May 25, 2010 **Statement of Work**

RECOVERY: Quality Management System (QMS) for The Cancer Genome Atlas (TCGA) Program

1 Introduction:

The Cancer Genome Atlas (TCGA) is a comprehensive, collaborative effort led by the National Institutes of Health (NIH) to map the genomic changes that occur in major types and subtypes of cancer. Researchers throughout the nation are using various genome analysis technologies, including high through-put DNA sequencing, to carry out this effort. A pilot project initiated in 2006, focused on three tumor types (brain, ovarian, and lung), established the scientific infrastructure and demonstrated the "proof of concept" needed to mount a large-scale cancer genome mapping project. Based on the success of the pilot, TCGA announced in September 2009 that it will map the genomes of at least 20 additional cancers over the next five years.

During the pilot phase TCGA generated 7 terabytes (TB) of data, spanning biospecimen information, patient information, and genome, exome and epigenetic data for both tumor and normal specimens per patient. The ability to ensure data completeness associated with each specimen required a coordinated effort across numerous institutions and information systems. This coordination will become increasingly difficult and important as the program grows by 8 fold in the coming five years. The value of the data generated in TCGA will lie in its quality, as all subsequent analyses and research outcomes will be dependent on the quality of the information generated. The Quality Management System (QMS) will serve as the basis by which the quality and value of the TCGA data may be measured.

Key to the program will be the establishment of a process and system to ensure data completeness and quality. To facilitate expansion of the program, TCGA will focus on quality as a best management practice, and is seeking support to define and implement a Quality Management System (QMS). The rest of this statement of work document outlines the purpose, requirements and scope of the TCGA QMS.

2 Scope

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the below:

2.1 Objective:

The objective of this project is to establish a Quality Management System (QMS) across the funded activities of the TCGA program, with the goal of identifying non-conforming data in a timely fashion to ensure data released to the public is of the highest quality possible.

The NCI anticipates the following activities will be in-scope to support the objectives of the project:

- Establish TCGA-Quality Management (QM) policies, processes and procedures in line with the program organization and goals
- Implement the QMS and train the staff within the Biospecimen Core Resources (BCR) and the Data Coordinating Center (DCC)
- Provide a means to identify, track and report non-conforming data
- Establish and implement internal audit policies, processes, and methods to verify compliance with the QMS
- Provide regular and detailed reports of the status of data quality at all stages in the TCGA workflow

2.2 Technical Description:

2.2.1 TCGA Workflow:

The TCGA program has a general workflow of tissue accrual to data generation, outlined in the following document (http://cancergenome.nih.gov/about/TCGA_Brochure.pdf). The workflow has many steps and generates terabytes of data from clinical and research centers all over the country. The next two paragraphs briefly describe the data flow for the purpose of highlighting the necessity for a QMS.

Tissue Source Sites (TSS) provide biospecimens (tumor and normal), along with clinical meta-data, to the Biospecimen Core Resource (BCR). The BCR is responsible for quality control (QC) prior to accepting the samples, and once accepted becomes the steward of the biological material, the subsequent derivative reagents, and the clinical meta-data. The BCR prepares the samples and isolates Deoxyribonucleic Acid (DNA) and Ribonucleic Acid (RNA) to provide to the Genome Sequencing Centers (GSC) and Genome Characterization Centers (GCC). The GSCs and GCCs produce an immense amount of digital information about the cancer and normal samples, which eventually end up at the Data Coordinating Center (DCC) and at the National Center for Biotechnology Information (NCBI) [outside the scope of TCGA and this contract]. From here, the data is available for download by the public, but is further analyzed by the Genome Data Analysis Centers (GDAC). Analyzed data is then uploaded to another partition of the DCC data servers and is also made available to the general public. Given the nature of the associated clinical meta-data, some information is considered personally identifiable information (PII) and is protected behind a secure firewall, as required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

The two (2) BCRs and the DCC serve as the primary resource of the TCGA biospecimens and data, respectively. The QMS will need to be implemented at these three (3) institutions and be able to communicate with their Laboratory Information Management Systems (LIMS), their Clinical Data

Management Systems (CDMS), and the TCGA data repository to both ensure compliance and track and report conforming and non-conforming data. Additionally, the TCGA-QMS shall receive meta-data on a variety of performance and workflow metrics from the other grant funded institutions (GSCs, GCCs, and GDACs) to support the program management duties.

2.2.2 Related QMS Guidelines:

The NCI is seeking to establish a QMS congruent with the guidelines described by the Clinical and Laboratory Standards Institute (CLSI) document HS1-A2, *"A Quality Management System Model for Healthcare; Approved Guideline – Second Edition"* (http://www.clsi.org/source/orders/index.cfm?section=Online_Store&task=3&CATEGORY=QM&PRODUCT_TYPE=SALES&SKU=HS01A2E). CLSI document HS1-A2 proposes Quality Management guidelines for organizations in the medical disciplines and these guidelines are based on a common set of 12 quality elements established by ISO 9001, typically referred to as Quality System Essentials (QSE). It is the intent of the TCGA Program office to employ a minimal QMS based on 9 of the 12 QSEs as outlined below. It will be the responsibility of the Contractor to define the quality policies, processes and procedures around these nine (9) QSEs as they relate to the TCGA program, however, the Contractor shall ***not*** attempt to make the TCGA Program or any part therein compliant with ISO 9001.

The TCGA QMS shall address the following QSEs:

In-Scope QSEs	Out-of-Scope QSEs
Documents and Records	Personnel
Organization	Process Improvement
Equipment	Facilities and Safety
Purchasing and Inventory	
Process Controls	
Information Management	
Occurrence Management	
Assessments	
Customer Service	

2.2.3 QMS Information Management and Reporting

A primary driver for this Statement of Work (SOW) is the amount of non-conforming data that is identified late in the TCGA workflow. The amount of time and money spent per sample, to go from biospecimen to fully characterized sample, is substantial, and the identification of non-conforming data at the end of the workflow cycle is costly, time-consuming, and threatening to the success of the program. To overcome the late stage identification of non-conforming data, the QMS must have the ability to implement a variety of workflow throughput measurements and data quality checks across the BCR biospecimen repository, the clinical meta-data repository, and the data coordinating center. The Contracting Officer's Technical Representative (COTR) and TCGA program management will require

regular updates on the project's productivity and quality of the information at each of the information repositories.

To support the regular data quality checks, the QMS must, at a minimum, provide the means to identify, manage, and track both throughput of samples and available data (including non-conforming data). Ideally, the QMS information management system (IMS) shall also support automated functions to reach into the various TCGA data repositories, perform a pre-defined list of data quality checks, capture the tests that passed and failed, and generate a summary report.

2.3 Tasks

2.3.1 Task 1: Requirements Gathering

The Contractor shall undertake a review of the quality practices of the TCGA program. Specifically, the Contractor shall focus on the roles and responsibilities of the BCRs and DCC, report the quality management needs, and refine the Quality Management Goals of the TCGA Program. A full requirements gathering process shall include the major stakeholders, to include staff from the TCGA Program Office, BCRs, DCC, GCCs, GSCs and Disease Working Group Co-Chairs.

2.3.2 Task 2: QMS Specifications and Proposal

The Contractor shall utilize the requirements information to outline a strategy and propose the specifications for the development of a program-wide QMS. The proposed QMS shall meet the needs of the Quality Management Goals of the TCGA Program, as well as support the program management requirements for oversight and reporting. The proposed specifications shall include the information management system the Contractor intends to employ. The NCI will support the use of COTS or Open Source Information Management Systems, but the IMS shall only capture, manage, and report the data elements necessary to fulfill the agreed upon objectives. All license fees for COTS solutions must be approved by the Contracting Officer's Technical Representative (COTR) prior to purchase.

2.3.3 Task 3: TCGA Workflows

All aspects of the TCGA program currently have workflows, although many of them are loosely defined. The Contractor shall develop a canonical workflow for all the major program activities, from tissue accession, through data generation, to information services. To accomplish this task, the Contractor shall utilize currently available Standard Operating Procedures, update and modify those workflows based on the requirements analysis from Task 1, and unify the SOPs into a single workflow.

2.3.4 Task 4: Quality Manual

The Contractor shall develop the Quality Manual in conjunction with the COTR and TCGA Program Office. The Quality Manual shall describe the structure and detail of the TCGA QMS to all the stakeholders. The primary users of the QM will be the TCGA management and funded participants.

2.3.5 Task 5: Quality Management System Documents

The Contractor shall define and develop the necessary documents that outline the Policies, Processes, Procedures, and Forms and Records for each of the 9 QSEs outlined in Section 2.2.2. These documents shall serve as the structure for the QMS and shall be as simple as possible while still serving their

function. The QMS policies shall be developed in conjuction with the COTR, TCGA Program Office staff, and considered to be living documents, up for review at all times. The Contractor shall manage these documents electronically, through the QMS Information Management System.

2.3.6 Task 6: QMS Information Management System

The Contractor shall implement an electronic record keeping system, capable of managing the information relevant to each of the nine (9) QSEs. Most importantly, the system shall focus on addressing the following QSEs:

- Documents and Records
- Information Management
- Occurrence Management

Additionally, the QMS IMS shall be able to identify, manage and track non-conforming data and outcomes. Occurrence management is a primary driver behind this task, so the ability to identify and report non-conformities early in the workflow shall be vital. The government anticipates this will require the programmatic integration with the existing informatics infrastructure at the DCC and BCRs. QMS Integration shall be completed within 8 months of the start date of the contract.

The IMS may be a Commercial-Off-the-Shelf (COTS) or Open Source system, but will not be government furnished, unless the Contractor is familiar with an adequate government owned IMS, which may be considered.

2.3.7 Task 7: Staff Training

The Contractor shall perform a series of staff training activities to adequately train the staff of the BCRs and DCC, as well as the NIH Program Management staff. Training activities may be a mix of on-site, in-person training, as well as virtual web meetings. The content and scope of the training sessions is the responsibility of the Contractor. The Contractor shall plan on no more than two (2) on-site training sessions per institutions.

2.3.8 Task 8: Assessments

The Contractor shall assess the two (2) BCR and DCC institutions, once per year, against the policies and procedures of the implemented QMS. In so doing, the Contractor shall determine what components of the QMS are most appropriate for assessment in order to meet the TCGA Program QM goals, develop the assessment criteria in conjunction with the NCI, and carry out the assessment process. The institutions to be assessed do not need to be compliant with any standards organization. The purpose of the assessment is to ensure a high level of data quality over the life of the program.

2.3.9 Task 9: Reporting

The QMS is meant to serve primarily the management of the TCGA Program. The Contractor shall develop reports designed to meet the throughput and quality metrics for the TCGA Program. A number of metrics regarding clinical meta-data, biospecimen management, and tumor genetics/genomics have already been identified, will be shared with the Contractor after contract award, and shall serve as a basis for a portion of the quality management reports. The COTR will work with the Contractor to

approve all report formats, content, and frequency. These reports will need to be an additional component of the QMS IMS. The reports will be tabulated information with graphical summaries and accessible via the internet.

2.3.10 Task 10: Transition Plan

The Contractor shall define a plan for transitioning the QMS to the government or to another contractor at the end of the contract, should the need arise. Thereafter, NCI or another contractor may be responsible for the continued execution of the QMS. To fulfill this task, the Contractor shall provide a detailed plan for transitioning all activities, information systems, data and records to the government (i.e., 3 months prior to the expiration date of the contract). The Transition Plan shall include but is not limited to the following elements:

- QMS Processes
- Review of current artifacts
- QMS recurring artifacts
- IMS hosting, administration, and reporting
- Audit processes
- Staff training (as outlined in Task 7)

A draft transition plan shall be submitted to the Government 90 calendar days before the the end of the contract. The government will review the plan and provide comments to the contractor within 15 calendar days after receipt... A final version of the plan shall be provided to the government 30 calendar days prior to the end of the contract. The transition period shall be the last 30 calendar days of the contract.

2.3.11 Task 11: Monthly Status Reports

At a minimum, the Monthly Status Reports (MSR) shall include:

- Activities completed
- Activities planned for the next month
- Issues to be addressed
- Actual Cost vs. Projected Cost (monthly and cumulative)

Additional sections and topics may be added as identified by the Contractor or the government.

2.4 Technical Requirements

This section describes the technical aspects required to successfully address the tasks outlined in Section 2.3

2.4.1 Task 1: QMS Requirements

The TCGA Program Office will require a thorough review of the quality management needs of the program. The Contractor shall review the current policies and reports of the program, the program structure, the SOPs for all the funded activities, and the information management systems to initiate the requirements process. After which, the Contractor shall meet with COTR, the necessary staff within the TCGA Program Office, the BCRs, DCC, GSCs, GCCs, GDACs, and Disease Working Groups to ascertain the

significant quality gaps and summarize their findings in a Requirements Document. Within 90 calendar days of the start date of the contract, the Contractor shall submit the Requirements Document. The audience for the Requirements Document will be the TCGA Program Management, and therefore, shall reflect the specific needs of the Program Management.

2.4.2 Task 2: QMS Specifications and Proposal

The Contractor shall deliver, within 3 months from the start date of the contract, a QMS Specifications and Proposal document. This document shall include the requirements findings, describe a process to address the requirements as they pertain to a QMS, and articulate the activities necessary to instantiate a QMS that shall meet the productivity and quality goals, objectives, and requirements of the TCGA Program. This document shall serve as the roadmap for the development of a QMS, it shall not serve as the Quality Manual. The purpose of the Specifications and Proposal document is to clearly define what is needed, why it is needed, and how it will be addressed.

2.4.3 Task 3: Workflows

The Contractor shall develop a canonical set of TCGA Program workflows, to be assembled from currently available workflows and SOPs. The initial compilation of workflows shall be completed within 120 days from the start date of the contract and submitted to the Government. This workflow will likely change over time and it shall be the responsibility of the Contractor to ensure all documentation is kept current. Where there are gaps in the program, not represented by a workflow or SOP, the Contractor shall alert the COTR to ensure the appropriate documents are produced by the appropriate entities.

2.4.4 Task 4: Quality Manual

The Quality Manual shall serve as the primary document to communicate and govern the QMS. The Quality Manual shall describe the TCGA quality policies and the structure of the QMS. The Quality Manual must provide a summary of the policies for each of the 9 QSEs to be included in the TCGA QMS. The Contractor shall have four (4) months from the start date of the contract to submit the Quality Manual. The COTR will approve the Quality Manual in writing. As the quality documents and SOPs are generated, the Quality Manual shall also provide references to all of the TCGA Program's quality policies, processes, and procedures. The audience for the Quality Manual will be the TCGA Program Management.

2.4.5 Task 5: Quality Management System Documents

The Quality Management System Documents serve as the backbone of the QMS. There shall be four (4) documents for each of the 9 QSEs: Policies, Processes, Procedures, and Forms and Records.

Policies – state the program's intent regarding each QSE. The compilation of the QSE Policies form the heart of the Quality Manual.

Processes – document how quality management activities happen within the TCGA program. The processes describe the activities necessary to accomplish the intent, the correct sequencing of activities for a successful outcome, and the entities responsible for the activities. The processes may take the form of workflows, charts, and tables.

Procedures – provide instructions on how to perform the steps in a given process activity. There shall be at least one procedure for each process. The procedures can be built upon the currently available SOP's from the funded entities of the program.

Forms and Records – describes the structure of the forms used to record information.

The Contractor shall submit an initial draft of the Policies, Processes, Procedures, and Forms and Records for each of the nine (9) QSEs no later than six (6) months from the start of the contract. It is expected that these Quality Management System Documents shall be living and modified continuously over the life of the Program. Additionally, these documents must be managed within the TCGA QMS IMS. The finalized documents are due no later than twelve (12) months from the start date of the contract.

2.4.6 Task 6: QMS Information Management System

The Contractor shall instantiate an electronic information management system (IMS) to facilitate the establishment and ongoing maintenance of the overall QMS no later than six (6) months from the start date of the contract. As detailed in the Section 2.3.6, the Contractor shall have discretion with selection of an IMS, but the IMS must be approved by the COTR in writing. The IMS shall meet the needs of the project, including integration with existing informatics systems (e.g. harmonization of data types and ontologies) as defined by the Requirements Document (Task 1), with extra capability in handling Occurrence Management and reporting of data quality checks and assessments. The QMS IMS shall be managed by the Contractor at the Contractor site, using Contractor equipment. The IMS shall also allow for complete accessibility of the data to the COTR and the TCGA Program Staff including the ability to log in remotely, manage the data, and generate reports for any purpose.

2.4.7 Task 7: Staff Training

The Contractor shall train all the TCGA Program Management staff and the staff of the two (2) BCRS and the DCC on the policies, procedures, and documents of the QMS. For the purpose of completeness, the Contractor shall assume that all relevant parties have no familiarity with a QMS. The Contractor shall have one (1) month to carry out the initial training and will be allowed to travel to the BCR and DCC locations. The Contractor shall train the COTR or other designated NCI staff on the details of the QMS IMS, for the purpose of managing the information and generating reports. The government anticipates training will have multiple phases and will be an ongoing requirement, but should begin immediately after approval of the QMS Documents and IMS are in place. A Staff Training Report shall be submitted one month after QMS IMS established and updated on a monthly basis.

2.4.8 Task 8: Assessments

As outlined in Task 8, the Contractor shall be responsible for assessments and audits of the BCR and DCC institutions, at least once per year. This currently constitutes three (3) organizations, and is not anticipated to change within the timeline of this project. The Contractor shall establish the assessment criteria, carry out the assessments, and provide a written summary of the assessments to the COTR within thirty (30) calendar days of completion of the assessments. Assessments for each of the BCR and

DCC institutions shall be executed on an annual basis, at a minimum, and as necessary to resolve data quality issues.

Additionally, the Contractor shall work with the BCR and DCC to establish automated data quality checks and audits. The types, number, and frequency of data quality checks and audits to be developed will be articulated in the Occurrence Management section of the Quality Management System Documents. The frequency of these checks shall be no less than once per month, and shall be summarized in a report to the TCGA Program Management.

2.4.9 Task 9: Reporting

The TCGA Program Management are required to provide program updates to the NIH leadership on a routine basis, therefore, the Contractor shall work with the COTR to establish the appropriate type, format, and frequency of reports to generate. At a minimum, throughput and data quality reports shall be provided to the TCGA Program Management every fourteen (14) days, in accordance with the Program reporting requirements. Additionally, the Contractor may be requested to generate reports concerning the real-time status of data quality.

2.4.10 Task 10: Transition Plan

The TCGA Program is expected to continue for at least five years, and may go well beyond this time frame. Therefore, it is essential that the government or another contractor be prepared to assume all responsibility for the oversight and execution of the QMS at the conclusion of the contract. The transition plan shall include a plan for transitioning all the duties and responsibilities of the Contractor, to include assessments, reporting, and training, as well as a plan to migrate the information management system.

2.4.11 Final Report

A final report shall be submitted. This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved.

2.5 Travel

It is expected that the Contractor will need to travel to the sites of the two (2) BCRs (locations to be determined) and the DCC (location to be determined) on multiple occasions during the requirements phase, the training phase, and for auditing. The contractor shall also travel to each of the GCCs, GDACs and GSCs (list available at: http://tcga.cancer.gov). TCGA consists of seven five GCCs, seven GDACs, and three GSCs.

3 Place of Performance

The work shall be performed at the Contractor facilities. It is anticipated that the Contractor will need to meet multiple times per month with the TCGA Program Office staff at the NIH campus.

Attachments:

1) **OS License Model: caBIG™ Open Source Software Licensing Guidelines DRAFT v.1**

caBIG™ Open Source Software Licensing Guidelines

DRAFT v.1

Release Date 4/20/06

The overall goal of caBIG™ is "to speed the delivery of innovative approaches for the prevention and treatment of cancer. The infrastructure and tools created by caBIG also are expected to have broad utility outside the cancer community." (See the caBIG™ Web site, http://cabig.nci.nih.gov). The rapid delivery of software tools demands a framework of principles and supporting documents that promotes sharing and appropriately protects the intellectual property rights of the creators while permitting commercial development when optimal to bring products and tools into use for the public good.

caBIG™ software development is based on an open source model, which means that source code for all caBIG™ software tools will be available to end-users. This approach is consistent with the philosophy supporting development of the "knowledge commons,"[1] which is created and fed by free and open distribution of intellectual property on the internet. We share the goal of the Science Commons, "to encourage scientific innovation by making it easier for scientists, universities, and industries to use literature, data, and other scientific intellectual property and to share their knowledge with others." [2] As is the case with the Science Commons, a recently established project of the on-line conservancy service known as the Creative Commons[3], we wish to "work within current copyright and patent law to promote legal and technical mechanisms that remove barriers to sharing." We are also informed by the Knowledge Conservancy,[4] a repository of published and copyrighted works that are publicly and permanently available on-line for noncommercial research use. Also instructive is the Open Source Initiative (OSI),[5] which promotes the ability of software developers to read, redistribute, and modify software source code to enhance the rapid evolution of particular software programs.

Beyond a commitment to sharing original source code, software developers must also determine whether subsequent modifications to the distributed version also be made publicly available. This decision has significant implications for the end users of the software. Others have done significant work in thinking about distribution models that fulfill the objective of open access to source code while at the same time permitting and encouraging commercial development. Covitz and Dubman[6] note "that publicly funded

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[1] *See, e.g.*, Bollier, D., *The Commons as an Emerging Model for Knowledge Creation & Governance,* Remarks at Rockefeller Foundation Conference "Collective Management of Intellectual Property: Tackling the Anti-Commons," Bellagio, Italy (November 2002) http://www.bollier.org/pdf/Bellagio_remarks11_21_02.pdf.

[2] http://science.creativecommons.org/

[3] http://creativecommons.org/

[4] http://rack1.ul.cs.cmu.edu/kc/mission.shtml

[5] http://opensource.org/

[6] Covitz, P. and Dubman, S., *On Public-Private Partnerships in the Area of Biomedical Informatics Software*, unpublished white paper, NCI Center for Bioinformatics (November 2003).

components can and should be released under a commerce-friendly open-source license. Private companies should be free to incorporate and extend open-source materials into commercial products without having to make their own code open-source." They also observe:

> "In a joint project that is anticipated to include both open-source and proprietary components, it is essential to map out in advance what the boundaries are. This is particularly true of scientific software. Reproducibility of a scientific result is often dependent upon full disclosure of the underlying algorithmic methods. Therefore, *no component that is necessary for the fundamental creation or interpretation of a scientific finding* should be implemented solely in a proprietary module. An open-source implementation of these types of components is critical. This implementation need not be highly polished or user-friendly; it just needs to be transparent[7] so that other groups can reproduce and validate findings."

The foregoing observations are embodied in the Berkeley/OpenBSD license, which illustrates the balance we seek to achieve for the distribution of caBIG™ software.[8] This license requires recipients of the software to comply with only two requirements: to give authors of software due credit for their creations, and to refrain from using authors' names to promote derivative products based on their work without permission. It allows free distribution, i.e., without charge or restriction, as long as the license terms are followed. By not imposing any restrictions on derivative works, others are allowed to modify the original software without having to distribute the modified version. This approach is embedded in the fundamental philosophy of caBIG™ and all developers in the caBIG™ initiative have agreed to develop software within this framework.

Most if not all of the institutions of caBIG™ developers will want to distribute caBIG™ software through license agreements that embody the principles stated above as well as protecting other institutional and individual developer interests. The following guidelines reflect our philosophy regarding the distribution of caBIG™ software:

1. Our intention is not to require that developers forego copyright and automatically place caBIG™ software source code into the public domain. Instead, our objective is to recognize that developers may seek to assert copyright within the framework of the caBIG™ initiative and provide a mechanism for making caBIG™ software source code available for public use.
2. We believe caBIG™ developers need to be given credit for their work, but also control the association of their name with products derived from the original work.
3. We wish to encourage free distribution, i.e., to provide rights to use, reproduce, modify, display, perform, sublicense and distribute original caBIG™ source code (or portions thereof) with or without modifications.

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[7] In the caBIG™ context, both the Training Working Group and the Architecture Working Space are organized to establish standards that will enhance transparency.

[8] http://www.openbsd.org/policy.html

4. The preservation of open source principles does not require that modifications of the original caBIG™ source code be made available by a licensee under the same terms and conditions as the original code.
5. We believe that licensees must include a copy of the license for the original caBIG™ source code with every copy of the original caBIG™ source code they distribute. In addition, no licensee should offer or impose any terms on any source code which modifies original caBIG™ source code that alters or restricts the applicable version of this license. In this way, the original intent of the caBIG™ developers with respect to original caBIG™ source code is preserved.
6. End user documentation must acknowledge the author.
7. We believe that, used in concert with and in the spirit of open source software development, intellectual property protection and copyrights and patents in particular can provide the incentives necessary to fund further research and to invest in the significant costs associated with bringing robust software to the general marketplace. As an example, the Red Hat Software version of Linux has enjoyed commercial success because that company offers technical support and warranties not available with the free version available from Linux. Other companies may offer more user-friendly interfaces or other improvements that caBIG™ developers may be unwilling to spend the time and effort creating for academic users.
8. While caBIG™ software is developed on an open source basis, developers may sometimes include proprietary software as a component of a larger software application. Documentation must make explicit the need to obtain licenses for any proprietary components.

It is strongly urged that these guidelines be adopted by institutions of caBIG™ authors that desire to distribute caBIG™ software through license agreements. For the convenience of such institutions, we have prepared a model software license agreement (attached) that reflects these guidelines. This license agreement may be tailored to suit individual institutional needs. In addition, caBIG™ institutions are free to use other agreements so long as those documents embody these guidelines and are otherwise consistent with any contractual obligations in connection with the caBIG™ initiative.

Model caBIG™ Software License Agreement, Version 1.0

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2. Your end-user documentation included with the redistribution, if any, must include the following acknowledgment: "This product includes software developed by _____ *[insert name of organization funded to participate in caBIG™]*." If You do not include such end-user documentation, You shall include this acknowledgment in the caBIG™ Software itself, wherever such third-party acknowledgments normally appear.

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