Policy on the Release of RADIANT Data

The RADIANT study is committed to sharing data with the scientific community and has adopted a data sharing policy that is posted on its public website. Recognizing that the RADIANT study is ongoing and its data bank is still accumulating information as cases are identified and RADIANT subjects are being followed, the RADIANT Study has established procedures to submit data to the NIDDK Data Repository in segments that reflect study progress. This reflects study milestones, such as screening/case identification, and assembling the study cohort following baseline measurements or the publication of interim results.

Periodically, the RADIANT study will release other data to the NIDDK Data Repository in a timely fashion relative to its progress as defined by the RADIANT data sharing policy. Access and availability of data submitted to the NIDDK Data Repository is determined by the NIDDK.

From time to time there may be other requests for RADIANT data that come from the community of investigators currently working on the RADIANT Study itself or from others who would like to collaborate with the RADIANT study. Access to the RADIANT data will be reviewed by the Data Access Committee of the study group.

The purpose of this document is to establish a policy for the release of RADIANT data not in the NIDDK Data Repository.

1. The request for RADIANT data must be based on a specific intended purpose and the requestor must agree that the use of the data is limited to solely that purpose.

2. Publication or presentation of the results of any analysis of the RADIANT data must follow the current rules and review of the RADIANT Publications Committee with respect to scientific merit, authorship, and funding attribution.

3. The requestor explicitly agrees that no attempt will be made to link the RADIANT data to any other data source that could potentially violate the confidentiality of any RADIANT Subject or in any way violate the explicit and implied consent under which RADIANT data has been collected.

4. If the data request comes from completely outside the community of RADIANT investigators, there must be a member of the RADIANT Steering Committee willing to serve as a sponsor and liaison with the RADIANT Study group who agrees to be responsible to RADIANT and to NIDDK to ensure compliance with these guidelines and those contained in the funding Notice of Grant Award.

Procedures:

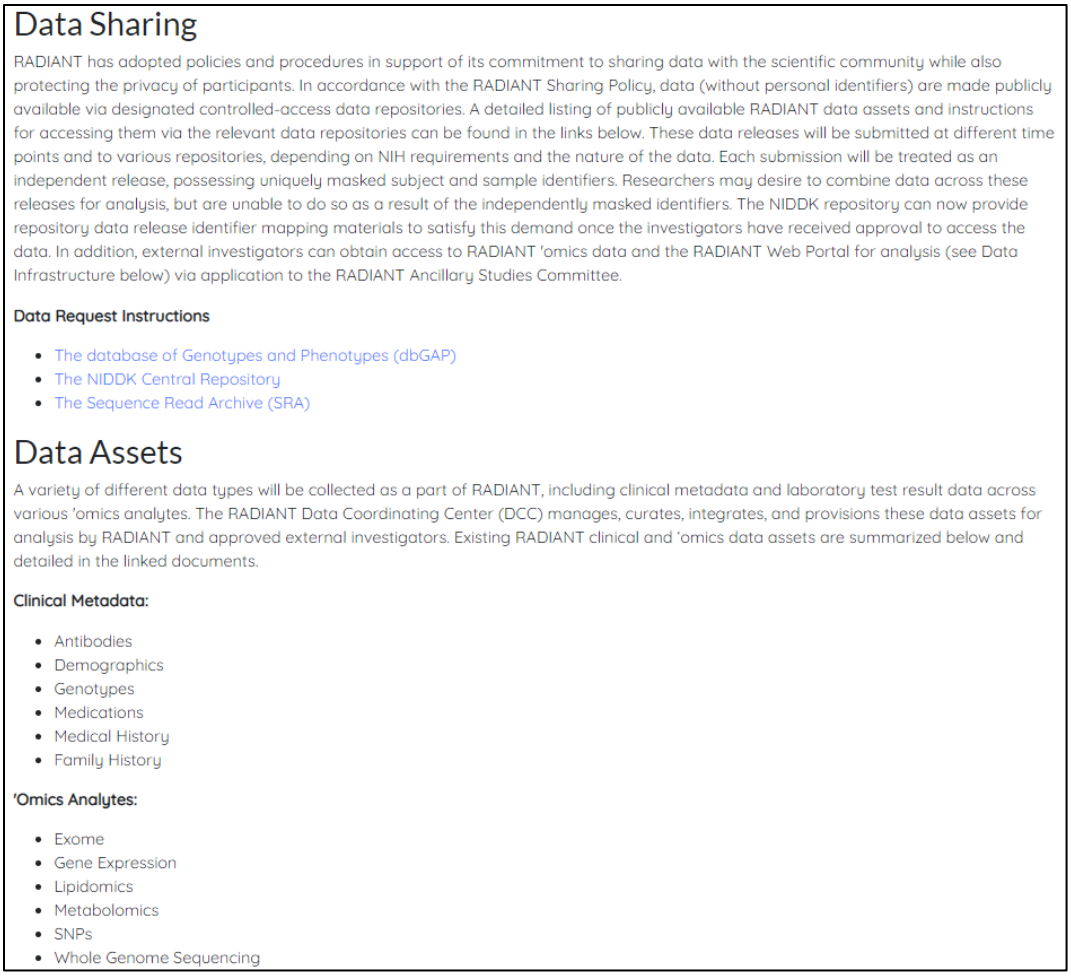
If the intended use of the RADIANT data requested is consistent with the goals and objectives of RADIANT, the request can be submitted as a manuscript proposal (using the existing proposal form) to the RADIANT Publications committee. The requestor will append a signed document attesting to agreement with the above stipulations. The RADIANT Publications Committee will conduct such reviews as it feels necessary before approving the request as it does with all other manuscript proposals that are submitted.

If the intended use of the RADIANT data requested is outside the scope of the RADIANT Study, the request can be submitted as an Ancillary Study to the Ancillary Studies Committee using the appropriate application form. The requestor will append a signed document attesting to the agreement with the above stipulations. Investigators proposing ancillary studies must obtain independent funding and demonstrate that the budget for the ancillary study is adequate to perform the study. The RADIANT Publications Committee will conduct such reviews as it feels necessary before approving the request.

Following approval by the appropriate RADIANT Committee, the RADIANT Data Coordinating Center will work with the requestor to evaluate the opportunity to conduct the analyses as delineated for the approved intended use itself or to produce a data set that allows the requestor to conduct such analyses themselves. As there are many factors that go into fulfilling a request (e.g., freezing the data as of a specific time point, recoding data to protect confidentiality, access to other RADIANT data sources such a dietary coding dictionaries, etc.) this will be decided on a case by case basis; the goal being the timely successful conclusion of the planned, approved, data analysis.

As a goal of the RADIANT Network is to develop a community resource to advance research in this area through the collection and dissemination of data and samples for access by the broad research community, RADIANT has planned a number of steps by which facilitate data access. They include:

- Data is made publicly available:
    1. via designated controlled-access data repositories.
        a. The database of Genotypes and Phenotypes (dbGAP)
        b. The NIDDK Central Repository
        c. The Sequence Read Archive (SRA)
    2. In addition, external investigators can obtain access to RADIANT 'omics data and the RADIANT Web Portal for analysis via application to the RADIANT Ancillary Studies Committee.
- The RADIANT public website will include information for researchers about where to find data, how to access it, and types of data available:



Data Sharing

RADIANT has adopted policies and procedures in support of its commitment to sharing data with the scientific community while also protecting the privacy of participants. In accordance with the RADIANT Sharing Policy, data (without personal identifiers) are made publicly available via designated controlled-access data repositories. A detailed listing of publicly available RADIANT data assets and instructions for accessing them via the relevant data repositories can be found in the links below. These data releases will be submitted at different time points and to various repositories, depending on NIH requirements and the nature of the data. Each submission will be treated as an independent release, possessing uniquely masked subject and sample identifiers. Researchers may desire to combine data across these releases for analysis, but are unable to do so as a result of the independently masked identifiers. The NIDDK repository can now provide repository data release identifier mapping materials to satisfy this demand once the investigators have received approval to access the data. In addition, external investigators can obtain access to RADIANT 'omics data and the RADIANT Web Portal for analysis (see Data Infrastructure below) via application to the RADIANT Ancillary Studies Committee.

Data Request Instructions

- The database of Genotypes and Phenotypes (dbGAP)
- The NIDDK Central Repository
- The Sequence Read Archive (SRA)

Data Assets

A variety of different data types will be collected as a part of RADIANT, including clinical metadata and laboratory test result data across various 'omics analytes. The RADIANT Data Coordinating Center (DCC) manages, curates, integrates, and provisions these data assets for analysis by RADIANT and approved external investigators. Existing RADIANT clinical and 'omics data assets are summarized below and detailed in the linked documents.

Clinical Metadata:

- Antibodies
- Demographics
- Genotypes
- Medications
- Medical History
- Family History

'Omics Analytes:

- Exome
- Gene Expression
- Lipidomics
- Metabolomics
- SNPs
- Whole Genome Sequencing

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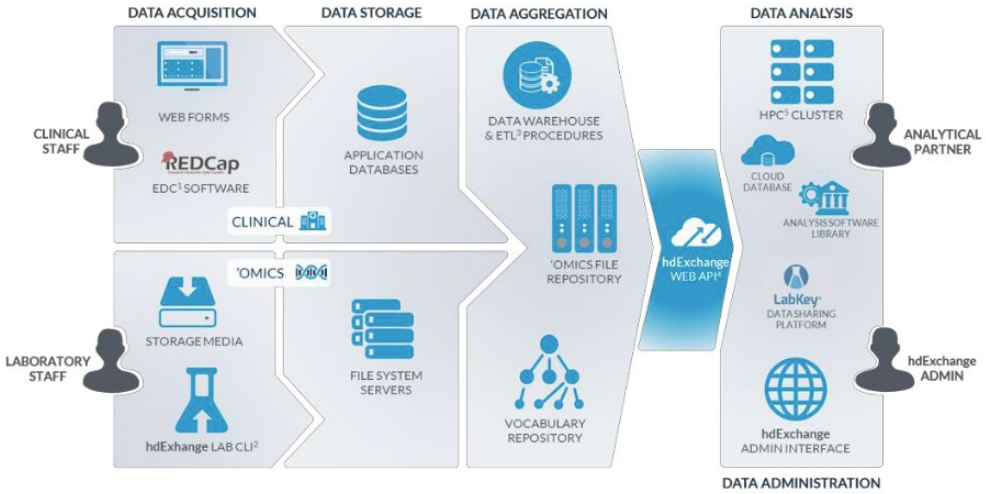
- With the approval of the RADIANT Steering Committee, the DCC will provide remote access to RADIANT data through a comprehensive platform for the acquisition, management, integration, analysis, and sharing of scientific data assets, particularly for the Big Data associated with ‘omics research. Access to this data infrastructure for RADIANT and approved external investigators is secured through advanced authentication and an integrated, token-based security model with data encryption. All identifiers are removed or dynamically masked to ensure research integrity and privacy of participants.

Data Infrastructure

In its role as the RADIANT DCC, the USF Health Informatics Institute (HII) has developed a comprehensive platform for the acquisition, management, integration, analysis, and sharing of scientific data assets, particularly for the Big Data associated with 'omics research. Access to this data infrastructure for RADIANT and approved external investigators is secured through advanced authentication and an integrated, token-based security model with data encryption. All identifiers are removed or dynamically masked to ensure research integrity and privacy of participants.

The figure below depicts the various components of the data infrastructure developed and employed in support of the RADIANT study.



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