Protocol Pre-Approval Processes for radiotherapy treatment on Clinical Trials; The RPC Experience

The Radiological Physics Center, in conjunction with cooperative clinical trial groups, protocol chairmen and quality assurance review centers, have developed a series of pre-approval processes. These are intended to assure the quality of treatment and to improve the quality of data submitted for patients entered onto cooperative clinical trials. The process typically involves protocols employing advanced technology or new treatment techniques. They are intended to verify that institutions meet the minimum requirements for protocol participation, and that institutions are clinically and dosimetrically equivalent to other institutions on the study before they are allowed to enter patients onto the trial. Early experience was gained from the 2 COMS studies which began in the mid 1980s. Recently, the RPC has been involved with the pre-approval processes for 6 other protocols: RTOG 95-17, RTOG 94-06, RTOG 98-05, GOG 165, SWOG 9438, SWOG 9704. Although pre-approval processes vary between studies, they all include: 1) completion of a 'knowledge assessment' questionnaire discussing equipment, dosimetry parameters and QA procedures; 2) benchmark case calculations; and 3) verification of experience by submission of one or more previous clinical cases. The pre-approval processes reduce the number of protocol deviations as seen with COMS, minimize dosimetry and clinical errors prior to patient registration, increase the understanding of the protocol requirements and lead to the development of protocol treatment evaluation tools.

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