

Getting Connected with caBIG™

DATA SHARING AND SECURITY FRAMEWORK

Achieving technical interoperability in and of itself will not deliver the full benefits of accelerated translational research and expedited care for the patient. These are only possible when researchers and oncologists have the information they need to do their work better. However, there are very important non-technical considerations, such as patient privacy protections and intellectual property interests, which affect the ability to make data available.

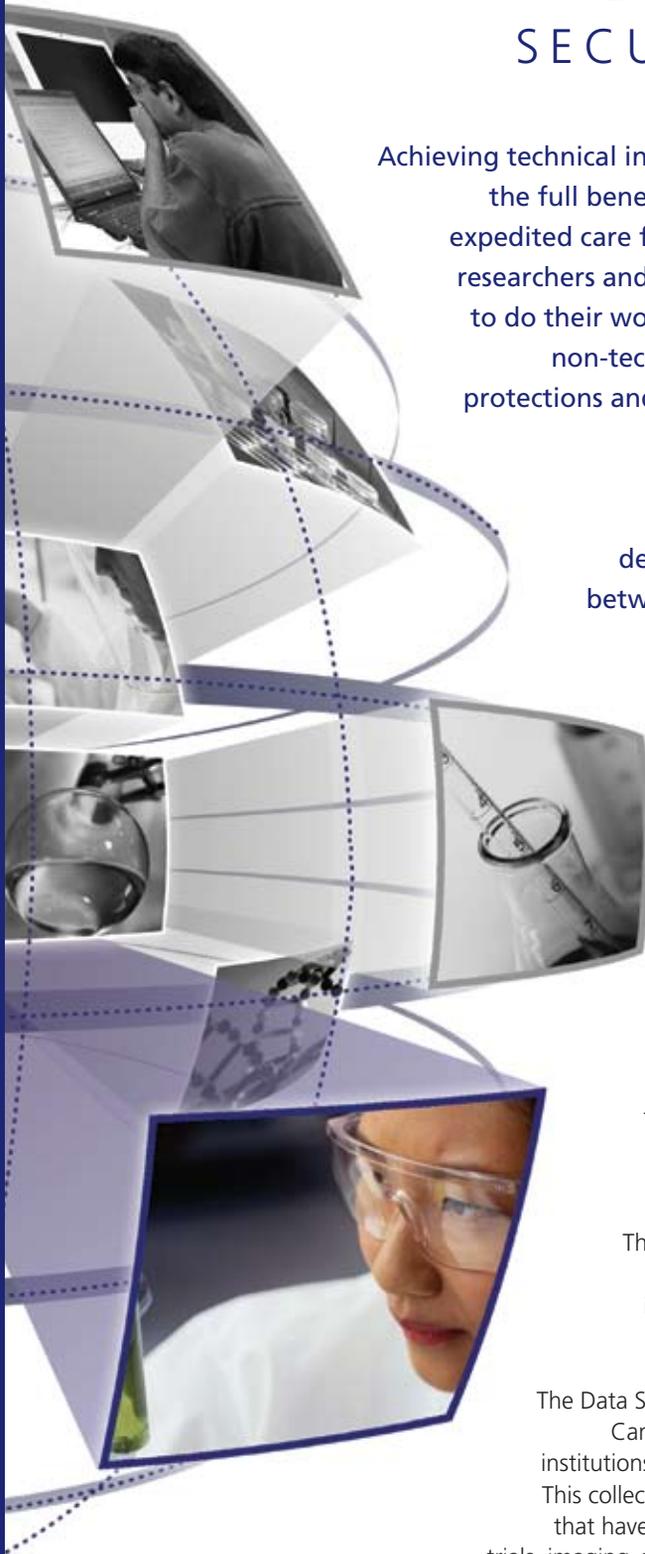
The Data Sharing and Security Framework is designed to facilitate appropriate data sharing between and among organizations by addressing legal, regulatory, policy, proprietary, and contractual barriers to data exchange.

When fully developed, the Data Sharing and Security Framework will consist of policies, processes, model agreements, and other materials that participating centers agree to help develop and to adopt as appropriate. Together, these documents will cover critical issues such as the creation of a trust fabric for accepting user authentication credentials from other institutions, standards for the levels of security that are needed for different types of data, and suggestions on how to share data subject to the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, as well as other applicable laws, regulations, and policies.

This document provides an overview of the Data Sharing and Security Framework. It outlines what tools may be included in this bundle, their specific function, and the role participating cancer centers are expected to play.

The Data Sharing and Security Framework promotes the National Cancer Institute's overarching goal to connect the people, institutions, and data in the cancer community through caBIG™. This collection of tools and capabilities is one of three "bundles" that have been designed to help support and streamline clinical trials, imaging, tissue banking, and integrative cancer research, and to provide the materials needed to join the secure caBIG™ data-sharing framework.

Visit <https://caBIG.nci.nih.gov/inventory> for more detailed information and access to caBIG™ resources.



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Component	Specific Objective
<p>caBIG™ Policies</p> <ul style="list-style-type: none">• caBIG™ Data Sharing and Security Framework (DSSF)• caGrid security policies for authentication (identity management) and authorization	<p>Facilitate the evaluation of the level of data sensitivity and the levels of access controls the institution will require for each data set to be shared</p>
<p>Processes and Best Practices</p> <ul style="list-style-type: none">• Suggestions for conducting the informed consent process in a manner that permits data to be shared via the caGrid and utilizes, when appropriate, model informed consent language (see below)• Expectations for sharing unpublished data (varies depending on data type)• Recommendations regarding incentives for sharing unpublished data• Suggestions for developing contract clauses for sponsored research projects that permit broad data sharing, including the use, when appropriate, of model contract clauses (see below)• Informational documents for IRB use in reviewing proposals for data sharing via the caBIG™ infrastructure that utilizes, when appropriate, the caBIG™ data sharing plan guidelines	<p>Facilitate approval across the institution of data sharing arrangements via the caBIG™ infrastructure</p>
<p>Model Documents</p> <ul style="list-style-type: none">• Standardized click-through agreements between data providers and users (e.g., data-related provisions in Data Use Agreements and Material Transfer Agreements)• Security-related agreements (for both data providers and users)• Model informed consent provisions• Model researcher questionnaires and data sharing checklists• Model contract clauses for sponsored research projects (including clinical trial agreements) to permit data sharing	<p>Facilitate and expedite the arrangements between institutions to share data</p>



caBIG™
cancer Biomedical
Informatics Grid™



Description

Cancer Center Participation Role

The DSSF provides an organization with a conceptual framework and implementing tools that facilitate an organization's data sharing activities. The DSSF implementing tools include a decision support tool that uses four types of factors to assess the sensitivity of any given dataset and to determine the desired data access controls.

The caGrid security policies and procedures set forth the requirements for providing the software and procedural infrastructure that provides the levels of access controls for each dataset as determined by the data-providing institution.

The Center will be expected to participate in the testing and refinement of DSSF by providing information about particular data sets it may share via the caGrid infrastructure and by determining the appropriate levels of data sensitivity and secured access controls for each dataset.

The Center will contribute actively to the testing of security controls that will be defined over the coming months by reviewing caBIG™ policy statements and providing expert input on the various levels of data access protections from the institution's perspective.

caBIG™ Policies

Best practices, suggested conduct, and proposed recommendations that will inform the researcher and the institution of the advantages of sharing data and community-developed methods for encouraging and recognizing data sharing among researchers across departments within a single institution and located at different institutions.

The Center will be expected to participate in the evaluation and refinement of best practices and suggested guidance documents, to pilot their use for internal approval processes, and to provide recommendations for further refinement based on such experiences.

Processes and Best Practices

Model agreements and other documents will expedite the negotiations between institutions for sharing data by providing simple standard agreements for most low and medium sensitivity data sets.

The Center will be expected to participate in the evaluation and refinement of model documents, to pilot their use for internal processes, and provide recommendations for further refinement based on such experience.

Model Documents

RESOURCES

Specific tool information:

<https://cabig.nci.nih.gov/tools>

Overview of caBIG™:

<http://cabig.cancer.gov>

Detailed information about caBIG™,
including training, compatibility, etc:

<https://cabig.nci.nih.gov>

For general information about "Getting
Connected with caBIG™":

https://cabig.nci.nih.gov/getting_connected

CONTACT

caBIGconnect@cancer.gov



NIH Publication No. 08-6384
Printed March 2008

