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Medical Devices Risk Assessment and Evaluation Process Prior to Human Trial

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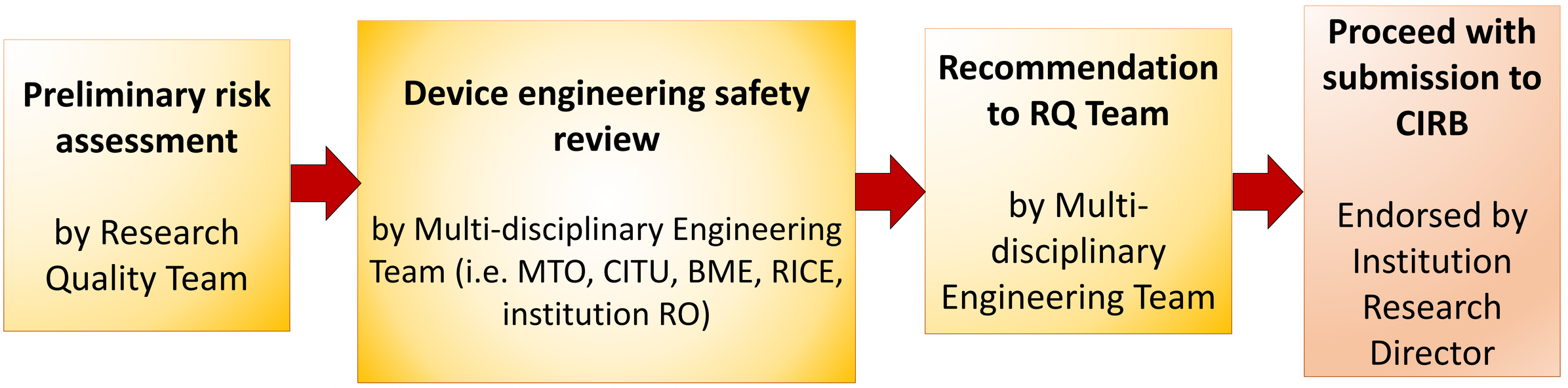
Introduction

With increasing regulation in the medical device marketplace and a rise in medical device innovation projects, there is greater emphasis on assurance of device effectiveness and safety for human clinical trials and ultimately, use in man. Risk assessment must be implemented early in the development phase appropriate to the device's risk classification.

A new assessment and evaluation process was therefore developed internally for medical device prototypes prior to its deployment in human trials. The process is aimed to achieve 1) a more systematic and critical assessment of safety risk levels, and 2) reducing potential risk of harm from medical device prototypes during human trials.

Method

A risk assessment workflow was developed, by referencing to the Design Failure Mode and Effect Analysis (DFMEA) and understanding industry best practices in product design for manufacture and assembly risk evaluation. The workflow was then introduced into medical device prototype assessments from the point of institutional review.



This workflow was developed in conjunction with SingHealth RICE, SingHealth MTO, SGH Clinical Innovation & Technology Unit (SGH-CITU) and SGH Research Quality (SGH-RQ).

Result

Since August 2020, we have piloted the assessment workflow and process on 3 projects, integrated with the existing CIRB application process within SGH RO. The developed process helped teams to ensure that the projects' device safety risk levels were within the acceptable range.

Conclusion

This risk assessment and evaluation process was effective in assisting institutional RO and PIs to determine the safety risk level of developed device prototypes to be deployed in human-facing trials and hence, reduce the risk of potential harm to study subjects.