FIPS 199/NIST 800-60 System Categorization

SYSTEM INFORMATION					
System Name	NCI Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS)			**IC**	National Cancer Institute
System Type	☐ General Support System ☒ Major Application ☐ Tier 2, 3, or 4			**Date**	6/7/2023
Overall System Security Category	Moderate			**SDLC Status**	Operational
Overall Impact Levels (High Water Mark)	**Confidentiality**	**Integrity**	**Availability**		
	Moderate	Moderate	Moderate		

System Description	The CTEP-ESYS is a Major Application (MA) that is the primary data collection mechanism for NCl's vast clinical trials program. The purpose of the system is to ensure patient safety and to meet the NCI CTEP's scientific, regulatory, administrative, and operational program mission. Specifically, it is used to document, track, monitor, and evaluate NCI clinical research activities. The CTEP-ESYS collects safety and clinical results data on ongoing clinical cancer trials (trials not yet completed). Data reporting and analysis in real-time are critical to ensuring adequate monitoring of ongoing clinical research. Timely data reporting and analysis also ensure effective planning for the required successor studies, thus accelerating the evaluation of promising new agents and regimens for patients with cancer.		
System Contacts	**Address**	**Phone and Email**	**Signature**
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INFORMATION TYPE(S), PROVISIONAL IMPACT LEVEL(S), ADJUSTED IMPACT LEVEL(S), RATIONALE						
Category of Information (800-60)	**Provisional Impact Levels**			**Adjusted Impact Levels**		
	Confidentiality	**Integrity**	**Availability**	**Confidentiality**	**Integrity**	**Availability**
D.20. l Research and Development	Low	Moderate	Low	Moderate	Moderate	Moderate
Rationale	Confidentiality was raised because of the presence of proprietary R&D information that should not be accessible to the public, and because its unauthorized release or access could cause serious adverse impacts to the NCl, individuals, or agency assets. Availability was raised to moderate due to the adverse event reporting requirements within the stipulated timeframe and also to ensure that there are no serious delays or disruptions to the information system availability that could have a serious adverse impact on research activities.					
D.19.1 Scientific and Technical Research and Innovation	Low	Moderate	Low	Moderate	Moderate	Low
Rationale	Confidentiality was raised because of the types of information available in the enterprise system, including protocols and protocol attributes, drug inventory and site distribution records, adverse event reports, site audit reports, Investigational New Drug (IND) submission records, Investigator registration details, and patient accrual details. Note that no patient-identifying information is stored in the system.					
C.3.5.6 Record Retention Information Type	Low	Moderate	Low	Moderate	Moderate	Low
Rationale	Confidentiality was raised to ensure adequate protection of the PHI data that is collected, stored, and processed in the system. Most of which is used for compliance reporting, program monitoring, and planning purposes. Some of these data elements are for internal use only and are reported to the FDA as required by law.					