Directory of Protocol Deviation & Violation (PDV) Codes V1.2
A Lexicon for Understanding & Communicating Protocol Deviations & Violations
N**orman M. Goldfarb**

INTRODUCTION & TERMS OF USE

The only clear consensus on the definitions of deviations and violations is that a deviation is a small violation and a violation is a big deviation. More precise definitions quickly degrade into guidelines with many gray areas.

Protocol Deviation & Violation (PDV) codes solve this problem by just listing them out. Scenarios, where necessary, differentiate between the classifications. This Directory details about 120 circumstances that may constitute a protocol deviation or violation, or just require a progress note.

If regulatory authorities, sponsors and IRBs create their own classifications, they can use PDV codes to communicate their special rules without confusion.

Perhaps even more importantly, a proper coding system gives us the ability to identify trouble spots, measure trends, and manage down the number of deviations and violations.

PDV codes also provide a foundation for training study personnel in GCP. Investigators and study coordinators can learn what NOT to do, and how to handle problems when they do arise.

Optional causation codes are also provided. These codes are most likely to be useful in classifying deviations and violations caused by a subject.

The current version of the Directory is available at no charge at
http://www.firstclinical.com/resources/codes.html

You may use this Directory freely within your company or institution. You may distribute the Directory (without modification) as you wish. Please send me suggestions for additions, modifications, clarifications, deletions, etc.

If you wish to join the PDV Code Governing Committee that administers this Directory, please let me know. With everyone's cooperation, we can establish a common language for understanding and communicating research activities.

Thank you!

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PROTOCOL DEVIATION & VIOLATION (PDV) CODES

Code	Problem	Violation	Deviation	Progress Note	Comments
	Informed Consent				
P1001	Executable informed consent form mailed to potential subject			X	
P1002	Executable informed consent form taken by potential subject			X	
P1003	Incorrect informed consent - unapproved version	X			
P1004	Incorrect informed consent - incorrect version	X			
P1005	Incorrect informed consent - incorrect study	X			
P1006	Consent not obtained for amendment	X			
P1007	Informed consent not obtained	X			
P1008	Informed consent not signed by subject	X			
P1009	Informed consent not initialed by subject		X		
P1010	Informed consent not dated by subject	X			
P1011	Informed consent signed but not properly dated by subject	X			
P1012	Informed consent not signed by physician	X			If required by IRB.
P1013	Informed consent signed but not dated by physician	X			
P1014	Informed consent not properly signed or dated by consenter	X			
P1015	Subject's signature dated by site personnel		X		
P1016	Subject's signature forged by site personnel	X			
P1017	Subject's initials forged by site	X			

	personnel				
P1015	Informed consent without required witness	X			
P1016	Informed consent without required authorized representative	X			
P1017	Informed consent improperly obtained (other)	X			
P1018	Informed consent obtained late	X			
P1019	Informed consent modified by subject	X			
	Enrollment				
P1101	Underage subject improperly enrolled	X			
P1102	Vulnerable subject improperly enrolled	X			
P1103	Subject enrolled without meeting medical condition eligibility criteria	X			
P1104	Subject enrolled without meeting medication condition eligibility criteria	X			
P1105	Subject enrolled without meeting test condition eligibility criteria	X			
P1106	Subject enrolled without meeting conflicting study eligibility criteria	X			Not enough elapsed time between studies.
P1107	Subject enrolled without meeting eligibility criteria, other	X			
P1108	Subject enrolled with approved exception			X	
	Tests				
P1201	Test incorrect	X			
P1202	Test not attempted	X	X		Violation if safety issue.
P1203	Test unsuccessful		X		
P1204	Extra test performed	X			
P1205	Test prior to window		X		Violation if safety issue.
P1206	Test after window		X		Violation if safety issue.
P1207	Test data lost		X		
P1208	Test performed by someone not on 1572 (if required)	X			

	Assessments				
P1301	Assessment incorrect	X			
P1302	Assessment not attempted	X	X		Violation if safety issue.
P1303	Assessment unsuccessful		X		
P1304	Extra assessment performed	X			
P1305	Assessment prior to window		X		Violation if safety issue.
P1306	Assessment after window		X		Violation if safety issue.
P1307	Assessment data lost		X		
P1308	Assessment performed by someone not on 1572 (if required)	X			
	Exams				
P1401	Exam incorrect	X			
P1402	Exam not attempted	X	X		Violation if safety issue.
P1403	Exam unsuccessful		X		
P1404	Extra exam performed	X			
P1405	Exam prior to window		X		Violation if safety issue.
P1406	Exam after window		X		Violation if safety issue.
P1407	Exam data lost		X		
P1408	Exam performed by someone not on 1572 (if required)	X			
	Procedures				
P1501	Procedure incorrect	X			
P1502	Procedure not attempted	X			
P1503	Procedure unsuccessful		X	X	Not a deviation if safety issue or subject objected.
P1504	Procedure prior to window		X		
P1505	Procedure after window		X		
P1506	Procedure data lost	X			Same as not attempted.
P1507	Procedure performed by someone not on 1572 (if required)	X			
	Specimens				

P1601	Specimen collection unsuccessful		X		
P1602	Specimen collected with wrong type of collection kit			X	
P1603	Specimen collected with expired lab kit			X	
P1604	Specimen mishandled			X	
P1605	Specimen mislabeled			X	
P1606	Specimen lost			X	
P1607	Specimen damaged in shipment			X	
	Data Collection				
P1701	Data collection incorrect	X			e.g., chart review
P1702	Data collection not attempted			X	
P1703	Data collection unsuccessful			X	
P1704	Data collection prior to window		X		
P1705	Data collection after window		X		
P1706	Data collection data lost			X	
P1707	Data incorrectly transcribed from source document to CRF			X	
	Visits & Telephone Calls				
P1801	Study visit before window		X		
P1802	Study visit after window		X		
P1803	Study visit missed		X		
P1804	Telephone follow-up before window		X		
P1805	Telephone follow-up after window		X		
P1806	Telephone follow-up missed		X		
	Documentation				
P1901	Documentation missing			X	Same as lost data
P1902	Documentation incomplete			X	
P1903	Documentation incorrect			X	
P1904	Documentation signed by incorrect person			X	
P1905	Documentation not signed correctly,			X	

	other				
P1906	Documentation back-dated			X	
P1907	Documentation not dated correctly			X	
	Study Drug				
P2001	Study drug administered before window		X		
P2002	Study drug administered after window		X		
P2003	Study drug not administered	X			
P2004	Study drug dosage incorrect	X			
P2005	Study drug administered incorrectly (other)	X			
P2006	Study drug administered based on incorrect randomization	X			
P2007	Incorrect rescue medication administered	X			
P2008	Prohibited concomitant medication taken			X	Contact sponsor
P2009	Study drug unblinded improperly by study personnel	X			
P2010	Subject took dose before window			X	
P2011	Subject took dose after window			X	
P2012	Subject missed dose			X	
P2013	Subject took wrong study dose			X	
P2014	Subject took dose incorrectly (other)			X	
P2015	Study medication lost			X	
P2016	Study medication damaged			X	
P2017	Non-subject took study medication			X	
P2018	Subject unblinded study medication			X	Contact sponsor
	Diaries				
P2101	Subject made diary entry before window			X	
P2102	Subject made diary entry after window			X	
P2103	Subject did not make diary entry			X	
P2104	Subject made diary entry incorrectly			X	

	IVRS				
P2201	Subject made IVRS entry before window			X	
P2202	Subject made IVRS entry after window			X	
P2203	Subject did not IVRS diary entry			X	
P2204	Subject made IVRS entry incorrectly			X	
	Subject Non-compliance				
P2301	Subject diet incorrect			X	
P2302	Subject not fasting before test or procedure		X		
P2303	Subject using improper contraception	X			
P2304	Subject not using contraception	X			
P2305	Subject non-compliance, other	X	X	X	Need scenarios
	Adverse Events				
P2401	SAE reported late	X			
P2402	SAE reported with incorrect data			X	
P2403	SAE reported with missing data			X	
P2404	SAE reported incorrectly, other			X	
P2405	SAE not corrected	X			
P2406	SAE not reported	X			
P2407	AE recorded late			X	
P2408	AE recorded incorrectly			X	
P2409	AE not recorded			X	

Causation Codes (Optional)

1	Study Personnel
2	Subject
3	Sponsor
4	CRO

5 Ethics Committee

9 Other

0 None

Note: Intention is not inferred.