October 24, 2016

Dear Colleagues,

We are pleased to provide you with important information regarding changes to the Scientific Review Committee (SRC) review process that we will be implementing immediately to ensure significant improvement in the efficiency of the SRC operation and to closely align its operations and mission with the NCI requirements. This we hope will reduce burdens on faculty and staff.

Because of our current electronic submission process please note that all cancer-relevant projects must still be routed through the SRC, but certain research will be exempt from board review and/or will be eligible for administrative review. Effective immediately:

- Retrospective chart reviews and tissue or biospecimen repository protocols with no hypothesis are now exempt from full SRC review, and will be approved administratively. Such projects should still be reviewed at the disease team level to ensure the highest scientific standards.
- Protocols that were previously peer reviewed by recognized peer review bodies are exempt from scientific review by the full committee, but will be administratively reviewed by the SRC Chair, Co-Chair, or other designee. This includes all National Cancer Trial Network (NCTN) studies. Per recent NCI guidance, this will also include Investigator-Initiated Trials (IITs) that were previously approved by another institution with a NCI approved Protocol Review and Monitoring System (PRMS) will not need to be approved by our SRC. Documentation of institutional PRMS approval must be provided when the study is initially submitted.
- The SRC will no longer mandate LOI review, however will be available to review LOIs for investigator initiated trials if the PI is interested in getting scientific input from the SRC. The expectations are that all LOIs will undergo review and approval at the disease team level, therefore an additional approval of the LOI at the SRC level is not required, but may be requested.
- Informed Consent Forms (ICFs) will no longer be required to be reviewed by the SRC. ICFs undergo formal review by the NU IRB.

Please note that:

- Any amendments/revisions that affect eligibility, sample size, change in treatment design, endpoints, statistical plan, or impact patient safety must be formally reviewed by the SRC at a full committee meeting.
- Any other revision will be eligible for an administrative approval. The Chair, Co-Chairs or their designees will review and approve these types of revisions individually within 3 business days.

We hope that these changes will serve to significantly improve the process for your clinical research efforts and appreciate your cooperation as we work towards more efficient processes for SRC operations.

Please direct any questions you may have regarding these changes to any one of us or to Sally Scherer, Interim Director of Research Oversight Systems, at s-scherer@northwestern.edu.

Sincerely,

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Al B. Benson III, MD FACP, FASCO
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