



Membership Questionnaire

Instructions:

To initiate the process of membership in the Kentucky Clinical Trials Network, an initiative of the Kentucky Lung Cancer Research Program, please complete this form in its entirety and attach copies of the requested documents listed.

Submit your completed questionnaire and requested documents to the Kentucky Clinical Trials Network:

Kentucky Clinical Trials Network Coordinating Center
2317 Alumni Park Plaza, Suite 100
Lexington, KY 40517

Fax: 859-257-1343

Email: kris.damron@uky.edu

If you have questions or need assistance completing this form please contact the Network Coordinating Center Team at 859-323-1109.

Thank You!

Section 1: Institution/Facility Information

Please complete the following information regarding your institution/facility:

Institution or Facility Name: _____

Mailing Address: _____

City: _____
State: _____ Zip: _____

If the street address of your institution or facility is different than the mailing address, please list your exact street address: _____

Phone: () _____ Fax: () _____

Website: _____

Does your institution/facility practice at different physical locations or offices that you would like to include as research sites? Yes No

If yes, please provide the following: (attach additional sheets, if needed)

Name of additional location: _____

Mailing Address: _____

Phone:() _____ Fax:() _____

Is your institution/facility part of a hospital or healthcare system that administratively covers your practice? Yes No

If yes, please provide the following:

Name of Healthcare System: _____

Mailing Address: _____

Contact person for the Clinical Research Office or related Business Office at above-listed Healthcare System- Name: _____
Phone:() _____

Please briefly describe the cancer-related healthcare services available at your facility:
(ie., chemotherapy, radiation, surgery, palliative care, in-patient services, etc.)

Please briefly describe the research goals of your facility: (please identify any research training, continuing education, personnel and equipment needs)

Does your facility have a guideline or policy requiring or encouraging use of NCCN Clinical Practice Guidelines? Yes No

Section II: Patient Population

Please estimate the number of cancer patients seen at your facility annually:

Lung _____ Head & Neck _____ Cervical _____ Prostate _____
Esophageal _____ Bladder _____ Pancreatic _____
AML _____ Renal _____
Other tobacco-related cancers _____

Please categorize the number of lung cancer patients seen at your facility annually by stage:

Stage IA: _____ Stage IB: _____ Stage IIA: _____ Stage IIB: _____
Stage IIIA: _____ Stage IIIB: _____ Stage IV: _____

Section III: Investigators

Please complete the following information for each physician at your institution/facility interested in participating in clinical trials through the Kentucky Clinical Trials Network. (attach additional copies of pages 4 & 5, as needed)

Name: _____

Phone: () _____ Fax: () _____

Cell/Pager: () _____

Email: _____

Mailing Address: _____

(if different than facility address) _____

City: _____

State: KY Zip: _____

Medical Specialties (check all that apply):

- | | | |
|--|---|---|
| <input type="checkbox"/> Hematology/Oncology | <input type="checkbox"/> Hematology | <input type="checkbox"/> Medical Oncology |
| <input type="checkbox"/> Pediatric Oncology | <input type="checkbox"/> Gynecologic Oncology | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Family Practice | <input type="checkbox"/> Internal Medicine | <input type="checkbox"/> Pulmonary |
| <input type="checkbox"/> Urology | <input type="checkbox"/> Radiation Oncology | <input type="checkbox"/> Critical Care |
| <input type="checkbox"/> Palliative Care | <input type="checkbox"/> Other specify: _____ | |

Board Certifications: (please check all that apply and list):

Board Eligible: _____

Board Certified: _____

Please indicate this physician's research interests: (check all that apply)

By cancer type:

- | | | | |
|-------------------------------------|--------------------------------------|---|-----------------------------------|
| <input type="checkbox"/> Lung | <input type="checkbox"/> Head & Neck | <input type="checkbox"/> Esophageal | <input type="checkbox"/> Cervical |
| <input type="checkbox"/> Pancreatic | <input type="checkbox"/> Bladder | <input type="checkbox"/> Prostate | |
| <input type="checkbox"/> AML | <input type="checkbox"/> Renal | <input type="checkbox"/> Other tobacco-related cancers: _____ | |

Treatment Type:

- | | | |
|---|--|--|
| <input type="checkbox"/> Therapeutic Intervention | <input type="checkbox"/> Screening/Early Detection | <input type="checkbox"/> Supportive Care |
| <input type="checkbox"/> Prevention/Intervention | <input type="checkbox"/> Epidemiological/Observational | |

Does this physician have prior clinical trials experience? Yes No

If Yes, how many years experience? _____

If No, skip to bottom of page 5, "Required Documents".

What type of research does this physician conduct? (check all that apply & estimate number of trials conducted in the past five years)

- Industry: _____ Cooperative Group: _____ Investigator-Initiated: _____
 Phase I: _____ Phase II & III: _____ Phase IV: _____
 IND: _____ IDE: _____ Externally Peer Reviewed

How many of the above-noted trials have the physician served as:

Principal Investigator: _____ Sub-Investigator: _____

Is this physician and/or this facility/institution part of a cooperative group? Yes No

Is yes, with whom is the affiliation? _____

How many patients does this physician **currently** have enrolled in clinical trials(active therapy)? _____

In the past year, has this physician met projected enrollment numbers? Yes No

Please identify any enrollment/recruitment difficulties and specify any assistance we may provide you:

Has this physician ever been audited by the FDA? Yes No

If yes, how many times? _____

What was noted on the 483(s) (Inspectional Observation)?

Please check all that apply:

- No Action Indicated (NAI) Voluntary Action Indicated (VAI)
 Official Action Indicated (OAI)

Did physician receive a Warning Letter?

- Yes; please attach copy. No

Did physician receive a Notice of Initiation of Disqualification Proceeding and Opportunity to Explain?

- Yes; please describe: _____ No

Has this physician ever been "Debarred", "Disqualified", "Restricted", or "Restricted with Assurances" by the FDA from participating in research?

- Yes; please describe & supply dates: _____ No
-

Required Documents - For each physician listed, please attach the following documents:

- **Curriculum Vitae – signed and dated in upper right hand corner**
- **Copy of current medical license (front and back)**
- **Copy of Human Subjects Protection Training Certificate**

These documents are required for all physicians as part of membership. To maintain membership a CV must be submitted every two years, and medical licensure prior to the expiration date.

Section IV: Research Team

Please identify members of your research team and provide their responsibilities related to clinical trials.

Name: _____ Yrs. Research Experience: _____

Title: _____ Degrees/Certifications: _____

Research Responsibilities: (check all that best describe responsibilities)

- Research Director Research Manager Research Nurse Study Coordinator
 Data Manager Research Associate Research Analyst Regulatory Coordinator
 Phlebotomist/Specimen Coordinator Other, please identify: _____

Phone: () _____ Cell/Pager: () _____

Fax: () _____ Email: _____

Name: _____ Yrs. Research Experience: _____

Title: _____ Degrees/Certifications: _____

Research Responsibilities: (check all that best describe responsibilities)

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Data Manager Research Associate Research Analyst Regulatory Coordinator

Phlebotomist/Specimen Coordinator Other, please identify: _____

Phone: () _____ Cell/Pager: () _____

Fax: () _____ Email: _____

Attach additional pages as needed to identify all research personnel.

Please attach a copy of a Human Subjects Research Protection training certificate for each person listed.

Section V: Investigational Product

Does site have a pharmacy that will handle investigational product storage, preparation, and accountability? Yes No

Will investigational products be managed by a pharmacist? Yes No

Please provide contact information for the person responsible for investigational products:

Name: _____ Credentials: _____

Phone:() _____ Fax:() _____

Delivery/Mailing Address: _____

City: _____

State: KY Zip: _____

Does site have secure storage facilities for the storage of investigational products? Yes No

Does site have a secure freezer for the storage of investigational products? Yes No

Does site currently have a manual defrost freezer (either -20° C or -70° C) that can be used for frozen sample storage? Yes No

Does site currently have a refrigerator in a secure location that can be used to store investigational products? Yes No

Are the temperature and access to all of the above freezer(s) and/or refrigerator(s) monitored? Yes No

Section VI: Laboratory

Does site have on-site phlebotomy services? Yes No
(collect and centrifuge blood serum/slides)

Does site have on-site laboratory facilities? Yes No

Has site ever worked with a central laboratory? Yes No
If yes, please list: _____

Does site have access to dry ice for the shipment of frozen samples? Yes No

Does site have a person trained and certified to ship biological specimens (Hazardous Materials, Dangerous Goods Shipping) as required by DOT and IATA in accordance with 49 CFR 172.704 and IATA DGR Section 1.5? Yes No

Does site have access to a pathologist to prepare and ship specimens, if required? Yes No

Please attach copies of current certifications that apply to your site and personnel:

- CAP and CLIA lab Certificates
- Haz Mat Shipping Certificate

Section VII: Institutional Review Board (IRB)

Does your Site have an OHRP Federal Wide Assurance (FWA)? Yes No
If yes, please provide the assurance number: _____

If your site is not physically located at the institution/site of the FWA IRB, is there a non-institutional agreement covering your clinic/office? Yes No

Does your site have an IRB? Yes No
If yes, please provide the following information for your site's IRB.

Check if you utilize a Central IRB:

Contact information for IRB:

IRB Name: _____

Address: _____

City: _____

State: _____ Zip: _____

Chairperson: _____

Email: _____

Phone:() _____ Fax:() _____

How often does the IRB meet?

Weekly Monthly Quarterly Other, specify: _____

What is the typical turnaround time for approving protocols and informed consents (from original submission to final written approval)? _____

Does your IRB charge a submission fee? Yes, please specify: _____ No

Does your site require an internal scientific review of the protocol?

Yes No

If yes, how often does the review committee meet? _____

What is the estimated turn around time? _____

Section VIII: Information Technology

Does your institution/facility have Internet access? Yes No

If Yes, check type of connection:

Modem (dial-up) Cable DSL T-1 (high speed)

Other (specify) _____

What computer operating system does your site use (windows 98, XP, Mac OSX, etc)?

Do you have information technology/computer support for your facility? (dedicated staff to assist you with computer problems) Yes No

What type of patient medical record does your site maintain?

Paper Electronic Both

If electronic/both please describe the system: _____

Is this system 21 CFR, part 11 compliant? Yes No

Research Personnel:

Do research personnel have access to a computer for daily use? Yes No

Have research personnel utilized any form of Electronic Data Capture? Yes No

Do the research personnel at this site have previous experience using Interactive Voice Response Systems (IVRS) for randomization or study activities? Yes No

Section IX: Confidentiality and Document Storage

Do you agree to ensure the security & confidentiality of research documents? Yes No

Do you agree to retain study documents for period of time determined by the Kentucky Clinical Trials Network? Yes No

(If retention requirements specified in other statutes or external agency's regulations are longer, the agency requirements will apply).

Kentucky Clinical Trials Network

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Version 2.0

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