Public Comment on Proposed Rule Amendment 10A NCAC 15 .0213

This comment respectfully addresses the proposed amendment to 10A NCAC 15 .0213, which raises significant concerns regarding its alignment with existing federal regulations and its potential to create unnecessary burdens for researchers and the Agency. The sections below detail how this proposal exceeds the Agency's authority and conflicts with established federal safeguards currently in place and includes a recommendation.

1. Federal Regulatory Framework and IRB Safeguards

Under federal law (21 CFR 812 and 45 CFR 46), any research involving human subjects and radiation-producing medical devices must have prior Institutional Review Board (IRB) approval. The FDA's rigorous regulatory process, combined with mandatory IRB oversight, already provides stringent protections for research participants. The proposed rule 10A NCAC 15 .0213, however, appears to allow certain research activities to proceed without IRB approval, contradicting these existing federal safeguards. The FDA has established clear requirements governing the use of FDA-approved medical devices in research, including off-label uses and investigational device exemptions. By creating a pathway outside of IRB oversight, the proposed amendment risks noncompliance with federal provisions designed to safeguard participant welfare and maintain consistent clinical standards. Such misalignment with federal regulations could place both investigators and the state regulatory authority at odds with well-established national policies.

2. Overreach and Duplication of Efforts

By requiring state-level review, the proposed rule adds a duplicate layer of regulation. This creates confusion and delays for researchers, clinicians, and the Agency itself. Overnight, hundreds, possibly thousands, of research projects would need to be submitted for state review, including study details, IRB approval paperwork, and personnel qualifications. The Agency would then need expanded resources with specialized expertise in research, clinical studies, and screening to handle this influx, stretching its capacity and the cost to the citizens of North Carolina.

3. Impact on Research Timelines

The clinical study and research community already spend significant time and effort preparing detailed documentation, which is then rigorously evaluated. The proposed 60-day response window for the Agency would further delay this process, hindering legitimate research endeavors without providing meaningful additional protections.

4. Recommendation

A simpler and more effective approach could be to ensure that all diagnostic and therapeutic radiation delivery on humans occurs under the oversight of a qualified physician. This measure would allow the state to directly address clear violations while maintaining alignment with the FDA's established protocols and federally mandated IRB oversight. Directing concerns about misuse of

equipment to the FDA, rather than layering additional state regulations, preserves the integrity of the research process, affirms the authority of the FDA, and better serves the interests and public health of the citizens of North Carolina.

In its current form, the proposed amendment to 10A NCAC 15 .0213 risks overstepping the Agency's authority, duplicating existing federal protections, and impeding worthwhile research. By respecting FDA regulations and mandatory IRB review, North Carolina can ensure patient safety without stifling scientific and public health progress from clinical studies, research, and screening.

Respectfully,

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