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1. Purpose & Scope

1.1 The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union (EU). It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document[2].

1.2 This SOP describes the dh

4.5.6 The TMF must be updated with all

5. Training

This is a 'read and understand' SOP. Please note that the Research Ethics, Integrity and Governance Team discourages the retention of hard copies of SOPs and can only guarantee that the most up1 0 0 rg/TT4 1Ar

PAF	Portfolio Application Form
PPI	Patient and Public Involvement
PVG	Pharmacovigilance Manager
QA	Quality Assurance
R&D	Research and Development
REC	Research Ethics Committee
RM(ATIMPS)	Regulatory Manager for ATIMPS
RM(P)	Regulatory Manager (Pharmaceuticals)
SAE	Serious Adverse Event
SDV	Source Data Verification
SI	Statutory Instrument
SIV	Site Initiation Visit
SOP	