

CLINICAL AFFAIRS UNIT

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

1.0000000000000000

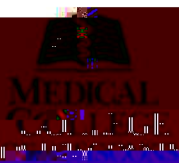
1.0000000000000000

1.0000000000000000

1.0000000000000000

Program Managers

Global Practitioners



Clinical Affairs Unit

4.01 DEFINITIONS

Standard of Care: The level of care that a reasonably prudent professional would provide under the same or similar circumstances.

4.02 Standard of Care Determination

4.02.1 Standard of Care

The standard of care is the level of care that a reasonably prudent professional would provide under the same or similar circumstances.

The standard of care is determined by the professional's training, education, and experience, and the current practice of the profession.

REVISION HISTORY

Version 4.01: 10/1/2019

Version 4.00: 10/1/2019

Version 3.00: 10/1/2019

Version 2.00: 10/1/2019

Version 1.00: 10/1/2019

The purpose of this document is to provide a standard of care for the Clinical Affairs Unit.

This document is intended to be used as a reference for the Clinical Affairs Unit.

APPROVED

DATE: 10/1/2019

Page number: 1 of 1

should contain the

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

of the body of

CLINICAL AFFAIRS

SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.1 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.2 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.3 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.4 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

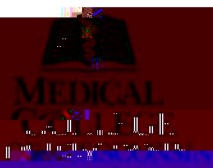
1.1.5 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.6 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.7 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.8 SOP on SOPS v4.0 Reviewed 3-16-2020- clean

1.1.9 SOP on SOPS v4.0 Reviewed 3-16-2020- clean



Clinical Affairs Unit

3/2/20

7/14/19

Review dates:

eSignature Addendum

All eSignatures below were executed using Florence
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.6):

Signed electronically by:

Date: *11-Feb-2022 @ 08:53 AM CST*

Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.