NIH NATIONAL CANCER INSTITUTE
BBRB Biorepositories and Biospecimen Research Branch

VER. 03.00

OP-0016-F2

## **GTEx Data Correction Form (DCF)**

Instructions: Complete this form when documenting data entry errors in CBR BRIMS and/or the CDR Data Services databases. Please contact the Study Management Group with all questions.

Effective Date: mm/dd/yyyy

Services dutubuses. Fied.	se contact the		jement dro	up with un	questions.	_
BSS:						
Case ID:						
Where can the data er	ntry error be f	ound? (Mar	k all that a	apply)		
CBR, GTEx Green Kit		CDR, GTEx Green Kit		CDR, GTEx Pin	k Kit	
CBR, GTEx Yellow Kit		CDR, GTEx Yellow Kit		Tissue Data Co	ollection Form	
CBR, GTEx Aqua Kit		CDR, GTEx Aqua Kit				
CBR, GTEx Pink Kit						
Other, specify	Ple	ease specify:				
To be completed by th	e site identify	ing the erro	r.			
Site identifying error:						
Brief description of da error identified:	ıta					
Date Study Manageme	ent					
Group first notified:						
Description of Error (	questions 1a,	1b, 1c and 1	ld) to be c	ompleted	by Error Sou	rce.
1. Error Description, E	rror Source					
a. Provide a detailed	description of	f the data en	itry error i	dentified.		
b. What is the approp	o. What is the appropriate data correction?					
c. Name of person re	equesting				d. Date requested:	

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Submit this form to the Study Management Group after completion of Questions 1a, 1b, 1c and 1d (if applicable, submit updated forms to the CBR)

Corrective Action to be completed by CBR (questions 2a, 2b and 2c) and, if applicable, the Study

	inagement Group.	by CDN (questions 2a, 2b and 2c,	, ana, n app	iloubic, t	iic Stady		
	Corrective Action, CBR		_				
a.	Provide a detailed description o	Provide a detailed description of the steps taken to correct the data entry error.					
D.	Name of the person		c. Date				
	authorizing corrective action:		authorized:				
	Corrective Action, CDR (If applic	<del></del>					
d.	Provide a detailed description of	of the steps taken to correct the	data entry e	rror.			
e.	Name of the person		f. Date				
	authorizing corrective action:		authorized:				
$\Gamma_{\Omega}$	rrection Verification to be comp	leted by Error Source (questions	3a 3h 3ca	nd 3d) a	nd if		
	plicable, CBR or the Study Manag			iia sa, a	π, π		
	Correction Verification, Error So		,				
a.	Were the steps detailed in 2a/2	d completed?		Yes	No		
	i. If No, explain.						
b.	Did the steps taken in 2a/2d resolve the data entry error detailed in 1a? Yes No						
	. If No, explain.						
	, .						
			1 -				
c.	Name of person verifying		d. Date				
	completion of data correction:		verified:				

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## **GTEx Data Correction Form (DCF)**

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Correction Verification to be completed by the CBR or Study Management Group, if applicable (questions 3e, 3f, 3g and 3h). 3. Correction Verification, CBR/Study Management **Group (If applicable)** Yes No e. Were the steps detailed in 2a/2d completed? i. If No, explain. f. Did the steps taken in 2a/2d resolve the data entry error detailed in 1a? Yes No i. If No, explain. h. Date g. Name of person verifying completion of data correction: verified: **Comments** 

If the error noted in this DCF is deemed significant by the Study Management Group or BSS, a Nonconformance Report (NCR), including a Root Cause Analysis and Corrective/Preventive Actions (CAPA) plan will be required from the originating entity.

Submit completed form to the Study Management Group.