FIPS 199/NIST 800-60 System Categorization

SYSTEM INFORMATION				
System Name	**NCI Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS)**		**IC**	NCI
System Type	☐ General Support System ☒ Major Application ☐ Tier 2, 3, or 4		**Date**	12/4/2017
Overall System Security Category	Moderate		**SDLC Status**	Operational
Overall Impact Levels (High Water Mark)	**Confidentiality**	**Integrity**		**Availability**
	Moderate	Moderate		Moderate

System Description	The purpose of the National Cancer Institute (NCI) Cancer Therapy Evaluation Enterprise System(CTEP-ESYS) is to assure patient safety, meet the NCI CTEP scientific, administrative and operational program mission, and all regulatory requirements for NCI CTEP clinical trials. Specifically, it is used to document, track, monitor, and evaluate NCI clinical research activities. CTEP-ESYS project is the primary data collection mechanism for NCI's vast clinical trials program. CTEP-ESYS collects safety and clinical results data on ongoing cancer clinical trials (trials not yet completed). Data reporting and analysis in real time are critical to ensuring adequate monitoring of the ongoing clinical research. CTEP-ESYS collects safety and clinical results data on 1,500 ongoing cancer clinical trials (trials not yet completed) that monitor more than 30,000 patients per year in more than 17 disease areas. Timely data reporting and analysis also assure effective planning for the required successor studies, thus accelerating the evaluation of promising new agents and regimens for patients with cancer. CTEP-ESYS does not collect any patient health information, but does collect non-identifiable patient meta-data (i.e, zip codes, patient initials, and month/year of birth).

System Contacts	Address	Phone	Email
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SIGNATURES

X

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Privacy Coordinator

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.20.1 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 NCI, individuals, or agency assets. Integrity was also raised because the reliability of the information contained in CTEP-ESYS must be high enough to ensure there are no serious disruptions or delays of research activities that rely on the data. Effects on future funding could also be seriously impacted if the data in the system are unreliable. 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.						
D.14.5 Health Care Research and Practitioner Education		Low	Moderate	Low	Moderate	Moderate	Low

INFORMATION TYPE(S), PROVISIONAL IMPACT LEVEL(S), ADJUSTED IMPACT LEVEL(S), RATIONALE						
Category of Information (800-60)	**Provisional Impact Levels**			**Adjusted Impact Levels**		
Rationale	Confidentiality was raised to ensure adequate protection of the PII 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.					
Rationale						
Rationale						