In accordance with the Collected Rules and Regulations 80.010, MU School of Medicine (SoM) requests approval for the sole source purchase of Clinical Research Management System (CRMS) from Forte Research Systems, Inc., Madison, Wisconsin, for $500,000 in implementation fees and $1,466,632 in ongoing software license fees for a total of $1,966,632 for a five-year term.

Within MU Health, 300+ clinical trials are currently managed by paper and non-standardized technology tools absent of a centralized system specifically designed to collect, process and manage clinical trial/research projects. Multiple review and audits have recommended the purchase of a CRMS to streamline key tasks, support compliance efforts, manage finances and provide robust reporting. Consultation with a number of major academic clinical research organization has shown a trend towards the use of a CRMS as a fundamental catalyst of clinical research growth.

After 14 months of investigation and software demonstrations, Forte Research’s OnCore product has been identified as the only product that provides critical features needed to support clinical trial/research administration activities. The functionality that sets OnCore apart from others includes:

- Integration with ClinicalTrials.gov – Many studies and journal articles require registering with ClinicalTrials.gov, which is currently a manual data entry process. In addition, it provides an additional recruitment tool, as the public can search the site for studies that might be going on in their area for a specific disease/condition.
- Access to share and receive previously developed protocol templates from other institutions
- Food and Drug Administration regulatory compliance for electronic signatures

Forte is the only company that keeps their software up to date with the study data required by the FDA. Without this integration, University personnel have to manually track what data is required each time studies are submitted. In addition, Forte is the only company whose software allows for investigators or coordinators to upload study information, automatically compiling required data referenced in the first item. Without the upload and compilation ability, University personnel would have to manually go through the study to find the required information, manually fill out a form, scan it, and upload it to the FDA’s website. These two functions save the University an inordinate amount of time and potential errors. No other vendor provides these functions.

Forte Research is the leading provider of CRMS software and has implemented OnCore in 72 organizations, 22 of which are multidisciplinary research organizations. This purchase will enable MU Health to standardize clinical trial processes and manage
budgeting, billing, patient safety, subject recruitment, reporting, and compliance activities in a single system.

The CRMS will be utilized by MU Health, predominantly by the MU School of Medicine, but it is potentially available for use by additional MU schools/colleges and other UM campuses.

The total $1,966,632 expenditure will be paid from the MU School of Medicine funds.
No. 6

Recommended Action – Sole Source – Clinical Research Management System, MU

It was recommended by Chancellor Cartwright, endorsed by President Choi, recommended by the Finance Committee, moved by Curator ________________ and seconded by Curator ________________, that the following action be approved:

that MU School of Medicine be authorized to purchase Clinical Research Management System from Forte Research Systems, Inc., Madison, Wisconsin, at a total cost of $1,966,632 over a five year term.

Funding is as follows:
MU School of Medicine Funds                   DS203-777200

Roll call vote Finance Committee
YES  NO
Curator Brncic
Curator Chatman
Curator Layman
Curator Snowden
Curator Sundvold

The motion ____________________.

Roll call vote Full Board:
YES  NO
Curator Brncic
Curator Chatman
Curator Farmer
Curator Graham
Curator Layman
Curator Phillips
Curator Snowden
Curator Steelman
Curator Sundvold

The motion ____________________.