KCMC Clinical Trials Unit	STANDARD OPERATING PROCEDURE	Effective Date	SOP-Number CTU 08-01
		Page 1 of 8	16 OCT 2006

Title: SUBJECT RECRUITMENT

SOP References: **Supersedes: N/A**

Author/Date: **Julieta Giner, RN**

Approvals/Date:

_____

John Crump, MB, ChB, DTM&H
KCMC-Duke Collaboration Site Manager

_____

John A. Bartlett, MD
KCMC-Duke Collaboration, Site Principal Investigator

	Review Date	Revision Date	Signature
Annual Review:			

Document History:

Version Number	Reason for Changes	Date
CTU 08-01	Initial release	16 OCT 2006

Title: SUBJECT RECRUITMENT

SOP References: **Supersedes: N/A**

Distributed to:	Name/Location	# of Copies	Name/Location	# of Copies

PURPOSE: Effective subject recruitment is critical in obtaining medical knowledge for best practice(s) in prevention, treatment, and disease management. It is important that the affected population is represented in all its diversity. Historically, special populations, such as seniors, women, children, and disadvantaged ethnic and racial communities were either not included in research or suffered greater risk than other populations who benefited from the scientific knowledge gained. Federal and international regulations governing human research were refined in the 1970s to protect human research subjects and to ensure equitable selection in the recruitment of study participants. In 1993 the National Institutes of Health (NIH) mandated that special populations be included in NIH-sponsored studies to allow them the same potential benefit of knowledge gained, including determination of whether various racial groups, gender and age-groups responded the same. The ability to effectively recruit study subjects that represent the community where the research is being conducted requires an understanding of belief systems within special populations and potential barriers to recruitment. Some problems and barriers that may exist are: distrust of institutions; ethical considerations; including the right of the subject not to be coerced into participating; cultural issues exacerbated by socio-economic disparities; language barriers; time and travel requirements; and role within the family/community. On the positive side, clinical research often times provides free or affordable medical care and referral for health management that special populations may be unable to access otherwise.

POLICY: The Principal Investigator, Clinical Research Coordinator and Research Nurse are responsible for recruiting subjects onto research studies approved by the Sponsor and Regulatory Authorities, in accordance with protocol specifications, US and local Federal agencies, Sponsor, Institution, and Institutional Ethics Committee(s)' regulations and guidelines. The Principal Investigator, Clinical Research Coordinator and Research Nurse will work together with the medical and greater community, or representatives of the community (Community Advisory Board) to educate and recruit research subjects. The Principal Investigator will sustain relationships and communications with community members throughout the research process.

RESPONSIBLITY: Principal Investigator, Clinical Research Nurse, and Research Nurse

A. DEFINITIONS:

Advertisement: A tool used for soliciting research subjects. Advertisement includes any material received by the public to encourage participation in research studies, including: posters, brochures, letters, radio and newspaper print. Advertisement soliciting research subjects must be reviewed and approved by the Institutional Ethics Committee prior to use, and should be limited to: the name and address of the clinical investigator, location and purpose of the study, eligibility criteria, and truthful description of benefits, such as free treatments.

Authorized Representative for Incapacitated Adult Subjects: Federal regulations that govern research involving human subjects define a legally authorized representative as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Individuals entitled to authorize consent to medical treatment generally have the authority to provide consent on behalf of another adult for participation in clinical research presenting the prospect of therapeutic benefit to the subject. These include: 1) Court-approved guardian; 2) health care agent; 3) spouse; 4) adult son and/or daughter; 5) parent; 6) adult brother and/or sister; 7) uncle and/or aunt; or 8) other adult kin.

Coercive: Undue influence that undermines free will and respect of the rights of an individual.

Confidentiality: The duty to protect private information. As applied to the medical profession, confidentiality is the act of maintaining personal information of patients and research subjects in confidence, preventing disclosure to others outside the immediate healthcare team unless authorized by the patient/research subject, or as required by Local or Federal law. Confidentiality also applies to accessing only what one is authorized to access and maintaining proprietary information belonging to an individual, organization or sponsor in confidence.

Community: A body of people having common rights, privileges, or interests, or living in the same place under the same laws and regulations.

Community Advisory Board (CAB): A group composed of community members who share common identity, history, language, culture or interests. Community Advisory Board Members come from the same community that they represent and serve as a liaison between the community and the organization. In clinical research, the CAB can help in the development of materials that explain the study to participants and can represent the participants' concerns to the researchers. The CAB can act as an advocate for the rights of human subjects, for greater access to treatments, or to help potential participants decide whether or not to participate in a clinical research study.

Food and Drug Authority: Public health agencies of the US and Tanzania that are charged with protecting its citizens by enforcing related public health laws that include use of biological agents in clinical research in human subjects and approval of medications for consumers.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

Human Subject: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or patient.

Incentives: Financial or in-kind payments (such as transportation, food, phone cards, vouchers, etc.) to human subjects for participation in research studies. Incentives are considered a recruitment tool. Research volunteers may be offered compensation for potential discomfort that they may endure as a participant in an investigational trial and for the amount of time that they must dedicate to the trial. Incentive information, including the type, amount and schedule of payment(s), as well as any possible costs to research volunteers must be approved by the regulatory bodies, and discussed and documented with potential participants during the informed consent process. Incentives cannot be so enticing (considered coercive) as to interfere with the free will of volunteering for participation in human research.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a signed and dated. (See Informed Consent Process SOP.)

Institutional Review Board (IRB) or Institutional Ethics Community (IEC): Multidisciplinary and multisectorial committee charged with continuous review and providing approval for all research protocols involving human subjects performed by members of the Institution. IRB/IEC are guided by ethical principals and regulations/laws set forth in the protection of human subjects. IRB/IEC consider: established regulations; risks to the subject; anticipated benefits to the subjects and others; reasonable importance of the knowledge to be gained; and, the informed consent process to be used.

Medical (Personal) Identifiable Information: Any information collected by health care provider or health plan that identifies the person, such as: name; phone number(s); address; dates, such as: birth date and dates of appointments; contact information; hospital record number; and, photographs.

Special Populations/Vulnerable Subjects: Individuals who may be at a disadvantage, whether real or supposed, compared to other prospective human subjects in their ability to voluntarily consent to whether or not to participate in a clinical trial. This may include individuals who are unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy if they refused to participate. Other examples of vulnerable subjects include: members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, persons kept in detention, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

B. PROCEDURES:

1. Patient Recruitment:

a. Collaboration:

i. The Principal Investigator, Clinical Research Coordinator and Research Nurse will collaborate with the IEC/IRB, Community Advisory Board,

Primary Care Provider, and community-at-large, through advertisement, meetings and health fairs for referrals of subjects to the clinical trials unit.

ii. The Research team will continuously update the IEC/IRB, medical community, participants, and community-at-large of research status and findings.

iii. The Clinical Research Coordinator (or designee) will maintain and supply demographic data for each research protocol to the IEC/IRB in order to document efforts in equitable subject selection. If demographic data reveals an unbalanced selection of eligible research participants, the Principal Investigator, Clinical Research Coordinator and Research Nurse will work together with existing medical services and the Community Advisory Board in identifying barriers and finding solutions.

b. Tools & Resources:

i. The Principal Investigator, Clinical Research Coordinator, Research Nurse and Community Advisory will develop and implement the use of approved recruitment tools, such as: advertisement, meetings, educational forums, and Provider referrals to recruit patients onto clinical trials.

ii. The Clinical Research Coordinator and Research Nurse Chart will conduct chart review and database searches in order to identify eligible research participants. Chart review and database searches will be conducted under applicable regulations and may require written approval either from the patient or approval from the regulatory bodies prior to any identifiable information being collected.

iii. The Clinical Research Coordinator (or designee) will not initiate contact with potential study participants until either the Primary Care Provider has referred the patient to the research unit, or the patient has contacted the Clinical Research Coordinator (or designee) directly. When subject's self-refer, the research team will act to obtain medical history and approval from the patient's primary provider, documenting all such efforts.

c. Recruitment Packet: The Clinical Research Coordinator and Research Nurse will provide potential study candidates with approved protocol-specific patient education material, a copy of the informed consent, information about healthcare management, general clinical trials information, and contact information.

d. Informed Consent Process: The Clinical Research Coordinator and Research Nurse will implement the informed consent process, including assessment of the capacity of the potential research subject to understand and provide legal consent, discussion, review and documentation of the informed consent process. (See Informed Consent Process SOP.)

This SOP has been read and understood by:

Name	Date
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	