New IDEAS Study Data Sharing and Publications Policy

I. General Principles Regarding Clinical and Image Data Sharing

Overall Policy Goal: This policy provides information and guidelines for individuals and corporations wishing to request access to clinical or image data archived during the New IDEAS Study. The New IDEAS Study is committed to giving investigators in academia and industry an opportunity to access data collected as part of the study for purposes consistent with its goals. This may include ancillary research studies, technology development, and educational initiatives. The following policy is drafted to provide reasonable access to data while allowing the New IDEAS Study Team to meet its obligation of ensuring the data will be used responsibly, and that providing access will not burden the New IDEAS Study's resources such as to impede its ability to pursue its primary research. Investigators interested in asking research questions of data collected as part of New IDEAS are encouraged to do so as a collaborative effort within the New IDEAS structure. This approach will engage the New IDEAS Study Team's "know how" related to the data and the trial which will provide the best opportunity for a successful analysis. Requests to collaborate with the New IDEAS Study should be addressed to the Research and Publications Committee (RPC).

It is expected that the New IDEAS Study Team will not be able to support all requests for collaborative analysis; and, therefore, the following policy for transfer of data to investigators for independent analysis is outlined below.

II. General Considerations

a. The New IDEAS Study archives the clinical and image data obtained as part of its research activity. This archive is a resource that can be used for secondary research studies, to guide further technology development, and for educational purposes. Access to CMS claims data used in the New IDEAS Study is handled separately and requires permission from CMS.
b. The New IDEAS Study encourages such use of its clinical and image data, however, has a responsibility to ensure that their use remains ethical, purposeful and consistent with the general goals of the Study.
c. Any individual or entity may submit a request for the clinical data, image data, images or biospecimen linked to clinical data archived by the New IDEAS Study.
d. The New IDEAS Study will provide requesters the raw data as it is archived in the database. However, requesters can specify subsets of data on the data request form.
e. In making data available to individuals and entities, the New IDEAS Study is only bound by its responsibility to guard the confidentiality of study participants, sites, and participating readers. No other responsibility is assumed by New IDEAS Study about the data, except as specified in other sections of this policy document.
f. New IDEAS Study data and images ordinarily will not be released to individuals or companies prior to the publication of the trial's primary aim manuscripts.
g. The identity (and identifiable information) of trial participants, sites and New IDEAS Study investigators will not be provided.

h. To the extent its resources allow, New IDEAS Study aids individuals and/or entities in gaining access to its data archive, and generally requests payment for the cost of providing the requested data. It must be appreciated that the resources available to fulfill data requests are limited which may result in a prolonged timeline to satisfy requests. Limiting the requests to essential data desired may expedite data availability.
i. Individuals and corporations accessing and using New IDEAS Study clinical or image data assume full responsibility for any and all uses of such data. Once the data has been successfully transferred, New IDEAS Study is relieved of any further responsibilities.

III. Process for Submitting Requests

a. The application form for requesting archived clinical, image and biospecimen data is available on the New IDEAS Study website. Any questions about the submission form should be emailed to IDEASResearchPub@acr.org.
b. In the case of independent researchers or corporations, requests should be of a research or educational nature or for purposes of technology development.
c. Before indicating in a grant proposal that clinical and/or image data archived by New IDEAS Study will be used to conduct the proposed research, an investigator should submit a request and obtain written approval from New IDEAS Study prior to submitting the grant proposal. New IDEAS Study treats such requests as it does any other, as detailed below.

IV. Clinical/Image Data Requests Review and Approval Process

a. The Research and Publications Committee (RPC), which reviews and decides upon requests for archived clinical, image, and/or biospecimen data sets on a regular basis, is composed of the following members:

a. The Chair, who is the lead statistician of New IDEAS Study.
b. Two other members of the New IDEAS Study team, including the Study Chair.
c. A representative appointed by CMS.
d. A representative of each of the participating manufacturers.
e. A senior researcher and representative with specific interest in Diversity, Equity, and Inclusion
f. A senior researcher with specific interest in biomarker and basic science research
g. A representative appointed by the Alzheimer's Association
h. A representative appointed by the American College of Radiology

b. The roles and responsibilities of the Data Access Committee related to data distributed under the data sharing policy include the following:

a. The scientific merit of the proposal
b. Whether the scope of the data request is consonant with the scope of the scientific project for which the data will be used
c. Whether the requesting party has sufficient resources to carry out the project
d. Whether the request overlaps or conflicts with primary or secondary New IDEAS Study aims.
e. The practical feasibility of fulfilling the request

The criteria, which may change from time to time, are widely promoted via the New IDEAS Study website.

V. Requestor's Responsibilities Regarding to Data Use

a. Access to New IDEAS Study archived clinical and image data is provided within the parameters described below.
b. The specific purpose for the data use must be agreed to by the individual requesting the material and New IDEAS Study at the time that the request is approved.
c. The data set may be used only for that purpose and only by the requesting party.
d. The data may not be passed on to or shared with a third party unless first agreed to by New IDEAS Study.
e. The data may be used only for the time period specified in the New IDEAS Study request approval.
f. In the case of corporations, New IDEAS Study must be informed of situations in which clinical/image data sets are passed on to collaborating corporations and the intent in sharing the material.
g. Those granted access to the New IDEAS Study archive are required to sign a statement indicating their agreement with all policies prior to being allowed access to New IDEAS Study clinical or image data.
h. Manuscripts must be submitted to the New IDEAS Study RPC at least one month prior to journal submission for review to ensure representations related to New IDEAS Study are accurate. Feedback to investigators is non-binding; however, investigators publishing manuscripts that appear to misinterpret New IDEAS Study data risk the submission of commentary or a letter to the editor by New IDEAS Study.
i. Any publication based on New IDEAS Study data/images must cite New IDEAS Study as the source of data.
j. Copies of published manuscripts must be submitted to New IDEAS Study headquarters at the time of publication.
k. The Biostatistics Center's and New IDEAS Study team's participation must be acknowledged in a manner appropriate to the nature and extent of its contributions, including authorship when warranted.