Introduction

The purpose of the best practice documents are to provide guidance on a process that is currently not covered by an existing Policy or SOP to facilitate study teams remaining compliant with current Clinical Trial Disclosure regulations and requirements. The intent is to remain consistent with current regulatory practices in other areas of clinical research and to apply those concepts to Clinical Trial Disclosure here at the University of Miami. It is also the intent of the GCTDP documents to provide practical suggestions and proven means of meeting the recommended guidelines.

This compilation of documents will included two sections, Best Practices, and Minimum Standards. These sections summarize the main recommendations of the documents in bulleted forms. The documents will also include recommended SOPs, workflows, or guidance documents, whether those documents or practices are departmental or institutional. A section titled Considerations provides information on what other workflows or processes are enhanced or impacted when following the practice outlined.

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