

## FIPS 199/NIST 800-60 System Categorization

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

<b>System Description</b>	<p>The CTEP-ESYS is a Major Application (MA) that is the primary data collection mechanism for NCI'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.</p>		
<b>System Contacts</b>	<b>Address</b>	<b>Phone and Email</b>	<b>Signature</b>
Jeff Shilling NCI Chief Information Officer	9609 Medical Center Drive Rockville, Maryland 20850	240.276.5549 jeffrey.shilling@nih.gov	
Karen Friend NCI Information System Security Officer	9609 Medical Center Drive Rockville, Maryland 20850	240.276.5055 karen.friend@nih.gov	
Shanda Finnigan System Owner	9609 Medical Center Drive Rockville, Maryland 20850	240-276-6058 shanda.finnigan@nih.gov	
Suzanne Milliard NCI Privacy Coordinator	MSC 2580, 31 Center Drive Bethesda, MD 20892	240.781.3340 suzanne.milliard@nih.gov	

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
<b>Rationale</b>	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. 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
<b>Rationale</b>	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
<b>Rationale</b>	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.					