

Contents

INTRODUCTION

ERROR! BOOKMARK NOT DEFINED.

ADMINISTRATION, COORDINATION AND MANAGEMENT	3
SOP: Writing & Versioning of Documents	3
Purpose	3
Scope	3
Glossary/Definitions	3
Responsibilities & Procedures	3
SOP: Site Visits	5
Purpose	5
Scope	5
Glossary/Definitions	5
Responsibilities & Procedures	5
SOP: Reimbursements from the University of Cape Town (SADaCC)	7
Purpose:	7
Scope	7
Glossary/Definitions	7
Responsibilities & Procedures	7
DATA AND DATABASE MANAGEMENT	8
DATA AND DATABASE MANAGEMENT	0
SOP: Username & Password Management	8
Purpose	8
Scope	8
Glossary/Definitions	8
Responsibilities & Procedures	8
SOP: Setup of User Rights & Data Access Groups	10
Purpose	10
Scope	10
Glossary/Definitions	10
Responsibilities & Procedures	10
SOP: Data Recording	12
Purpose	12
Scope	12
Glossary/Definitions	12
Responsibilities & Procedures	13
General	13
Source data	13
Paper CRF data	14
Electronic CRF (eCRF) data	14
RESEARCH AND ETHICAL, LEGAL AND SOCIAL IMPLICATIONS	16



Documents" p26)	16
Assent Form (7-18 years) (See "Forms and Documents" p32)	16
ASSESSMENT OF HAEMATOLOGICAL PARAMETERS	17
SOP: Measure - Complete Blood Count	17
Definition	17
Purpose	17
Scope	17
Description of Protocol	17
Specific Instruction	17
Protocol	18
SOP: Measure Reticulocyte Count	20
Definition	20
Purpose	20
Description of Protocol	20
Specific Instructions	20
Protocol	20
FORMS AND DOCUMENTS	22
Form: Site Assessment Checklist	22
Identification	22
Description & Location	22
Contacts	22
On-site Facilities	23
Data Management-related computing	23
Own SOPs/Guidelines	24
SADaCC SOPs/Guidelines	24
Form: Informed Consent for a Research Database and Biobank on Sickle Cell Disease	26
Form: Assent Form (7-18 years)	31
APPENDIX	33