Instructions for Accessing Data Through the CDAS Website

Data and/or images from several studies are available for request through the <u>Cancer Data Access System</u> (CDAS) website. In order to obtain access to these data/images, you must do the following:

1. Submit a CDAS Project Proposal

If you have not already registered with the Cancer Data Access System, you will need to <u>register</u> using one of several available login services. You will then be asked to fill in your private profile.

Once you are logged in to CDAS, you can submit a project proposal. Submitting a project proposal involves several steps:

- You must agree to the Data Use Policies. In particular, you must agree not to identify or
 contact any patients or physicians whose information is contained in the data. You must
 also agree to publicly display your research proposal (provided in your request) on this
 website, to occur once you receive access to the data.
- You must fill in your the Project Details. To complete the project details, you will be
 asked to provide your contact information, provide the name and a brief description of
 your project (500 words or less), and list any researchers collaborating with you on the
 project.
- You must list all users who you approve to access the data. You will be asked to provide their names, institutional affiliations, and e-mail addresses. Additional approved users may be added following project submission.
- Once your project proposal is complete, you must submit it for review.

2. Project Proposals are Reviewed by CDAS and NCI Staff

All projects are reviewed to determine if you will be given access to the requested data.

All project proposals are first reviewed by CDAS staff. Prior to the NCI review, all projects will be examined by CDAS staff. CDAS staff will make an initial assessment of whether the sensitive data requested (if any) are available and are necessary to answer your research question(s). CDAS staff may ask for additional information to determine if your project proposal will be approved. CDAS staff will either pass your project proposal to NCI for a secondary review or will deny the proposal. Once CDAS staff makes a determination, you will be notified.

All project proposals are then reviewed by NCI. The review will determine (1) if your project addresses a scientific question and (2) if the data available through CDAS are appropriate for

answering that question. The review will not assess the project's scientific merit, nor will it check to see if another researcher is engaged in a similar project. You may check the list of Approved Projects to determine if someone else is performing similar research and you may consider contacting them to collaborate on the effort. NCI may request additional information in order to process your project. Once NCI makes a final determination on your project, you will be notified whether your project has been approved or denied. The NCI reviewers are part of the senior leadership for each study.

3. You Must Complete a Data Transfer Agreement (DTA)

Once NCI approves your project proposal, you will likely be required to complete a Data Transfer Agreement (DTA) before you can access the requested data. (NIH personnel are not required to complete a DTA but must instead agree electronically to the CDAS Data Use Policies if they have not done so already.)

DTAs are required for each research project to protect the confidentiality of the identity of study participants. While already-prepared standard datasets meet the requirements of the HIPAA privacy rule for de-identified datasets by the removal of 18 key identifiers, some risk remains that the data could be used to re-identify participants and exploit that information in some way. The DTA requires researchers to implement specific safeguards against the discovery of study participants' identities.

In addition, an Agreement is required by HIPAA for certain data available from CDAS. Certain identifiers such as date of diagnosis may be released in a Limited Data Set as specified by HIPAA if they are essential for a specific research project. The DTA satisfies HIPAA's requirement.

The process for executing a DTA is as follows:

- You and an authorized signatory at your institution will be asked to sign a Data
 Transfer Agreement (DTA). Once the DTA is signed by both parties, you will upload the
 DTA. If there are collaborators at other institutions, then a DTA will need to be
 completed for each institution requiring access to the data.
- CDAS staff will review your DTA for completeness.

Once the DTA has been executed properly and the requested data are available, CDAS staff will grant you access to the requested data. You will be notified once you are given access to the data. In order to access the requested data:

- Log in to your account.
- Navigate to My CDAS and click on your project.
- Select "Deliverables" from the menu to see the data for which you have been granted access.