New IDEAS Study Data Sharing and Publications Policy

I. Overview

This policy provides information and guidelines for parties wishing to access clinical, imaging and/or archived biospecimen data during the New IDEAS Study. Requests for these data by academic or industry investigators for ancillary research studies, technology development, and/or educational initiatives should be consistent with New IDEAS Study goals. The New IDEAS Study Team plans to meet its obligation of ensuring the data will be used responsibly and outlines herein the process for reasonable access to data as to not burden the 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) at IDEAS-ResearchPub@acr.org.

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 clinical, imaging, and biospecimen 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 Centers for Medicare & Medicaid Services (CMS) claims data used in the New IDEAS Study is handled separately and requires permission from CMS.
b. The New IDEAS Study encourages the use of clinical, imaging, and biospecimen data. However, it has a responsibility to ensure that their use remains ethical, purposeful and consistent with the general goals of the Study.
c. The New IDEAS Study will share raw, deidentified clinical and imaging data as it is archived in the New IDEAS database via the Global Alzheimer's Association Interactive Network (GAAIN) Platform and Laboratory of Neuro Imaging (LONI), respectively (*Note: Available images include only amyloid PET*).
d. The New IDEAS Study allows any individual or entity to submit a request to access New IDEAS biospecimen data through the New IDEAS Biospecimen Request Process described herein. Applicants will be expected to share the results of their biospecimen analyses to contribute to the larger public-facing New IDEAS dataset. Applications will not be considered for approval if the applicant objects to sharing these data (*Note: Requests accompanied by requests for images and clinical data will require a separate Data Use Agreement (DUA) with The American College of Radiology (ACR) for review and execution by the applicant).*
e. The New IDEAS Study provides only data collected on protocol case report forms and stored in the New IDEAS main database. Dates will be coded as a unit of time from amyloid PET scan date. Any derivations are the sole responsibility of the applicant. Data will be de-identified by removing or re-redacting all 18 data elements specified in the HIPAA Privacy Rule.

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f. 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.
g. New IDEAS Study data and images ordinarily will not be released to individuals or companies prior to the publication of the study's primary aim manuscripts.
h. The identity (and identifiable information) of participants, sites and New IDEAS Study investigators will not be provided.
i. To the extent its resources allow, New IDEAS Study aids individuals and/or entities in gaining access to its data archive. It must be appreciated that the resources available to fulfill biospecimen 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.
j. 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.
k. 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. Role of the Research and Publications Committee (RPC)

a. The RPC reviews and decides upon requests for archived biospecimen data sets on a regular basis, is composed of the following members:

- The Chair, who is the lead statistician of New IDEAS Study;
- Two other members of the New IDEAS Study team, including the Study Chair;
- A representative of each of the participating manufacturers;
- A senior researcher and representative with specific interest in health disparities;
- A senior researcher with specific interest in biomarker and basic science research;
- A representative appointed by the Alzheimer's Association; and
- A representative appointed by ACR.

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

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

IV. Biospecimen Data Requests Submission, Review and Approval Process

a. The application form for requesting archived biospecimen data is available on the New IDEAS Study website. In the case of independent researchers or corporations, requests should be of a research or educational nature or for purposes of technology development.

b. The timeline for review, contracting and sample fulfillment may vary depending on the nature of the request.
c. Representatives from the RPC, specifically a senior researcher with an interest in biomarker and basic science research and a member from the study's Biostatistical Center, Brown University, will complete a logistics review of the applicant's application.
d. Projects that pass the initial logistics review will be reviewed by the RPC for scientific review and approval. Rejected applications will be returned to the applicant with feedback for consideration and resubmission, if applicable, at the time of rejection.
e. If the application is approved, an estimate of the cost for the preparation and delivery of data, and the timeline for fulfilling the request is developed and shared with the applicant. From the time the request is approved, the requestor's samples will be held for six months. If delivery of relevant contracting activities is not executed in that timeframe, then request for extension can be submitted, reviewed and approved by leadership. (*Note: Applicants should plan for a minimum of 8 weeks or longer from submission date to data fulfillment. Larger biosample requests take longer to fulfill, and requests are fulfilled in the order that they are approved*).
f. Prior to receiving biospecimens for analysis, the applicant will complete relevant contracting steps as outlined herein:
    a. The applicant will execute a Materials Transfer Agreement (MTA) with the Alzheimer's Therapeutic Research Institute (ATRI), the storage laboratory for New IDEAS biospecimens. ATRI will coordinate the shipping of samples which includes.
    b. The applicant will execute a Data Use Agreement (DUA) with the American College of Radiology to allow for the following to occur:
        i. The applicant will provide ACR with a copy of the results of all analyzed samples, in a mutually agreeable format. The applicant agrees that these data will be combined with the larger New IDEAS dataset and shared on GAIIN and LONI, respectively, within one year of the data being generated.
        ii. ACR will share with the applicant the clinical/imaging data identifier after the applicant provides their analyses to ACR. The identifier is used to link the biospecimen samples to the public clinical and imaging dataset on GAAIN and LONI, respectively.
g. Applicants will be required to complete an Annual Check-in with the Alzheimer's Association for progress updates on use of the data.
h. Applicants may contact newideas@acr.org for a status update on their application or progress towards sample fulfillment at any time.

V. Applicant's Responsibilities Regarding Data Use

a. Access to New IDEAS Study archived biospecimen 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 biospecimen data.
h. Manuscripts must be submitted to the New IDEAS Study RPC (IDEAS-ResearchPub@acr.org) 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 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.

VI. Review and Updates

This Policy will be reviewed annually and updated as needed to reflect changes in laws, technologies, and organizational practices. For additional information, please contact the New IDEAS Operations Team at newideas@acr.org