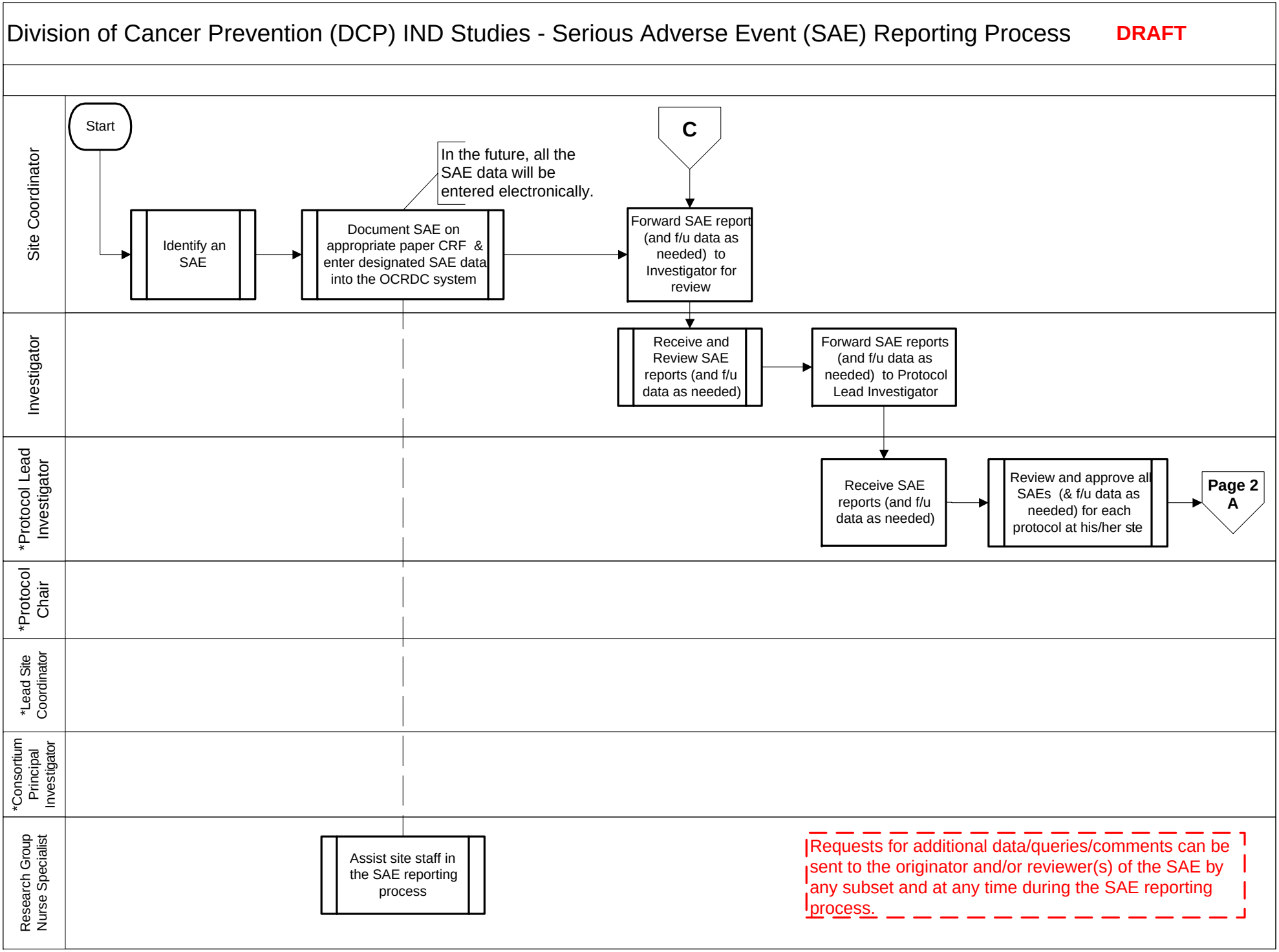
Division of Cancer Prevention (DCP) IND Studies - Serious Adverse Event (SAE) Reporting Process

DRAFT



*** = Consortia Roles**

Division of Cancer Prevention (DCP) IND Studies - Serious Adverse Event (SAE) Reporting Process (Page 2)

DRAFT

Site Coordinator

Investigator

*Protocol Lead Investigator

Site Leader

*Protocol Chair

*Lead Site Coordinator

*Consortium Principal Investigator

Regulatory Reviewer

Requests for additional data/ queries/comments can be sent to the originator and/or reviewer(s) of the SAE by any subset and at any time during the SAE reporting process.

A

Receive request for follow up data

Prepare follow up data

A

Sign paper SAE report (& f/u data as needed)

Forward SAE report (and follow up data as needed) to the Regulatory Reviewer

Ensure all SAEs are reported to DCP (Medical Monitor)

A

Receive request for follow up data

Prepare follow up data

Review all SAEs for each protocol at his/her site

Review all SAEs for his/ her protocol

Ensure all SAEs are reported to the Consortium Principal Investigator

Monitor SAE from Consortium Participating Organizations according to the Lead Organization Multi-Institutional Monitoring Plan (MIMP)

Ensure SAE review according to the Lead Organization Multi-Institutional Monitoring Plan (MIMP)

Review SAEs reported by the Protocol Chair(s)

Ensure all SAEs are reported to the DCP (Medical Monitor) by all Consortium Organizations

Request follow-up data as required

A

Receive SAE report (and follow up data as needed)

Evaluate SAE reports (& f/u data as needed) submitted by sites

Conduct regulatory review of the SAE reports

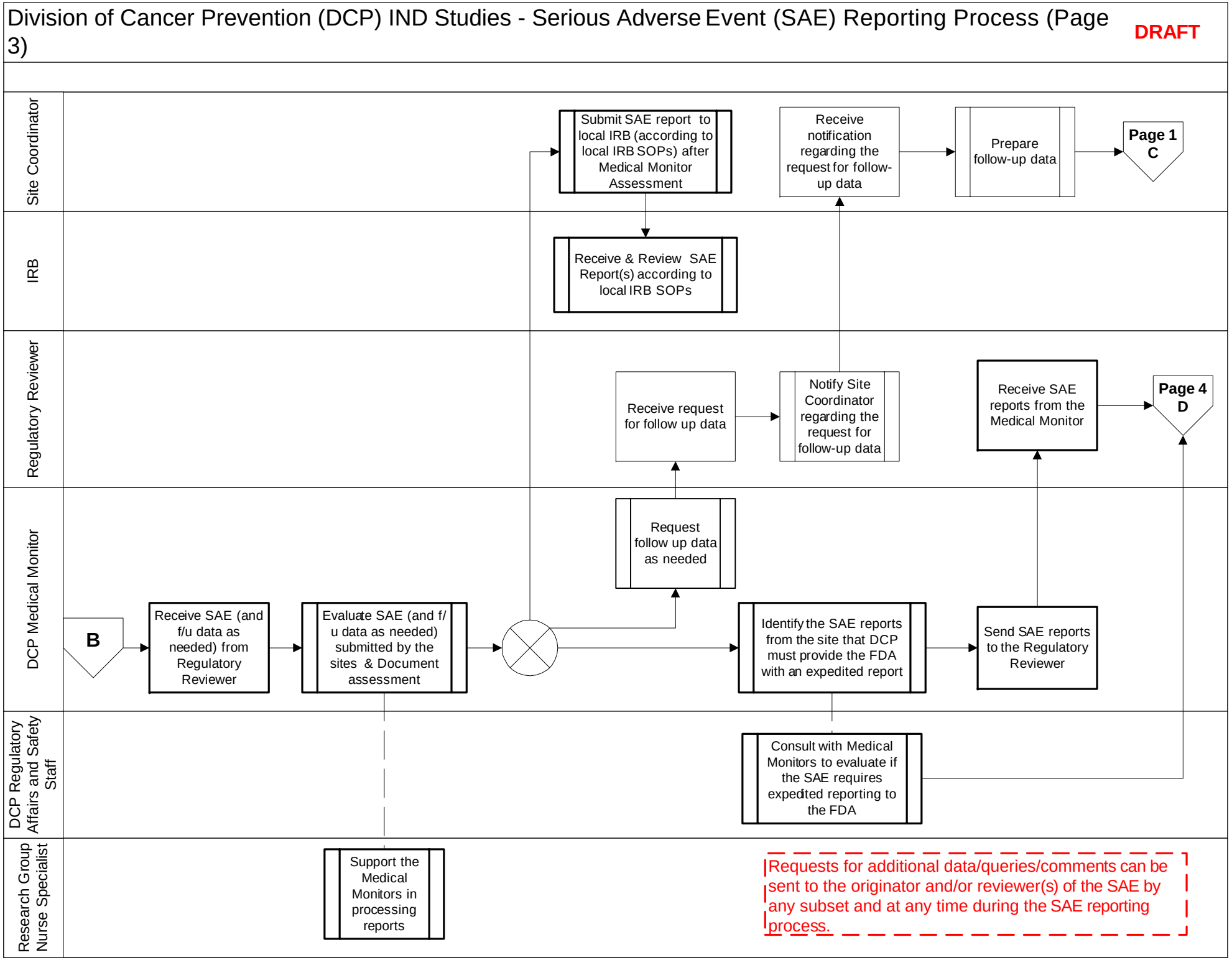
Send reviewed SAE reports to DCP Medical Monitor

Page 3 B

*** = Consortia Role**

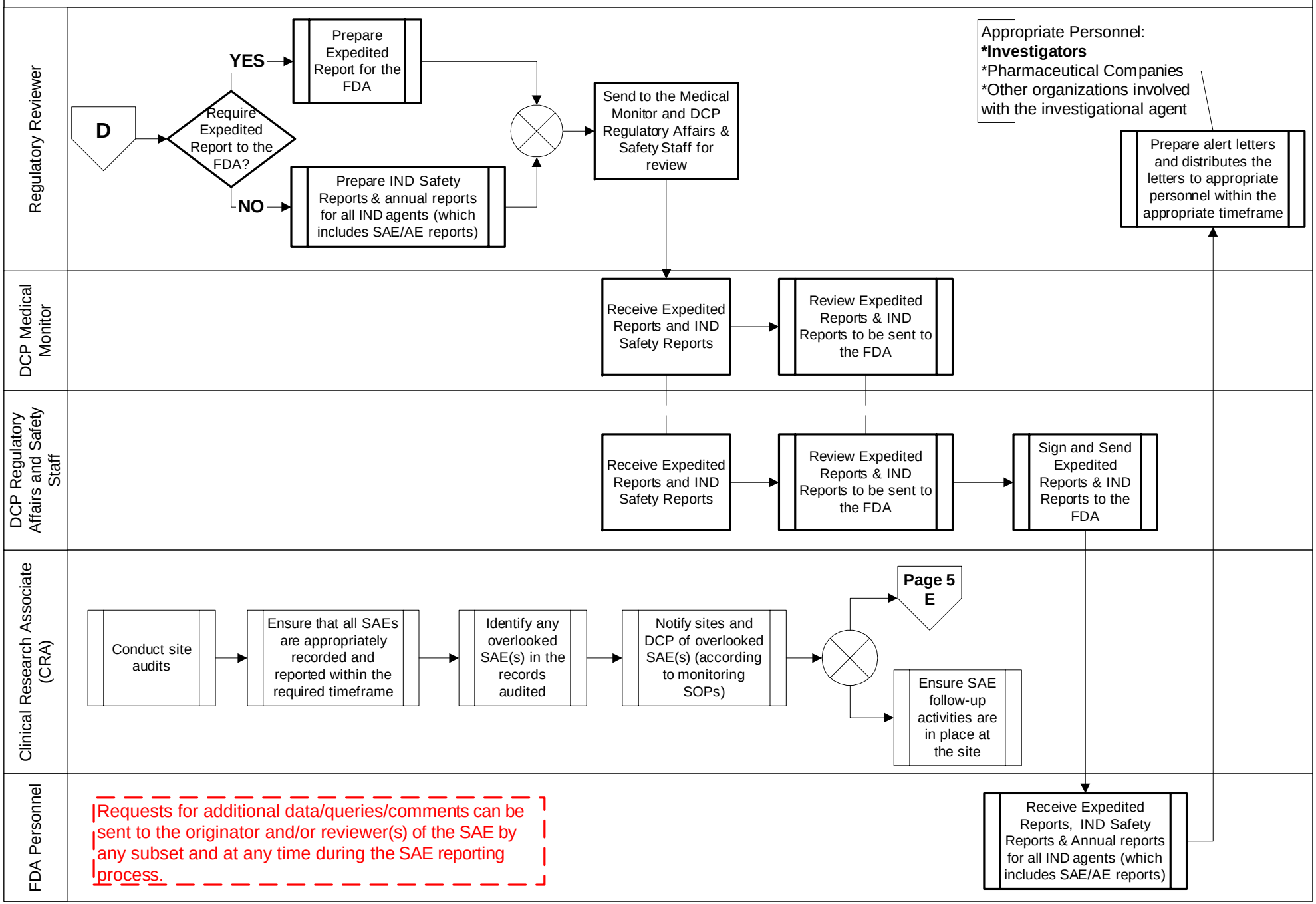
Division of Cancer Prevention (DCP) IND Studies - Serious Adverse Event (SAE) Reporting Process (Page 3)

DRAFT

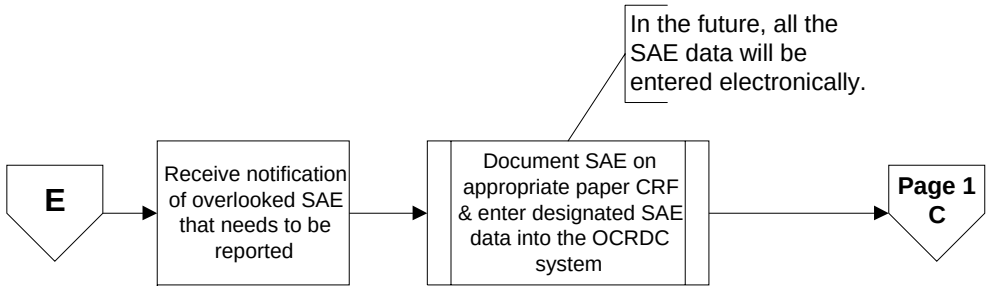


Division of Cancer Prevention (DCP) IND Studies - Serious Adverse Event (SAE) Reporting Process (Page 4)

DRAFT



Division of Cancer Prevention (DCP) IND Studies - Serious Adverse Event (SAE) Reporting Process (Page 5) **DRAFT**

Site Coordinator	
Investigator	
*Protocol Lead Investigator	
*Protocol Chair	
Clinical Research Associate (CRA)	
FDA Personnel	

Requests for additional data/queries/comments can be sent to the originator and/or reviewer(s) of the SAE by any subset and at any time during the SAE reporting process.

*** = Consortia Role**