****

Request to Use an External IRB\*

**[ ]  NCI Central IRB [ ]  NMDP IRB**

**[ ]  Advarra IRB [ ]  Western/Copernicus IRB**

**[ ]  Greater Plains Collaborative (GPC) IRB *(specify)***

**[ ]  Other *(specify)***

**\*For reliance on a CTSA Regional partner (CMH, UMKC, St. Luke's, University Health), please use the form specifically for those studies**

Directions:

1. download, complete and save this form to your desktop / files.
2. access the myIRB system at: <https://kumcmyIRB.huronresearchsuite.com>
3. Complete the SmartForm Tabs
	1. In the “Basic Information” section of the smart form, always Choose “single-site study” for item #4, Choose “Yes” for item #5, AND choose “KUMC” for Item #8.
4. Upload Additional documents indicated on the checklist at the end of this form.

### I. Study Information

**KUMC Principal Investigator:**

|  |  |
| --- | --- |
| Email:       | Phone:       |
| **Alternate Contact Person** (e.g., Project Coordinator)**:**       |
| Email:       | Phone:       |  |

**Protocol Title:**

|  |
| --- |
| **Sponsor:**       |

**Clinical Research Start Up (UKHSRR) ID #**       *(if applicable)*

*To obtain a Clinical Research Start Up (UKHSRR) # go to* [*https://redcap.kumc.edu/surveys/?s=KFJYK87MAJ*](https://redcap.kumc.edu/surveys/?s=KFJYK87MAJ)*. If you have any questions, please contact* *OCTA@kumc.edu*.

**Is this study an Investigator Initiated Trial that needs to be reviewed by a Commercial IRB?** (Institutional Conflicts of Interest, need of expertise, or under a separate agreement)

[ ]  Yes [ ]  No

**Is this study Secondary Use /Chart Review to be reviewed by a Commercial IRB?**

[ ]  Yes [ ]  No

**II. Locations of the Study**

1. Check all KUMC/UKHS-affiliated study locations under the KUMC investigator’s responsibility:

[ ]  Outpatient Clinics and Research Centers

[ ]  Outpatient clinics owned by KUMC or the University of Kansas Health System

[ ]  CTSU

[ ]  Landon Center on Aging

[ ]  Hoglund Brain Imaging Center
[ ]  Ziel Institute

[ ]  KU Wichita Center for Clinical Research

[ ]  KU-MPA clinic: Specify

[ ]  Midwest Cancer Alliance sites

[ ]  Inpatient Setting

[ ]  University of Kansas Hospital

[ ]  Other hospital: Specify

[ ]  Classroom setting

[ ]  KUMC campus-Kansas City

[ ]  Other classroom setting: Specify

**(b)** In what states will the KUMC principal investigator conduct the study? *(Check all that*

 *apply)*

[ ]  Kansas

 [ ]  Missouri

 [ ]  Other states: Specify

**III. Study Populations**

Check any vulnerable populations that are being specifically selected for enrollment:

[ ]  Children/Minors (under 7 years of age) [ ]  Persons with impaired decision-making

[ ]  Children/Minors (7 – 11 years of age) [ ]  Economically/educationally disadvantaged

[ ]  Children/Minors (12 -17 years of age) [ ]  Prisoners

[ ]  Pregnant women [ ]  KUMC Students/Residents/Fellows

[ ]  Fetuses/Neonates [ ]  KUMC Employees

Number of Persons Planned to be Enrolled at KUMC:

 or

Number of Charts/data Planned to be reviewed at KUMC:

**IV. Study Procedures**

Indicate whether this research project includes any of the following procedures.

**(a)** [ ]  Yes [ ]  No Use of Radiation or a Radioisotope?

*If the study involves any form of radiation or use of a radioisotope, then complete the Radiation Safety Form RS06, posted on the RSC website:* [*http://www2.kumc.edu/safety/forms.html*](http://www2.kumc.edu/safety/forms.html) *Upload the RSC form in the “Supporting Documents” tab in the myIRB system.*

**(b)** [ ]  Yes [ ]  No Testing for reportable diseases (HIV, Hepatitis, TB, etc.)?

**(c)** [ ]  Yes [ ]  No Testing for illegal drug use?

**(d)** [ ]  Yes [ ]  No Genetic Testing?

**(e)** [ ]  Yes [ ]  No Human Gene Transfer (e.g., Recombinant DNA, viral-based vectors,

genetically modified cells)?

**(f)** [ ]  Yes [ ]  No Submission of genetic data to national repositories (such as dbGAP)?

**(g)** [ ]  Yes [ ]  No Whole Genome Sequencing?

**(h)** [ ]  Yes [ ]  No Storage of Blood / Tissue for purposes not related to this project?

**(i)** [ ]  Yes [ ]  No Investigational surgical procedures?

**(j)** [ ]  Yes [ ]  No Audio taping or videotaping? *(Please be aware of storage requirements*

 *per the KUMC Record Retention Policy)*

**V. Study Conduct at KUMC**

Indicate which study activities will occur at KUMC locations (check all that apply)

[ ]  All procedures outlined in the protocol

[ ]  Subset of protocol procedures; Specify

[ ]  Recruitment

[ ]  Consenting

[ ]  Data analysis

[ ]  Data coordination

[ ]  Specimen analysis

[ ]  Other; Specify

**VI. Request for a waiver or alteration of HIPAA at KUMC**

[ ]  **Request for** **Waiver of HIPAA Authorization *(****Complete the questions below if your study involves health information and you are requesting a waiver of HIPAA. Please complete this even when the external IRB has completed their own waiver review.****)***

|  |  |
| --- | --- |
| Explain why the research could not practicably be conducted without access to and use of the protected health information. |  |
| Describe the plan to protect identifiers from improper use and disclosure. |  |
| Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (how and when identifiers will be destroyed). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers. |  |
| Describe the plan to ensure that identifiable health information will not be reused or disclosed to unauthorized persons or entities.  |  |
| Explain why the research could not be practicably carried out without a waiver of privacy authorization (i.e., why it is not practicable to obtain written authorization from the patient).  |  |

**VII. Data Security**

**If data will be collected and/or stored at KUMC, please complete the following data security questions.** *\*\*Please note: Starred responses will require review by KUMC Data Security*

1. How will subjects be identified? (Check all that apply)

[ ]  Selection during the course of usual clinical care

[ ]  Chart reviews by persons involved in the patients’ care

[ ]  Chart reviews by persons not involved in the patients’ care

[ ]  Self-referral in response to IRB-approved ads or Websites

[ ]  Referrals from outside physicians

[ ]  Database searches; specify the database:

[ ]  HERON Data Repository

[ ]  Pioneers Research Participant Registry

[ ]  Other; Specify:

1. How will data be recorded for your research protocol? (Check all that apply)

 [ ]  In paper format; specify the location where paper will be stored:

[ ]  Records will be kept in a secure location and only accessible to personnel approved on the study.

[ ]  Other (specify):

[ ]  In Electronic format; where will electronic study data be housed?

[ ]  **High Risk Data** - [*Note: High risk means* ***any*** *identifiable research data. The five options listed below are the only approved locations for research data that has not been stripped of the 18 HIPAA identifiers. See the KUMC Data Classification Policy/Guidance for more information.*]

[ ]  Server hosted by a research sponsor or data coordinating center, with which KUMC has an approved sponsored research agreement.

[ ]  KUMC VELOS/CRIS System

[ ]  KUMC REDCap server

[ ]  KUMC P: drive (The principal investigator should request a P: drive location by emailing kumc-security@kumc.edu)

[ ]  KUSM-Wichita P: drive (The principal investigator should request a P: drive location by emailing itswichita@kumc.edu)

[ ]  **Low to Moderate Risk Data** - [*Note: Low or moderate risk data means data that has all 18 HIPAA identifiers removed. See the KUMC Data Classification Policy/Guidance for more information.*]

[ ]  KUMC department network drive (e.g., G, K, R, or S drive)

[ ]  KUSM -Wichita department network drives

[ ]  Encrypted CDs/DVDs – *for imaging studies only*

[ ]  KU Lawrence server

[ ]  Other servers, devices or drives\*\* Specify:

**Detailed Description of the Technology that will be used During the Course of the Study to Capture, Record, or Transmit Data**

Please select which technology(ies) will be used in this *study (check ‘yes’ or ‘no’ on each one and answer the questions in the relevant required section below the table if applicable).*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Technology Type** | **Examples****(Descriptions of the technology are offered in the respective sections below)** | **If Yes, Answer the Required Questions** |
| [ ]  Yes [ ]  No | **Mobile technology**  | *For example, e-diary, iPhone, Android devices, iPods, tablets, or other wireless devices.*  | Complete section (c) below |
| [ ]  Yes [ ]  No | **Website survey, or similar tool**  | *For example, REDCap survey, surveys on external websites* | Complete section (d) below |
| [ ]  Yes [ ]  No | **Cloud based storage** | *Cloud storage is a cloud computing model in which data is stored on remote servers accessed from the internet, or "cloud." Examples include Dropbox, Google Drive and other Google services, iCloud, Amazon Web Services, Microsoft Azure, etc. (This category does not apply to servers hosted by pharmaceutical sponsors or data coordinating centers.)*  | Complete section (e) below |
| [ ]  Yes [ ]  No | **Wearable Technology**  | *Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate monitors, pulse oximetry sensors, and glucose sensors.* | Complete section (f) below |
| [ ]  Yes [ ]  No | **Phone, Video or Web Conferencing**  | *Examples include Zoom, Adobe Connect, Skype for Business, Facetime, Acano, etc.*  | Complete section (g) below |
| [ ]  Yes [ ]  No | **Text messaging/secure messaging** | *Examples include MyChart, Outlook, text, etc.*  | Complete section (h) below |
| [ ]  Yes [ ]  No | **Mobile Applications**  | *Examples include electronic patient-reported outcomes (ePRO), Apple health, Garmin connect, Fitbit, etc.*  | Complete section (i) below |

1. **MOBILE TECHNOLOGY**

*Electronic devices that allow for offsite or remote data capture directly from study participants. For example, e-diary, iPhone, Android devices, iPods, tablets, or other wireless devices.*

***Also complete the mobile app section below if a mobile app will be used with the mobile technology.***

[ ]  Yes; who does the mobile technology belong to?

[ ]  **Sponsor provided device**, not owned by KUMC

[ ]  **Study participant owned device**

[ ]  **KUMC provided device\*\***

* + Is the mobile technology password protected?

[ ]  No

[ ]  Yes, password protected

1. **WEBSITE SURVEY, OR SIMILAR TOOL**
* Name of the website survey, or similar tool you are using:
* Who developed the site, survey, or tool?

[ ]  Commercially available

[ ]  Sponsor

[ ]  Internal (KUMC)

[ ]  Principal Investigator

[ ]  Other (specify):

* Is the data encrypted at rest? [ ]  No\*\* Yes [ ]

*Data at rest is data that is sitting on a file server, data stored in a spreadsheet on a desktop or laptop, ultrasound images on the hard drive of the ultrasound machine, files or images on an iPad, tablet or smartphone.*

* Is the data encrypted in transit? [ ]  No\*\* Yes [ ]

*Data that is being transmitted includes uploading or downloading to a website, sending data via email, using protocols such as FTP to transmit data, etc.*

1. **CLOUD BASED STORAGE\*\***
* Name of the cloud-based solution:

*Examples include Dropbox, Google Drive and other Google services, iCloud, Amazon Web Services, Microsoft Azure, etc. (This category does not apply to servers hosted by pharmaceutical sponsors or data coordinating centers.)*

*Note: The University does not currently have an approved cloud-based storage solution. In order to use this type of technology, additional review by KUMC Information Security will need to occur. Review may take up to 30 days.*

1. **WEARABLE TECHNOLOGY**

*Wearable technology is simply anything that is worn (on the wrist, clipped to a belt, even imbedded in clothing) that contains sensors that pair with a web connection or Bluetooth to connect wirelessly with a mobile technology. Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate monitors, pulse oximetry sensors, and glucose sensors.*

***Also complete the mobile app section below if a mobile app will be used with the wearable device.***

* Name of the device
* What information must the participant provide when the wearable is registered to them?
* What type of data will be collected and provided to the researcher?
* What type of data will be collected and provided to the company?
* Is the data encrypted at rest? [ ] No\*\* Yes [ ]
* Is the data encrypted in transit? [ ] No\*\* Yes [ ]
* When and how will the wearable be de-activated from the user
* The study team has reviewed the terms of agreement and/or privacy policy and will inform participants on how their data will be collected via the wearable.

[ ]  Yes

[ ]  No

1. **PHONE, VIDEO OR WEB CONFERENCING**

*Examples include Zoom, Adobe Connect, Skype for Business, Facetime, Acano, etc.*

* Name of the conferencing system:
* The recordings capture: [ ]  images [ ] video [ ] audio
* Will recordings be transmitted over the Internet? [ ]  Yes [ ]  No
* How will recordings be secured to protect against unauthorized viewing or recording:
1. **TEXT MESSAGING/SECURE MESSAGING**

*Examples include MyChart, Outlook, text, etc.*

* What type of messaging will be used: [ ]  Text [ ]  Email [ ]  Other
* How will the messaging be delivered:

[ ]  Standard text messaging on a mobile device

[ ]  Separate application; name of the application

[ ]  Secure email

[ ]  Unsecure email

[ ]  Other\*\*

* What is the purpose of the messaging:
1. **MOBILE APPLICATIONS**

*Software applications that can be run on a mobile device (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity) or a web-based software application that is tailored to a mobile platform but is executed on a server. Examples include electronic patient-reported outcomes (ePRO), Apple health, Garmin connect, Fitbit, etc.*

* + Name of the application:
* Who developed the mobile application?

[ ]  Commercially available [ ]  Sponsor [ ]  Internal (KUMC) \*\*

[ ]  Principal Investigator\*\* [ ]  other (specify):

* + Explain how the app will be used in the study:
* What type of data will be collected within the app and provided to the study team?
* If applicable, what type of data will be collected and provided to the company?
* Is the data encrypted at rest? [ ] No\*\* Yes [ ]
* Is the data encrypted in transit? [ ] No\*\* Yes [ ]
* When and how will the data be securely wiped from the device
	+ The study team has reviewed the app terms of agreement and privacy policy and will inform participants on how their data will be collected via the mobile app

[ ]  No

[ ]  Yes

**VIII. Funding Information**

**(a)** Will you be providing payment to subjects?

[ ]  No

[ ]  Yes Total amount:

 *\*Payments should be described in the consent form*

**(b)** When will payments be disbursed?

(c) Will subjects be paid using Clincard?

**(d)** Has the contract been submitted to the Research Institute?

[ ]  Yes

[ ]  No

[ ]  N/A, e.g., NIH Cooperative Group Trials

**(e)** Does the consent discussion about payment for injury match the contract provisions?

[ ]  Yes

[ ]  No

[ ]  Pending

**(f)** Name ofFunding Source (Please match this with information on the KUMC myIRB system Study Funding Sources Question).

**IX. Conflict of Interest for All Study Team Members**

**Prior to approval, a current COI disclosure form must be on file for all KUMC study personnel. The following questions relate to the study named in this application.**

**NOTE: Principal Investigators are responsible for addressing these questions on behalf of the entire study team.**

***\*Immediate family is defined as spouse, dependent children and personal household.***

**(a)** [ ]  Yes [ ]  No With regard to publicly traded entities, do any of the investigators

or their immediate family have financial interests in the *aggregate*

 of at least $5,000 which are related to the sponsoring entity or in an

 entity whose products or services are being evaluated?

Financial interests include:

* Honoraria,
* Income for consulting and speaker’s bureaus,
* stock/stock options, and
* sponsored travel

that have been received or acquired within the past year or are expected to be received or acquired during the course of the project.

**(b)** [ ]  Yes [ ]  No With regard to private entities, which could be the sponsoring

entity or an entity whose products or services are being evaluated:

-Do any investigators or their immediate family have *any* equity interests (i.e., regardless if value) which may include:

* ownership interests, or
* stock holdings or options?

-Have any investigators or their immediate family received remuneration in the amount of at least $5000? Remuneration includes, but is not limited to:

* consulting or speaker fees,
* management fees

received during the past year or are expected to be received or acquired during the course of the project.

**(c)** [ ]  Yes [ ]  No Is any investigator, or their immediate family:

* a paid or unpaid member of an advisory or executive board, or
* have a paid or unpaid executive relationship

with the sponsoring entity or in an entity whose products or services are being evaluated?

**(d)** [ ]  Yes [ ]  No Do any investigators or their immediate family receive:

* gift funds
* educational grants, or
* subsidies or other financial support for professional activities

from the sponsoring entity or an entity whose products or services are being evaluated?

**(e)** [ ]  Yes [ ]  No Are any investigators or their immediate family an inventor of, or

have an ownership or royalty interest in, any intellectual property

utilized in this protocol?

**(f)** [ ]  Yes [ ]  No Does KUMC or the KUMC Research Institute have an ownership

 or royalty interest in any intellectual property utilized in this

 protocol?

1. [ ]  Yes [ ]  No For drug/device studies only: is the sponsor of the study a

 different party than the manufacturer of the drug or device?

**(h)** If you answered “Yes” to any of the above, please describe in detail. Affirmative answers will be forwarded to the KUMC Conflict of Interest Committee.

|  |
| --- |
|  |

**Instructions for completing your Request to use an External IRB submission.**

***Please Note: Mark only what applies to this submission. Incomplete submissions will be returned without review***

|  |  |
| --- | --- |
| **Principal Investigator is a KUMC faculty member** | [ ]  |
| **List all individuals who will interact with participants or access identifiable records in the Study Team Members section of myIRB.**  | [ ]   |
| **Confirm that all individuals listed on the study team are current in their human subjects training and Conflict of Interest Requirements.** | [ ]   |
| ***ENSURE THE FOLLOWING DOCUMENTS ARE UPLOADED IN myIRB:*** |
| ***STUDIES RELYING ON AN EXTERNAL IRB*** *(NCI CIRB and Secondary Use/Chart Review studies please skip down to specific checklists below)* |
| **Study Protocol *(study-wide* *version that has been approved by the external IRB*)** | [ ]   |
| **Initial External IRB Approval Letter for the Study as a whole (***not site-specific***) (if the study has also received continuing review approval, please also include the most current study wide approval document that confirms the most current expiration date)** | [ ]  |
| **Consent Form(s)** * ***Tracked* *version/s only*** of the **KUMC-specific consent form/s.**

The KUMC HRPP has *negotiated KUMC-specific boilerplate consent language* with each commercial IRB. This language is also used for revising templates for other external IRBs. The *boilerplate language* needs to be inserted into the consent form that is already IRB-approved for the study as a whole. KUMC’s Boilerplate Consent Language for External IRBs is posted on the Reliance Forms webpage at: <http://www.kumc.edu/human-research-protection-program/institutional-review-board/irb-reliance-resources/reliance-forms-and-templates.html>* **Confirmation that changes made to the boilerplate template information (or not using the boilerplate language) are approved for the cost, payment and injury sections** (Changes should be confirmed through side comments on the consent form(s))
	+ Costs (Health System Research Billing)
	+ Injury (Contracts Office)
	+ Payment (RA Portfolio Manager)
	+ Use of gift cards (RA Finance Office)
	+ No changes made to template information
* **Confirmation that Sponsor has approved consent changes** (Upload email from the sponsor. Please include this email in your submission to the external IRB)
* ***Clean******version/s*** of the **Sponsor consent form/s** approved by the external IRB for the study as a whole.
 | [ ]  [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |
| **KUMC-Specific Recruitment materials (if applicable)** Examples include emails, letters, flyers, posters, radio/tv ads, etc. | [ ]   |
| **Ancillary Approval documents** (Radiation Safety, PRMC, COI etc.) **(if applicable)** | [ ]   |
| **NCI CIRB STUDIES ONLY** |  |
| * NCI CIRB approved Protocol
* Initial application to the NCI CIRB
* Most recent NCI CIRB approval (with current expiration date)
* Request to Use an External IRB application
* NCI Consent template
* Proposal local consent form(s) – *tracked changes* so IRB can see the local changes
* Proposed local consent/HIPAA combination forms – clean pdf with both the consent language and HIPAA attached (starting on an odd-numbered page).
* The separate HIPAA authorization that includes our 3 local entities
* RSC approval letter, Biosafety approval (as applicable)
* PRMC approval letter
* CIRB-approved Study Specific Worksheet that shows our local PI as approved to conduct the study here
* Email confirmation from PI regarding if persons with impaired decision-making will be enrolled or not
 | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |
| **SECONDARY USE/CHART REVIEW STUDIES ONLY** |  |
| * Request to Rely application (HIPAA waiver section needs to be completed) (UKHSRR# not applicable)
* Protocol
* Data Collection Sheet
* Overall study wide IRB approval letter
* External IRB HIPAA waiver (if applicable and for reference only)
 | [ ] [ ] [ ] [ ] [ ]  |

**Thank you for your submission. Please feel free to contact the IRB office with questions:**

**IRBreliance@kumc.edu**