

Policy & Procedures

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Article 1. The Kentucky Ambulatory Network (hereafter referred to as KAN) is housed in the Division of Community Medicine/Department of Family & Community Medicine of the University of Kentucky College of Medicine (UKCOM).

Section 1.01 Mission

- (a) KAN seeks to enhance the ability of office-based clinicians to deliver high-quality primary health care to their patients through collaborative and translational research conducted in primary care practices.

Section 1.02 Vision

- (a) To be a national leader in practice-based research.

Section 1.03 Goals

- (a) To maintain and grow KAN by creating and maintaining relationships with researchers, primary care clinics and systems, and clinicians throughout Kentucky.
 - (i) Objectives
 - 1) Maintain a working relationship with all colleges of the University of Kentucky and external partners.
 - 2) Establish and develop new relationships with clinical practices and health organizations that share the same purpose and mission of the network.
 - 3) Retain researchers, clinics, and practitioners as KAN members.
- (b) To develop areas of research priorities based on the needs and interests of the Kentucky community and the members of KAN.
 - (i) Objectives
 - 1) Create and maintain a database of all members of KAN, including areas of research interest.
 - 2) Collect patient demographic and clinical data among participating clinics and entities of KAN.

- (c) To offer research resources to researchers, clinicians, and partners of KAN.
 - (i) Objectives
 - 1) Support the KAN Advisory Board (KAB).
 - 2) Offer advice and expertise for all stages of research development, implementation, and dissemination.

- (d) To maintain a forum for members of KAN to communicate and express research interests, including dissemination of research findings.
 - (i) Objectives
 - 1) Maintain and update a KAN website and list serve that functions as a mode of communication and information dissemination.
 - 2) Distribute a quarterly electronic newsletter that will display ongoing activities and achievements of KAN.
 - 3) Conduct a yearly KAN conference that allows members to participate.

Article 2. KAN Advisory Board

Section 2.01 Overview

- (a) The function of the KAN Advisory Board (KAB) will be to review and approve or disapprove any research proposal that has the intent to utilize network resources. In addition, the board will oversee and uphold the implementation of the policies and procedures of KAN. All members of these boards are seated on a voluntary basis and may include representatives of any KAN partner.

KAB – This board will be responsible for ensuring that a study’s proposal is consistent with the mission, vision, and goals of KAN. More importantly, the board represents the various communities of its members. Hence, these members serve as advocates and will assess the proposal’s importance to their community and the community of the intended study, ensuring that the study is performed ethically and with the community in mind.

Section 2.02 Members

- (a) Members of the KAB will represent the various segments and partners of KAN. Each member of the board is serving on a voluntary basis. The KAB will have one chairperson as well as members representing various communities and KAN partners. The KAB chairperson can be nominated or self-nominated and vote by the KAB.

KAB – This board will consist of members from Kentucky communities and KAN partners. There is no limit in the number of board members.

- (i) KAB Chair
- (ii) KAN Director
- (iii) KAN Coordinator
- (iv) Community partners

Section 2.03 Governance

- (a) All meetings will follow Robert's Rules of Order. Each meeting will be led by the board's chairperson. The board will meet twice a year, with at least one meeting being in-person.

Section 2.04 Selection

- (a) Each member of the board will hold at least 3-year terms. There is no limit to the number of terms each member may hold. Selection will be based on invitation by board members or the KAN Director to ensure adequate representation of KAN. The Chair of the KAB will serve a 1-year term. There is no limit to the number of terms each member may hold.

Article 3. KAN Organization

Section 3.01 The administrative structure of KAN may change based on the resources that are allocated and secured by KAN. At a minimum, there is a KAN Director and supported by at least one staff position.

Article 4. KAN Membership

Section 4.01 Overview

- (a) Membership to KAN is completely voluntary. All members must meet the criteria listed below.

Section 4.02 Definition/Criteria

- (a) A member must be:
 - (i) A clinician (MD, DO, PA, NP, RN) in primary care which includes family medicine, general internal medicine, geriatrics, general pediatrics, obstetrics/gynecology, or a research/health care professional (PhD, DrPH) or health administrator.
 - (ii) Willing to fill out the required membership form to provide information about their training, demographic characteristics, and experience.
 - (iii) Willing to designate one member of the practice or system as the contact member who must fill out a second form describing characteristics of the practice.
 - (iv) Willing to display a furnished certificate in the waiting room of the practice that identifies the site as a KAN member clinic.
 - (v) In agreement that participation in KAN studies affects practice routines in varying degrees. Studies may ask for completion of brief data collection forms (only part of which needs to be filled out by the practitioner). Some studies require informed consent from parents and/or patients. However, minimal disruption to the clinician's busy clinic schedule is one of KAN's highest priorities.
 - (vi) In agreement that KAN practices are not required to participate in all studies, but are expected to remain active in the network by participating on a regular basis when available and requested.

Section 4.03 Recruitment

- (a) All clinicians contacted by KAN will have the option to join on a voluntary basis. KAN continually recruits all practices located in the Commonwealth of Kentucky.

Section 4.04 Community Faculty Assignment

- (a) KAN members who do not have an appointment with the UKCOM may have the opportunity to apply for a community faculty position with the UKCOM. Any member who has interest in applying for community faculty status may initiate the process by sending a letter of intent to the KAN Director.

Section 4.05 Retainment

- (a) Retention of members will be a high priority for KAN. This will be accomplished by ensuring that the resources for members are available and adapted over time as the needs of members change.

Section 4.06 Withdrawal from KAN

- (a) Any member may withdraw from KAN at any time. It is preferable that a member withdraw when there are not active studies at their site. Withdrawal may occur by simply contacting any staff member of KAN. A confirmation letter regarding intent to withdraw from KAN will be sent to the member.

Article 5. Research Policy

Section 5.01 Research Priorities

- (a) The KAN Director, staff, member clinicians/partners, and board members determine the research agenda of KAN. The interest and dedication of the member clinicians are crucial for research projects to succeed. The opinions of members will be regularly solicited over time through surveys, e-mails, and meetings.
- (b) Study proposals submitted to KAN by principal investigators must be aligned with KAN's mission, vision, goals, and current research objectives. The total body of work undertaken by KAN will be consistent with the following principles. Projects must:

- (i) be designed and implemented collaboratively with KAN
- (ii) address a question of importance to primary care and public health
- (iii) have the potential to influence practice and health care delivery
- (iv) have the support and interest of the members and partners of KAN
- (v) be led by an experienced principal investigator or co-investigator
- (vi) have adequate funding as determined by KAN
- (vii) have the potential for scholarly outcomes

Section 5.02 Submitting a Research Proposal

- (a) All potential research projects must be formally proposed to the KAN Director or designated staff member in writing. All projects must be screened by the KAN Director or designated staff member in order to utilize the resources provided by KAN. The KAN Director or designated staff member has the ability to refuse or accept any research proposals. Once a proposal is screened and allowed to proceed, the proposal, using the appropriate forms, will be sent to KAB members for final review.
- (b) Research proposals will be reviewed and voted upon by the KAB. A proposal must be approved by a majority of members from the KAB to become a KAN project. Voting may take place at regular board meetings or by e-mail. If a member is not present at the board meeting, he/she will be asked to vote by e-mail such that all board members will be given the opportunity to vote on all proposals. Board members will be given a set deadline to return their vote. A non-response within the designated time-frame for returning a vote is recorded as no objections to the study proposal.
- (c) Unless permitted by the KAN Director or designated staff, all research must be supported by funding. At times, the KAN Director or designated staff member understands that preliminary data must be collected for grant application purposes. Nonetheless, approval must be obtained from the KAN Director or designated staff member, with input from the KAB, when there is no funding to support the study.
- (d) All members of KAN who are participating in research projects

must complete Human Subjects Training.

- (e) When possible, the Principal Investigator of the research project should submit a summary of any grant application(s) which intends to use KAN resources prior to submitting the grant.

Section 5.03 Human Subjects Training

- (a) Any individual who participates in research projects as deemed appropriate, including all KAN member clinic sites, must complete Human Subjects Training which will be available through the University of Kentucky website.

Section 5.04 Study Conduct

- (a) Every study that is accepted by the KAN Director or designated staff member as well as the KAB must have a research team assigned with sufficient expertise in research methods and adequate statistical analysis.
- (b) A member external to the University of Kentucky serving as the principal investigator must complete a memorandum of understanding that must be signed before the commencement of a study.
- (c) Once a study proposal is accepted by the KAN Director or designated staff member as well as the KAB, the member investigator must first meet with the KAN Director or designated staff member and the appropriate KAN members to identify KAN assistance/resources required for the project. This meeting will include discussions on budgets, study design, timeline, grant writing processes, IRB processes, study methods, and publication/presentation procedures for the accepted research proposal. At any time, if deemed warranted, the KAN Director, designated staff member, or KAB may terminate KAN's involvement (resources, assistance, subjects, etc.) in a research project if patient safety is at risk, inappropriate or unethical research methods are being conducted, or if the best interests of KAN and its members are neglected or unattainable at the time of the research project.
- (d) Clear lines of authority and responsibility are necessary to facilitate communication among all members of the project team. This is particularly important when the project's principal investigators are

geographically disperse. Day-to-day operation of a KAN project will be guided by the following policies:

- (i) For each funded project, the Principal Investigator and KAN Director will jointly develop a specific implementation plan. Implementation planning will include clear lines of accountability for defined portions of the budget. Each individual will be responsible for their respective portion of the budget.
- (ii) Modifications and reallocations of funding dollars within a project budget period (even those permitted under expanded authorities) will be documented by the Principal Investigator and summarized in the annual progress report to the funding agency.

Section 5.05 Data Collection and Maintenance

(a) Clinic Sites

- (i) Anyone who is active in data collection, informed consent, or any part of a research study must have completed the Human Subjects Training.
- (ii) Every effort must be made to maintain a study participant's confidentiality. When possible, no personal identifying information should be collected or be made accessible to non-research staff.

(b) Data Storage

- (i) All data will be entered, summarized, and analyzed in centralized designated KAN offices. At times, analysis may be done in a consultant's or partner's location with whom an agreement of confidentiality is understood.
- (ii) All sensitive material will be located and stored in files located in a centralized KAN location or an approved partner location.

Section 5.06 Secondary Data

- (a) KAN will support and encourage researchers in the development, acquisition, and analysis of external data. The purposes may be for primary or preliminary studies including

student or resident research.

Section 5.07 IRB

- (a) All research projects that are accepted and performed within KAN will be approved by the Institutional Review Board (IRB) of the University of Kentucky and any other IRB board representing any outside partner. The policy and procedures of each IRB will be followed for any research project with human subjects that will be conducted by KAN.

Section 5.08 Grants and Funding

- (a) All research projects must be funded unless permitted by the KAN Director or designated staff. All grants must designate KAN and the University of Kentucky College of Medicine and any collaborating partner as the institute(s) that the research is being conducted through. Any disbursement of funds that are designated within the initial grant will be completed through the Office of Sponsored Projects Administration of the University of Kentucky or equivalent office at a partner's institution if the Principal Investigator is from another institution. An external agreement must be signed and completed through such an office if such funds must be distributed.
- (b) The KAN Director is ultimately responsible for the success of each project and the overall well-being of KAN. The following policies are intended to provide the KAN Director with adequate oversight of project activities.
 - (i) The KAN Director and KAB must approve modifications in study protocols.
 - (ii) Modification in the budget that moves funds from one project component (as defined in the implementation plan) to another must be agreed upon by the KAN Director and the PI to ensure feasibility and completion of the project.
 - (iii) The KAN Director has the authority to establish and enforce administrative procedures that minimize the vulnerability of KAN and its members in the financial and administrative management of federal research grants.
 - (iv) The Principal Investigator can appeal the KAN Director's decision in writing. The appeal should be sent to the KAN Director and will be reviewed by the KAB.

Section 5.09 Student Research

- (a) KAN promotes student and resident primary care-related research projects
- (b) Pre-doctoral, medical, and public health students, as well as postdoctoral fellows and residents of UKCOM or KAN partners may utilize KAN resources under the following conditions:
 - (i) A proposal defining the goals of the research project shall be completed by the student or resident.
 - (ii) The proposal may be submitted for approval to the KAB if the student's project is an original study utilizing KAN resources.
 - (iii) All research activities related to the approved research project shall adhere to the policies governing KAN research (Article 5) and scholarly outcomes (Article 6).

Article 6. Publication and Presentation Policy

Section 6.01 Published Reports

- (a) KAN expects all of its research to result in publishable reports in the academic press. All Principal Investigators must adhere to the following:
 - (i) The KAN Director and Principal Investigator must meet to establish a reasonable timeline to submit a publishable manuscript to a peer reviewed journal for each KAN project. The timeline will take into account project specific circumstances such as data collection and analysis.
 - (ii) All manuscripts must be reviewed and approved by the KAN Director or designated staff member to ensure KAN is credited for its involvement and the quality of the manuscript is appropriate. The Principal Investigator, however, retains all rights and privileges to the manuscript.
 - (iii) The Principal Investigator is responsible for the accuracy of the data results and its interpretation.
 - (iv) All manuscripts, publications, and presentations must acknowledge KAN in their work.

Article 7. Communication and Exchange

Section 7.01 Website/Internet/List-Serve Services

- (a) A website for KAN provides information and enables the exchange of information with members of the KAN community, prospective members, and the general public.
 - (i) The KAN website will:
 - 1) Be maintained by a faculty or staff member on the KAN team to ensure that the website remains dynamic.
 - 2) Provide a link to primary care related resources.
 - 3) Facilitate better institutional and community communication both internally and externally via the web.
 - (ii) The List Serve
 - 1) The KAN Listserv is a moderated, electronic mail distribution list for KAN members. It is used to disseminate notices regarding conferences and workshops, data availability, calls for papers, positions available, etc., as well as requests for information.
 - 2) The purpose of the KAN Listserv is to foster discussion of primary care research among KAN members and serve as a means of disseminating KAN information. Information provided by members is for reference purposes only and is not to be used for research projects, books, or other potentially profit-making endeavors without written permission of the author of the original post. The messages posted are the opinions of individual members and not the opinions of KAN.

Section 7.02 Meetings

- (a) The KAN meetings are utilized to review KAN research activities and any other KAN business.
 - (i) It is the responsibility of the board chairperson to convene meetings of KAN and to keep minutes of KAN meetings as well as documentation of KAN decisions. This will be done with assistance of KAN staff.
 - (ii) It is the responsibility of KAN board members to attend regularly convened meetings.

- (iii) The KAN staff is responsible but not limited to coordinating the KAB and other KAN meetings. It is also the KAN staff member's responsibility to record and transcribe minutes as well as maintain records of all meetings.

Section 7.03 Other Forms of Communication

- (a) KAN will openly communicate with its members on what research and scholarly activities are being done within KAN.
 - (i) KAN will maintain an electronic newsletter (The KAN Newsletter) to be mailed/emailed out regularly to all members and partners of KAN.
 - (ii) Per Section 6.01, KAN will develop and maintain a Listserv for its members.
 - (iii) KAN has a website, <http://www.mc.uky.edu/kan/index.asp> to disseminate research information and provide resources.

Article 8. Library Liaison

- (a) KAN will have a designated library liaison to help in the dissemination of library services to network members.

Article 9. The Policy and Procedures of KAN are consistent with the University of Kentucky policies and of the State of Kentucky and federal regulations.