**KUMC CONSENT TEMPLATES FOR SURVEY RESEARCH**

**This document contains three sample consent templates and guidance for their use. Feel free to contact** **IRBhelp@kumc.edu** **with questions about any of our resources.**

**TEMPLATE #1 Survey consent template – anonymous survey, not involving PHI\***

**TEMPLATE #2 Survey consent template – not anonymous, not involving PHI\***

**TEMPLATE #3 Survey consent template – involving access to, or collection of, identifiable patient information**

**PHI Checklist**

***\*Please consult the PHI checklist when planning your study. If the study accesses or creates data associated with any of the PHI identifiers, then the consent form must incorporate the required HIPAA elements.***

**TEMPLATE #1**

**Survey consent template – anonymous survey, not involving PHI**

Dear [XX]

[Researchers identify themselves]. We are contacting you because you are a [student, patient, provider with/who…]. We are recruiting research participants to help us [define purpose of the study]. Participation involves completing a survey that will take about [XX] minutes. No identifiable information will be collected about you, and the survey is anonymous. In addition to the survey questions, we will request [e.g. age, gender, educational status, health status]. [*Insert instructions here, such as:*  The survey is posted at….; or, When you have completed the survey, please place it in the box/envelope…]

There are no personal benefits or risks to participating in this study. Participation is voluntary, and you can stop taking the survey at any time. [*If students/residents are being surveyed, include this statement:* Participation or declining will have no impact on your academic evaluations.]

If you have any questions, please contact [insert researcher’s contact information.] For questions about the rights of research participants, you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or IRBhelp@kumc.edu.

Sincerely,

[Researcher information]

**TEMPLATE #2**

**Survey consent template – not anonymous, No HIPAA**

Dear [XX]

[Researchers identify themselves]. We are contacting you because you are a [student, patient, provider with/who…]. We are recruiting research participants to help us [define purpose of the study]. Participation involves completing a survey that will take about [XX] minutes. In addition to the survey questions, we will collect [e.g. age, gender, educational status, health status]. [If you are collecting direct identifiers such as name, email, phone, etc. or if you are using photos of participants, provide exact details about these variables and explain the purpose for which they are being collected.]

There are no personal benefits or risks to participating in this study. Participation is voluntary, and you can stop taking the survey at any time. [*If students/residents are being surveyed, include this statement:* Participation or declining will have no impact on your academic evaluations.]

If you have any questions, please contact [insert researcher’s contact information.] For questions about the rights of research participants, you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or IRBhelp@kumc.edu.

Sincerely,

[Researcher information]

[Because personal identifiers are being collected, please include a signature block below as appropriate. For online surveys, the signature block can be replaced with an indication of consent, such as an “I agree...” statement. You may contact the IRB office if you have a request to not obtain signature.]

If you agree to be in the study please sign and date below:

Printed name:

Signature: Date

**TEMPLATE #3**

**Survey consent template – involving access or use of identifiable patient records**

***[Department Letterhead]***

Dear [XX]

We are contacting you about a research study at the University of Kansas Medical Center (KUMC) being done by [PI name]. Our study include patients who [have XX… , are being treated for…, had surgery for, etc.]. We hope the study is useful in [improving services for XX, understanding patient needs, planning new services, etc.].

The study involves [completing a survey, having a phone interview, etc.] that will take about [XX] minutes. In addition to the survey questions, we will ask for personal information such as [e.g. age, gender, educational status, other demographics]. [If you are collecting direct identifiers such as name, email, phone, etc. or if you are using photos of participants, provide exact details about these variables and explain the purpose for which they are being collected.]

In appreciation of your time, we will provide a $[xx] gift card. We will record your name and address to track the gift cards. [Alternatively, insert a statement that there is no payment for participating in the study.]

Being in this study is optional. You can get services at KUMC without being in the study.

The information collected for this research may be placed into your medical record and combined with information from your standard clinical care. If added to your medical record, The University of Kansas Health System clinical staff may use and share this information for clinical purposes.

When we analyze the data, we will replace your name with a code number to protect your privacy. The list that connects your code number to your name will be kept in a secure location.

We will do our best to protect the privacy of your information. It is possible that information shared outside KUMC might be released by others. If this happens, your information will not be protected by the HIPAA laws.

We will keep your study information indefinitely.

If you want to cancel your permission to use your health information, please write to [PI Name]. The mailing address is [PI Name], University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. We will stop collecting any additional information about you. We may use and share information that was gathered before they received your cancellation.

If you have questions about this study, please contact [insert researcher’s contact information.] For questions about your rights as a research participant, you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or IRBhelp@kumc.edu.

Sincerely,

[Researcher information]

If you agree to be in the study please sign and date below. You will be given a signed copy of this consent form to keep for your records.

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Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

**PHI CHECKLIST**

The Health Insurance Portability and Accountability Act (HIPAA) governs Protected Health Information (PHI). If any of the following demographic characteristics are paired with information about past, present, or future physical or mental health, or information about the payment of health care, the resulting information is **Protected Health Information** under federal law.

* Names
* 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:
	+ The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
	+ The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
* 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;
* Telephone numbers;
* Fax numbers;
* Electronic mail addresses;
* Social security numbers;
* Medical record numbers;
* Health plan beneficiary numbers;
* Account numbers;
* Certificate/license numbers;
* Vehicle identifiers and serial numbers, including license plate numbers;
* Device identifiers and serial numbers;
* Web Universal Resource Locators (URLs);
* Internet Protocol (IP) address numbers;
* Biometric identifiers, including finger and voice prints;
* Full face photographic images and any comparable images; and
* Any other unique identifying number, characteristic, or code

***To qualify as de-identified data, each of the elements listed above must be removed.***

Note: a de-identified data set may include a tracking code or other numbering system, provided that:

1. the tracking code is not related to information about the individual
2. the re-identification algorithm is not disclosed to the data recipient