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University of Wisconsin-Madison MR IRB Application	Study # : 2014-1072 Principal Investigator: DIXON KAUFMAN

View: SF: Shared: Basic Study Information

BASIC STUDY INFORMATION

* 1.1 Indicate the appropriate IRB. NOTE:
  - If you are unsure which IRB to select, please refer to the guidance or contact an IRB office for assistance.

○ Education and Social/Behavioral Science IRB

○ Health Sciences IRB

● **Minimal Risk IRB (Health Sciences)**

* 1.2 Provide a short, lay-terms study title.

Kidney Outcomes

* 1.3 Provide the full, formal study title. NOTE: This is the title that will appear in correspondence.

Outcomes of Kidney Transplant Recipients

* 1.4 Is this study being transferred from another institution?

Answer Yes to this question only if
a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and
b) they plan to open a study here that is already IRB-approved at their previous institution.

○ Yes ● **No**

* 1.5 Identify the Principal Investigator.

DIXON KAUFMAN

View: SF: Shared: Consent: General

INFORMED CONSENT: GENERAL

* 1.1 What consent process or waivers of consent are you requesting for this study?

Waiver of informed consent

View: SF: Shared: Consent Waiver

WAIVER OF INFORMED CONSENT

* 2.1 Are you requesting a waiver of informed consent for all components of the study?

● **Yes** ○ No

2.2 If your study enrolls minors, are you requesting a waiver of assent and parental permission?

○ Yes ○ No

☑ Not Applicable

* 2.3 Provide a justification for how the following criteria for a waiver of informed consent will be met: 1) The study involves no more than minimal risk to the subjects; 2) The waiver will not adversely affect the rights and welfare of the subjects; 3) The study could not practicably be carried out without the waiver. If the study team is requesting a waiver of informed consent to use identifiable information or identifiable biospecimens, also provide justification why the research could not be practicably carried out without using identifiable information or identifiable biospecimens.

1) The study presents no more than minimal risk to subjects

This study will be of very minimal risk to the subjects. There is no physical risk to subjects. The only potential risk is a breach of confidentiality. We have carefully reviewed our study procedures to ensure that the risk of a breach of confidentiality has been minimized as much as possible. No individual PHI will be released in presentation or publication. The data that will be used under this protocol are collected as part of a transplant recipient's clinical care and is not conducted specifically for research analysis. Only aggregate statistical output, representing groups of subjects in which individuals cannot be identified, will be released. Only authorized study key personnel identified in this application as using PHI will have access to the data used for the study.

2) The waiver will not adversely affect the rights and welfare of subjects

Since there are no physical risks to subjects in this study and only a very minimal risk of breach of confidentiality, we believe the welfare of the subjects in this study will not be adversely affected. We will not be contacting patients for additional information. Extensive measures, that in many cases exceed current data security standards, will be taken to protect the privacy rights of the study participants as described in this application. No PHI will be sent outside of this institution.

3)The research could not practicably be carried out without a waiver of informed consent.

Obtaining individual waiver of informed consent from this large number of subjects would be impossible due to access, resource, and time limitations. Access problems include a significant number of subjects for various reasons:
• living but lost to follow-up that cannot be located
• being seen only annually at UWHC
• no UWHC follow-up visits because the subject is receiving all follow-up care locally due to insurance coverage limitations, lack of transportation, physical conditions limiting travel, or other hardships

In addition, there are subgroups of subjects that present additional challenges. Many of the subjects would not be due for an onsite visit for many months up to a year. Based upon past experience, a significant number of the subjects would require repeated phone contacts to clarify the request for consent and ensure return of a response. The number of different languages spoken by the non-English speaking subjects is sizeable. The services of interpreters would be

required to translate consent forms and to communicate with these subjects. Excluding the data of any of these subgroups of subjects would bias the analysis and excluding their combined data would compromise the credibility of an analysis. Furthermore, we would like to analyze data derived from future patients and believe that it would be impracticable to obtain informed consent from these individuals as well because those conducting the analyses are unlikely to interact with the individuals. In addition, individuals will not be identified for specific analysis until after their clinical data is already entered into HealthLink.