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* * * Personnel Information * * *

Principal Investigator

UMKC defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.

Name of Principal Investigator	Degree (MD/PhD/BSN/etc.)	Title
Winders, Chris		Director
Email	**Phone**	**Fax**
eprotocol1@keyusa.com	816-235-5370	
Research Department	**UMKC Status** Check ALL that apply	**Mailing Address**
	Faculty	
	Staff	
	Other	

ALL research personnel are required to complete Human Subject Research training from CITI within the last 2 years prior to engaging in any research-related activities. Go to CITI Program to complete.

The Research Compliance Office will verify the last date of completion below.

CITI Training Date	Type of CITI training completed.

Starred items indicate required fields whenever that section is completed.

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* * * Subject Checklist * * *

Subject Checklist

Select All That Apply :

- Children under 18
- Pregnant women
- Fetuses/neonates
- Prisoners

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Military personnel
Adult Volunteers
Economically/educationally disadvantaged
Mentally Ill
University students
University employees
Illiterate
Homeless
Public officials/candidates for public office
Institutionalized patients/residents
Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
Healthy Individuals
Other (please specify):

---

* * * Study Location * * *

Study Location

Select All That Apply - NOTE: Check "Other" and input text: 1.) If your study location is not listed, or 2.) If you would like to list details of your already-checked location (e.g., specific school within a school district)

UMKC
Truman Medical Center (TMC)
Children's Mercy Hospital (CMH)
Other University/College
Other Medical/Health Care Facility
School/School District
Other (please specify)

Has this protocol been submitted to any other Institutional Review Board not listed above?

Is this a multi-site project? (A multi-site study is one where different PIs at different institutions are conducting the same study or aspects of the same study.)

Will UMKC function as the coordinating center or lead institution?

(Please submit an IRB approval or Letter of Permission/Support from TMC or CMH if applicable, and for any site not under the jurisdiction of the UMKC IRBs.)

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* * * General Checklist * * *

General Checklist

Select All That Apply :

IRB Authorization Agreement (Please upload completed IAA form in Attachments section.)

Federally Sponsored Project

Program Project Grant

Training Grant

Industry-Sponsored Clinical Trial

Project is associated with the School of Public Health (faculty and/or student)

Cooperating/Collaborating Institution(s) Institution where recruitment will occur
OR Institution where Collaborating PI will conduct associated research.

Interview

Questionnaire/Survey

Subjects will be compensated for participation

Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval in Attachments section.)

Radioisotopes/radiation-producing machines, even if standard of care
If applicable, PI should check with the RSC Compliance Officer to determine whether or not an application needs to be submitted to RSC.

Human blood, cells, tissues, or body fluids
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Tissues to be stored for future research projects
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Tissues to be sent out of this institution as part of a research agreement
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Human Embryos
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Use of Patient related equipment? If Yes, specify what equipment is being

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used.

Medical equipment used for human patients/subjects also used on animals. For questions regarding animal use approval, contact Jodi Troup, IACUC Compliance Officer: troupj@umkc.edu or 816 235-5669.

Protocol involves studying potentially addicting drugs.

Investigational drugs, reagents, or chemicals

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)

Investigational Device

This study involves drugs or devices regulated by FDA

Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).

Is the study posted on www.ClinicalTrials.gov?

If Yes, Specify number:

If No, Explain the reason below.

Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.

The principal investigator or other research personnel have a financial, personal, or professional conflict of interest related to the study as defined in UMKC's Conflict of Interest Policy.

Class Project

Other (clarify in text box to the right)

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* * * Funding * * *

NONE--This project does not have any funding. If you want to add Funding for the study, please uncheck "NONE."

Funding

Add external and internal grant funding source(s) below: Federal Government, Other Gov. (i.e., State, local), Foundation or Other. Select "None" above if there is no external funding for the study.

UM Research Board

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Federal Government

Other Gov. (i.e., State, local)

Foundation

Other

Funding for this study was secured by the UMKC Grants Management Office

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*** * * Expedited Paragraphs * * ***

PLEASE READ: For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.

Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application.If none of the expedited criteria are appropriate for your project, please move to the next screen WITHOUT checking any of these criteria; your protocol will be reviewed by the full IRB. Note: The IRB will make the final determination if your protocol is eligible for expedited review.

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) and (b) are met.

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

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b) Research on medical devices for which

i) An investigational device exemption application (21 CFR Part 812) is not required; or
ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. **Prospective collection of biological specimens for research purposes by non-invasive means.**

Examples:

a) Hair and nail clippings in a non-disfiguring manner;

b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

c) Permanent teeth if routine patient care indicates a need for extraction;

d) Excreta and external secretions (including sweat);

e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

f) Placenta removed at delivery;

g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more

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invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

j) Sputum collected after saline mist nebulization.

4. **Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b) Weighing or testing sensory acuity;

c) Magnetic resonance imaging;

d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimen) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects - 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

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46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b) Where no subjects have been enrolled and no additional risks have been identified; or

c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

---

* * * Summary,Purpose,Background,Study Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

blah

Complete Sections 1 - 16. Specify N/A as appropriate. Do not leave any required sections blank.

1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

3. Background

a) Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

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4. Study Procedures (If this is a student project, the methods section of the thesis or dissertation proposal must be attached in section #16 - Attachment section.)

a) Describe sequentially and in detail ALL procedures in which the research subjects will be involved.

- Include how the data will be collected (i.e. in person or online), number of sessions, amount of time per session, and duration or period of time over which the research will take place, etc.
- For school-based research where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and non-subjects will be located during the research activities.
- Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.
- Use any diagrams, charts or tables necessary to make subject participation clear to readers. Attach additional pages if necessary.
- Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.

Please note: Do NOT respond "See Attachment Section". If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).

b) Alternative Procedures. Describe alternative procedures, if any, that might be advantageous to the subject. Describe the important potential risks and benefits associated with the alternative procedure(s). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.

c) Will subjects be followed after their active participation is complete?

If yes, explain why and describe how:

d) Will subjects have access to the study treatment/procedure after completing the study?

If yes, explain why and describe how:

e) Will subjects be audio recorded?

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f) Will subjects be videotaped?

g) Will subjects be photographed?

(Explicit consent must be obtained for the use of any of these methods.)

h) Study Endpoint. What are the guidelines or end points by which you can evaluate the alternative treatments during the study? If one treatment proves to be clearly more effective than another (or others) will the study be terminated before the projected total subject population has been enrolled? When will the study end if no important differences are detected?

i) Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).

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* * * Drugs and Devices * * *

5. Drugs and Devices

Device

Will the study be registered on an online website?

If yes, state which website(s):

If no, explain why not:

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(If the study will be registered on ClinicalTrials.gov, the consent form must contain the required language about it.)

---

* * * Subject Population (a-d) * * *

6. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include requested participant number and description of each group requested). (Input N/A if not applicable)

a) Requested Participant Description (Include number of participants that you plan to study and description of each group requested, if applicable).

b) What is the rationale for studying the requested group(s) of participants?

c) If women, minorities, or minors are intentionally excluded, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. N/A

d) State if any of the subjects are students, employees, or laboratory personnel. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it. N/A

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* * * Subject Population (e-h) * * *

6. Subject Population (Input N/A if not applicable)

e) Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)

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Identify inclusion criteria.

Identify exclusion criteria.

f) Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire) in the Attachment Section (#16).

g) Will bilingual or multilingual subjects be recruited?

h) Will non-English speaking subjects be recruited?

If yes, state language(s) spoken (other than English):

---

* * * Subject Compensation and Costs,Recruitment Process * * *

7. Subject Compensation and Costs Section

a) Will subjects receive compensation for participation?

Total amount (in dollars or equivalent)

b) Form of Compensation:

- N/A
- Cash
- Check
- Gift card/certificate
- Voucher
- Raffles/lotteries
- Course/extra credit
- Reimbursement only
- Other (please specify):

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c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

d) For raffles include the number of prizes, nature and value of each prize.

e) For course or extra credit, describe the available alternatives to participation in the research.

f) Will subjects or their health care providers be required to pay for any study related procedures or products?

If yes, explain:

g) Who is responsible for costs incurred due to injury/harm?

8. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- List any specific agencies or institutions that will provide access to prospective subjects.
- Identify who will contact prospective subjects and how.

b) Describe solicitation through the use of advertising. (Include plans for using posters, flyers, announcements, newspaper, radio, television or internet ads, face to face interactions, direct mail or phone contact, subject pools, etc.)

c) Planned Subject Identification Methods:

N/A

Direct advertising

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Chart/database review
Living conditions (e.g., nursing home residents)
Class participants
From PI's own practice/clinic
Circumstance (e.g., homelessness)
Referrals
Organization mailing lists
Other (please specify):

d) Planned Recruitment Materials/Methods:

N/A
Flyers/posters
Phone Scripts
Letters to providers/schools/organizations
Television ads
Newspaper ads
Letters to prospective subjects
Radio ads
Oral Scripts
PowerPoint presentations
Other (please specify):

***(All advertising must be submitted for review in its final printed/recorded form)**

e) Will the PI use a centrally coordinated advertisement program?

f) Will a central 800# facility be used for recruitment?

If yes, identify the calling company:

Note: Attach copies of ALL recruitment materials in the attachment Section

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* * * Risks * * *

9. Risks (Input N/A if not applicable)

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) **PI's evaluation of the overall level of Risk. (Please check one: minimal or > minimal.)**

Minimal (everyday living)
> Minimal (greater than everyday living)

b) **Discuss the risks of the proposed research. Specify the risks(s) associated with each procedure or test. Consider both physical and psychological/emotional risks. (If applicable, include possible breach of confidentiality.)**

c) **How will subjects be assessed for adverse events?**

d) **Is there a plan to monitor study data for subject safety?**
If yes, discuss who will monitor the study data and describe the monitoring plan:

e) **Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

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* * * Benefits * * *

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10. Benefits

a) Discuss any potential direct benefits to subjects from their involvement in the project that would justify involvement of subjects in this study.

b) Discuss any potential indirect benefits to society that would justify involvement of subjects in this study.

c) Briefly assess the risk/benefit ratio of the subject's participation. (Include consideration of alternative therapy, benefit to the class of patients, and benefits to society. Describe the subjects' alternatives to participation in the study.)

---

* * * Procedures to Maintain Confidentiality * * *

11. Procedures to Maintain Confidentiality

a) If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.

b) Explain how you will protect subjects' privacy.Note: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Please keep this definition in mind as you respond to this item.

c) Describe how you will maintain the confidentiality of subjects' information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.

d) Who will have access to study records or specimens? (Please identify specific team members by name.)

e) Will data be collected anonymously (i.e., NO identifying information from subjects will be collected, recorded, or linked to the study data)? If not, please explain.

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f) If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the proposed research. It includes data or specimens collected for research and non-research activities.

g) Will subjects be asked to give permission for release of identifiable data (e.g.,information, videotapes), now or in future? If so, explain here and include appropriate statements in consent materials.

h) If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?

i) If identifying information will be collected and linked to data/specimens, explain at what stage identifiers will be removed from the data/specimens. If identifiers will be retained, explain why this is necessary and how confidentiality will be protected.

j) If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.

k) Explain why, where, in what format, and for how long data/specimens will be retained. Data storage must comply with UM System data <a href="http://www.umsystem.edu/ums/fa/management/records/guide/rrg01801"target="_blank"> retention and <a href="http://infosec.missouri.edu/classification/"target="_blank"> security policies. Please contact UMKC Information Services with questions (email: callcenter@umkc.edu, phone: 816-235-2000).

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* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

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a) Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

b) Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

c) Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $10,000 during the previous 12 months or are expected to exceed $10,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $10,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

Minimizing Risks and Disclosure to Subjects

i) Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?

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If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

By submitting this form, you are attesting that you have read the UMKC HRPP Policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Link to UMKC's Conflict of Interest Policy: http://ors.umkc.edu/office-of-research-services/conflict-of-interest.

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* * * Informed Consent * * *

13. Informed Consent

See sample consent forms at http://ors.umkc.edu/research-compliance/irb/irb-forms

Please provide consent process background information below.

Informed Consent

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* * * Assent Background * * *

14. Assent Background

(Complete if applicable)

Assent Document: A form or script of the information that will be conveyed to the child about the study. In general, researcher must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent from suitable for a 17 year old is not usually suitable for a 7 year old child).

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Assent Waiver: No child assent will be sought at all. This means that the IRB is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefits that is important to the health or well being of the child.

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

See sample consent/assent forms at http://ors.umkc.edu/research-compliance/irb/irb-forms

Provide assent process background information, in the space below, for each Assent Form, Alteration Form (i.e., Cover Letter or Verbal Script), and Waiver.

Assent Background

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* * * HIPAA * * *

15. Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement Authorization). For more information, consult HIPAA Privacy Rule for Research.

If this page is not active you must return to the General Checklist and check the box regarding the use of PHI in this research.

a) **Does the study involve the use of PHI from an UMKC covered entity?**

If yes, please contact your Privacy Board/HIPAA Officer (Please visit http://ors.umkc.edu/research-compliance/hipaa)

b) **Does the study involve use of Protected Health Information (PHI) from a covered entity outside of UMKC (i.e. another organization or institution)?**

If Yes, explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained.

c) **Does the study involve use of a "limited data set"?**

If Yes, patient authorization for use of the data set is not required; however, you must have a data use agreement in place with the entity from which the data will be obtained as required by HIPAA. Attach a copy of the agreement in the Attachments section

Protected Health Information (PHI) is health information with one or more of the following identifiers. For more information see: http://www.hhs.gov/ocr/hipaa/

1. Names
2. Social Security numbers
3. Telephone numbers
4. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by

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combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locations (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, character, or code (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

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* * * Attachments * * *

16. Attachments

Attach relevant documents here. These could include:

- **Collaborating Investigator's IRB approval and approved documents**
- **Conflict of Interest information**
- **Debriefing Script; Grant/Sub-contract**
- **HIPAA Authorization Form from HIPAA-covered entity**
- **Interview/Focus Group Questions**
- **Investigator's Brochure**
- **Letters of Agreement/Cooperation from organizations who will help with recruitment**
- **Methodology section of associated Thesis or Dissertation project**

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- Questionnaires
- Radiation Control Office approval material
- Recruitment Material (e.g., flyers, email text, verbal scripts)
- Sponsor's Protocol; Surveys
- Other files associated with the protocol (you can upload most standard file formats: xls, pdf, jpg, tif, etc.)

Please be sure to attach all documents associated with your protocol. Failure to attach the files associated with the protocol may result in this protocol being returned to you for completion prior to being reviewed. Students: Be sure to attach the Methods section of your thesis or dissertation proposal. If this protocol is associated with a grant proposal, please remember to attach your grant.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

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* * * Obligations * * *

Obligations

Obligations of the Principal Investigator include the following:

Provide all subjects a copy of the signed consent form, if applicable.

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel.Training must be updated every two (2) years.

Submit the Continuing Review Form in order to maintain active status of the approved protocol. This form must be submitted to the IRB at least 30 days (AHSIRB) or 45 days (SSIRB) prior to the date of expiration.

Submit the Protocol Violation Form to report protocol Deviations/Violations or the Event Reporting Form to report Adverse Events (AEs) or Unanticipated Problems that occur in the course of the protocol.

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Final Report - The IRB will be notified when the study is complete. To do this, complete the IRB Expedited/Full Board Report Form and select the "Final Report"

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the UMKC IRB.

I agree that no subject will be enrolled nor will any data intended only for research use be collected prior to issuance of an IRB approval.

I understand that I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all of the applicable policies and regulations.

I understand that for the purposes of the UMKC IRB "anonymous" means the HIPAA definition of de-identified data. (See Help Screen for definition)

I have completed the CITI Human Subjects Research Protection Course and the certificate is either attached to this application. A copy of current CV must also be included.

This study will not begin until the investigator receives written final approval.

The Principal Investigator has read and agrees to abide by the above obligations.

Please click "Check for Completeness" to your left to continue to the next step. If the protocol is complete and ready for submission, please click "Submit Form" to your left to submit your protocol for IRB Review.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Consent Forms	Letters
12/04/2014	NEW FORM CREATED			