SUNY Downstate IRB & Privacy Board
FORM 21-2: Corrective & Preventative Action Plan (CAPA) Form
(Version 06.01.2022)
Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.
Note: Free Adobe Reader available at: www.adobe.com

*A **CAPA** is written to:*

- *Identify a discrepancy or problem in the conduct of the clinical research study,*
- *Note the root cause of the identified problem,*
- *Identify the corrective action taken to prevent recurrence of the problem, and*
- *Document that the corrective action has resolved the problem.*

In general, the tone of the CAPA should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study. For example, it may be appropriate to:

- *Clarify or add information regarding site-specific regulatory file requirements,*
- *Clarify or add information regarding source document standards,*
- *Document and address any issue that is protocol- and/or site-specific that cannot be resolved without a change from previous procedures.*

*A **CAPA** should be signed by the author and PI, submitted to the IRB for review, kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site's documents and procedures. In addition, if a Data and Safety Monitoring Board (DSMB) is handling the data management of the clinical research study, please forward a copy to the DSMB.*

When completed, do the following:

- *The completed form must be submitted to the IRB.*
- *Share the findings with your entire study team.*
- *Keep the completed form as documentation of on-going oversight of your monitoring of the conduct of the study.*
- *Report any reportable events to the Downstate IRB that are encountered.*
- *Report any required events to Sponsor or DSMB.*
- *Retain the original copy of this assessment with the research records.*

Section 1: General Information:

Principal Investigator:

Project Title:

IRBNet#:

Section 2: Overall Findings:

Include a summary of observations in bulleted format with sufficient detail and outline any specific finding below.

Section 3: Specific Findings/Issues:

Provide a list of specific findings regarding regulatory documentation, informed consent, participant files, privacy, security, confidentiality, or other documents. Include a brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items:

Section 4: Root Cause:

Provide the reason(s) that the issue(s) arose:

Section 5: Corrective Actions:
Describe the corrective actions taken or planned by the research personnel. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.

Section 6 : Best Practice Recommendations:
Include any best practice recommendations and indicate if these will be accepted by the PI:

Section 7 : Implementation:
Describe the procedures used to document resolution of the problem, the personnel who are responsible for the procedures, etc.:

Section 8 : Effective date of resolution:
Provide effective date for corrective action:

Section 9 : Evaluation/Follow-Up:
Describe plan/procedure to evaluate the implementation and completion, personnel who are responsible for the evaluations, timeframe for the evaluation, etc.:

Section 10 : Conclusions:
Summarize the review and provide contact for questions; if a response is required, identify a timeline for the response.

Section 11: Comments:
Provide any additional comments or information not noted above:

Section 12: Acknowledgements:

The CAPA Author and PI must sign below.

Please e-sign using Adobe software:

1) Open form in Adobe software.
2) Use Fill & Sign tool to complete.
3) Confirm all responses are correct.
4) Click on Red Signature tab to sign.
5) Save file.

Note: Free Adobe Reader available at: www.adobe.com

CAPA Author (print name):

Signature of CAPA Author _____ Date _____

Principal Investigator (print name):

Signature of Principal Investigator _____ Date _____

REMINDER: All CAPA Forms must be submitted to the IRB for review and acknowledgment. The IRB may require additional actions if necessary.