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Date: February 26, 2021

To: Carolina Clinical Research Community

From: Andy Johns 
Senior Associate Vice Chancellor for Research

RE: Notice of Approval Requirement for Clinical Research Support Systems

One of the University's strategic research goals is to grow clinical research. As part of this goal, we are evaluating the overall clinical research support infrastructure to identify gaps and opportunities that can be addressed to help us achieve this growth goal. Much of the infrastructure at the University is designed to support clinical research but is also in place to ensure that the University can remain compliant with constantly changing standards and regulations. There are already several initiatives under way to improve our infrastructure, including the implementation of the OnCore clinical research management system and Advarra EDC (Electronic Data Capture). There are also efforts underway to evaluate solutions that can be implemented to support workflows for electronically obtaining consent, maintaining electronic regulatory binders, and many more. More information will be provided about each of these initiatives soon.

As we work to improve the University's support and compliance infrastructure for clinical research through the implementation of these systems, it is critical that we adopt standards for how the University community will use these solutions in support of clinical research. Efficient and compliant workflows cannot be achieved unless we standardize through the use of these University-adopted and audited systems. Given these goals, we are implementing a new requirement: **Any unit which proposes to purchase or implement any electronic system or solution for the support of clinical research must request (in advance) approval for the proposed solution.** Requests should be submitted in writing to the Office of the Vice Chancellor for Research (vcr@unc.edu) and will be reviewed to ensure that the use of the proposed solution is consistent with efforts already in process and that the proposed solution is deemed appropriate and compliant for the intended use.

We look forward to the coming year and beyond as we realize the benefits from these exciting initiatives and appreciate the partnership with the clinical research community to ensure continued success.

CC:
University Procurement/Finance
Information Technology Services