CMS approval needed for: Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.						
If your study is NOT submitted and approved under the CMS guidelines, the study is considered to be Non-Qualifying for coverage of routine costs under the CMS NCD 310.1. You can still conduct your study but the coverage by insurances will be limited.						
Ensure that you (your sponsor) follows the FDA requirements for Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
III devices require Premarket Approval. A description of device classification and a link to the Product Classification Database is available at "Classification of Medical Devices."						
Have you received approval for use of your research device at UK?						
Does your device need engineering review?						
REGULATORY						
Certificate of Confidentiality *All NIH sponsored clinical trials automatically fall under a certificate of confidentiality if needed per the study protocol. Studies not sponsored by the NIH must request a certificate of confidentiality if needed. For more information go to https://www.research.uky.edu/sites/default/files/56-ori_summary_on_coc.pdf.*						
Does your study have a certificate of confidentiality?						
If yes and data is entered into Epic, is a system in place to assure confidentiality?						
Institutional Review Board (IRB) *If your study involves human subjects either IRB approval or an IRB waiver must be obtained.*						
Are you using the UK IRB?						
Are you using a central IRB?						
If a central IRB, do you have a reliance agreement in place?						
Has IRB approval been received?						
Does your research project involve nurses at UK Healthcare as subjects, or is it being conducted by a nurse(s) from UK Healthcare?						
If yes, contact the UK Nursing Research Council before conducting the study. A student who is also a UK employee but is not doing their research at UKHC does not need NRC approval.						
Clinical Trials.gov						
Does your study need to be registered on ClinicalTrials.gov? If you have any questions						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
about ClinicalTrials.gov, please contact UK's Clinical Trials Compliance Administrator.						
If yes, what is the assigned NCT number (found within your ct.gov account)?						
Institutional Biosafety (IBC) (if applicable)						
Does the study need to be registered with the Institutional Biosafety Committee (IBC)? For more information, http://ehs.uky.edu/docs/pdf/bio_ibc_registration_0001.pdf						
Has IBC approval been received?						
Radioactive Material						
Does your study involve the procurement, use, storage and disposal of radioactive material and radiation-producing devices?						
If yes, visit https://www.research.uky.edu/office-research-integrity/irb-application-instructions-radiation-safety for more information.						
Biobanking						
Will any biobanking be done as part of the research?						
If yes, has biobanking language been included in the consent?						
Genetic Testing						
Will any genetic testing be performed?						
If yes, has genetic testing language been included in your consent?						

Item	Yes	No	N/A	Date Received	Date Completed	Comments
TRAINING						
Human Subject's Protection (HSP) *All key personnel working on studies involving human subjects must complete HSP training. https://www.research.uky.edu/office-research-integrity/human-subject-protection-hsp-training-faqs*						
Have all key personnel completed HSP training?						
Responsible Conduct of Research (RCR) *All full-time faculty, staff, graduate students, and trainees (undergraduates, postdoctoral fellows, visiting scientists) who participate in research or creative work, including individuals supported in part or fully through research funding, grants, or contracts are required to complete the Responsible Conduct of Research (RCR) course initially and then every 2 years.*						
Have all required key personnel completed RCR training?						
Good Clinical Practice (GCP) (if applicable) *Individuals who are conducting research trials for drugs, biologics or devices should complete GCP training. GCP training is required for all NIH-sponsored studies and/or if you are using any CCTS services.*						
Have all required key personnel completed GCP training?						
DOT/IATA (if applicable) *The University requires all faculty, staff and students who are involved in any aspect of shipping dangerous goods (e.g., packing, labeling, transporting, etc.) to attend a DOT/IATA Initial Training course.* *The initial course is held in a classroom setting so class size is limited and pre-registration is required. Register at https://ehs.uky.edu/classes/classes_env_0001.php#dot_iata.*						
Have all staff shipping dangerous goods completed DOT/IATA training?						
Institutional Biosafety (IBC) (if applicable) *https://ehs.uky.edu/classes/*						
Have all required key personnel completed IBC training?						