

HUMAN RESEARCH PROTECTION INSTITUTIONAL REVIEW BOARD

IRB ADVERSE EVENT/UNANTICIPATED PROBLEM/INCREASED RISK REPORT

NOTE: The form is subject to the disclosure requirements of Florida Sunshine Laws.

PI Supervisor/ Administrator Signature:	ECTION 1	Approved Research Protoco To be completed by the p			
PI Supervisor/ Administrator Signature: Date: MM Ministrator Signature: Date: MM			•		
PI Supervisor/ Administrator Signature:			Teleph	none:	
PI Supervisor/ Administrator Signature: Date: MM				Date:	_
SECTION 2 Investigators must report all adverse events that were not included in protocol, consent or program m including: Unexpected adverse events where participants are exposed to a reportable event – an actual harm required (e.g., breach of confidentiality, loss of records or computer-based participant information, le employability, loss of insurability, criminal or civil litigation, embarrassment, humiliation, discriminat stigmatization); Serious adverse events (e.g., resulted in death, was/is life threatening, required hospitalization, resure persistent or significant disability or incapacity, any medical event that requires treatment to prevent previous medical outcomes); and Expected adverse events of moderate or greater severity associated with the research study. Adverse events must be reported to the IRB within five (5) working days of occurrence or knowledge occurrence. All Adverse Event/Unanticipated Problem/Increased Risk Report Forms are subject to the disclosure requirements of Florida Sunshine Laws and are reviewed by the full IRB for discussion and recommendation at the next scheduled IRB meeting, or earlier. Check one: Initial Report Follow-up Report					MM/DD/YY
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	• Unexpecting required (comployable stigmatizaria) • Serious apersistent previous required (comployable stigmatizaria)	eted adverse events where parents, breach of confidentiality, willity, loss of insurability, crimination); adverse events (e.g., resulted a cor significant disability or incomedical outcomes); and	articipants are exposed to a reportable exposed for records or computer-based part and or civil litigation, embarrassment, hurin death, was/is life threatening, require apacity, any medical event that requires	vent – an actual icipant informati imiliation, discri d hospitalization treatment to pro	harm is not tion, loss of mination, n, resulted in event any of th
	Unexpected required (employable stigmatiza Serious apersistent previous reduced required (demonstrative) Expected decorate events much courrence. All Addisclosure requirement requiremen	eted adverse events where pa (e.g., breach of confidentiality, pility, loss of insurability, crimi- nation); adverse events (e.g., resulted in the or significant disability or incomedical outcomes); and ad adverse events of moderate ast be reported to the IRB was diverse Event/Unanticipated ments of Florida Sunshine I	rticipants are exposed to a reportable ex- loss of records or computer-based part nal or civil litigation, embarrassment, hu in death, was/is life threatening, require apacity, any medical event that requires the or greater severity associated with within five (5) working days of occurred Problem/Increased Risk Report Follows and are reviewed by the full IR	vent – an actual icipant information, discrided hospitalization treatment to protect the research strence or knowledgers are subjectives.	harm is not tion, loss of mination, n, resulted in event any of the tudy.
Location of Adverse Event:	Unexpected required (employability stigmatizales) Serious apersistent previous recurrence. All Addisclosure requirementation and recurrence are commendation are commendation and recurrence are commendation and recurrence are commendation are commendation are commendation are commendation and recurrence are commendation are commen	eted adverse events where par (e.g., breach of confidentiality, bility, loss of insurability, crimination); adverse events (e.g., resulted in a consignificant disability or incomedical outcomes); and adverse events of moderate ast be reported to the IRB was liverse Event/Unanticipated ments of Florida Sunshine In at the next scheduled IRB in	reticipants are exposed to a reportable ex- loss of records or computer-based part nal or civil litigation, embarrassment, hu in death, was/is life threatening, require apacity, any medical event that requires are or greater severity associated with within five (5) working days of occurred Problem/Increased Risk Report For Laws and are reviewed by the full IR meeting, or earlier.	vent – an actual icipant information, discrided hospitalization treatment to protect the research strence or knowledgers are subjectives.	harm is not tion, loss of mination, n, resulted in event any of the tudy.

College of Central Florida does not discriminate against any person on the basis of race, color, ethnicity, religion, gender, pregnancy, age, marital status, national origin, genetic information, sexual orientation, gender identity, veteran status or disability status in its programs, activities and employment. For inquiries regarding nondiscrimination policies contact Dr. Mary Ann Begley, Director of Diversity and Inclusion – Title IX Coordinator, Ocala Campus, Building 3, Room 117H, 3001 S.W. College Road, 352-291-4410, or Equity@cf.edu.

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Check all that apply:	Unexpected			
	Breach of confidentiality			
		iter-based participant information		
	Loss of employability	nor swea paraerpant arrormation		
	Loss of insurability			
	•			
	Criminal or civil litigation			
	Embarrassment			
	☐ Humiliation			
	☐ Discrimination			
	☐ Stigmatization			
	Other: (specify)			
	Serious			
	Resulted in death			
				
	Was/is life threatening			
	Required hospitalization			
		ignificant disability or incapacity		
	Any medical event that re-	quires treatment to prevent any of above		
	Related/possibly related to rese			
Describe the event:				
If you have any remaining q	uestions about CF's IRB process, c	contact the IRB chair at <u>ie@cf.edu</u> .		
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Date Received by IRB Chair				
or Designated Representative:		Date Distributed to IRB:		
IRB Recommendation:	☐ Changes to Consent Form			
	Reconsenting			
Date:				
	Referral to: (specify)			
	Other: (specify)			

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