**FREQUENTLY ASKED QUESTIONS ABOUT REDCap, DATA SHARING, AND DATA PROTECTION**

Question: Does everyone who submits a proposal to the ISERC need to view the e-learning module on Kijabe Hospital Data Protection.

ANS: YES-insert link

Question: I have a Research or Quality Improvement Project where I want to collect data. How do I get access on Kijabe’s redcap platform?

                ANS: use the form to request Kijabe REDCAP access <https://redcap.kijabehospital.org/surveys/?s=MC4PPTWD4RCKXXP8>

Question: I am a visiting consultant or a visiting student. I am invited to work in a Kijabe department, but at the end of my time I will need to do a presentation at my home institution.  I am doing QI work and not research. Do I need to get ISERC approval?

ANS: All visitors who collect data for any purpose, research or QI, and who will present that data outside Kijabe Hospital, must submit their proposal to the ISERC Chair. Any data from Kijabe work, presented for credit or otherwise, that is used outside the Kijabe Hospital domain must have ISERC approval AND a Kijabe Hospital Principal Investigator.

Question: Do all projects (research or quality improvement) with data that goes outside our boarders (Kijabe domain) need a formal Data Sharing Agreement?

ANS: NO, but all projects with data that goes outside our borders need a data protection plan clearly outlined in their research proposal and approval of the ISERC. This data protection plan must clearly stipulate that data will be stored at Kijabe Hospital. Any copy of the data that moves outside the Kijabe Domaine must be de-identified data only. That data can only be utilized for the stipulated purpose described in the ISERC and only with the express permission of the Kijabe Hospital Principal Investigator.

Question: When do I need a formal Data Sharing Agreement?

                ANS: When the work is part of a formal contractual relationship, i.e. funded grant, and especially where multiple stakeholders are involved, a formal data sharing agreement would be expected. That said, only fully de-identified data can move outside the Kijabe Domaine. This is to comply with Kenya’s Data Protection Act.

Question: What is the difference between anonymized data and de-identified data?

ANS:

Anonymized data can be un-masked and a researcher could go back to link it to an individual patient.

De-identified data is data you can never trace back to the original patient. The only way to trace data back to the original patient is IF you contact the Kijabe PI so they can access the internal linking document. This can be done only with permission of the PI who is following the stipulated procedure per protocol

 Question: What is linking data and why do you need a linking?

Linking data contains specific patient identifying data. Identifying data includes the Kijabe Hospital ID number and other data (i.e. phone, name/Date of birth, etc).

In research to protect an individual’s patient information, study data should not be stored with identifying information. A unique study identifier should be utilized. In order to link data to a patient, there must be a linking document. This link would connect the patient ID number or other identifying data (phone, name/Date of birth, etc) to a unique study identifier number. The link data are accessible only to Kijabe PI, or specified study staff. This link data should NEVER leave the Kijabe Domaine. Kijabe ID linking to study ID are linking documents. All linking data are Kijabe only data and stay at Kijabe only.

Kenya Data Protection Law states that Kijabe Hospital must maintain the original data and only a copy of the de-identified data can leave the local Domaine.

Question: Who needs to sign a non-disclosure agreement?

ANS: anyone working with patient data at Kijabe Hospital. For Kijabe staff this is done during their on-boarding or contracting process. For visitors, visiting consultants, and students this should be done prior to seeing patients, as part of their on-boarding process.

Question: I am a visiting consultant or visiting student. When I leave Kijabe do I lose my access to the Kijabe REDCap database I have been working on?

ANS: Yes, however, if you have an approved ISERC protocol, you may continue to do data analysis using a copy of de-identified data, at the request of the Kijabe Hospital Principal Investigator. Your access to a copy of the data should be surrendered at the close of the study as part of final reporting and clearance procedures.

Question: I am a Kijabe staff. When I leave Kijabe do I lose my access to the Kijabe REDCap database I have been working on?

ANS: Yes, however, if you have an approved ISERC protocol, you may continue to do data analysis using a copy of de-identified data, at the request of the Kijabe Hospital Principal Investigator. You access to a copy of the data should be surrendered at the close of the study as part of final reporting and clearance procedures.