

**Rare and Atypical Diabetes Network (RADIANT)
Data and Materials Distribution Agreement
(August 8, 2019 version)**

Note: This agreement is a .pdf and can be filled in electronically. It must be completed and signed before any data or biological materials will be released. Please send a completed copy of this agreement, along with one copy of the proposal application and one copy of the IRB approval (if not affiliated with RADIANT), to:

**RADIANT Publications
University of South Florida
3650 Spectrum Blvd., STE 100
Tampa, FL 33706
Email: publications@atypicaldiabetesnetwork.org**

Access to RADIANT data requires an association with the study and agreement to abide by study policies and procedures. It is understood that data contain no personal identifiers; i.e. are de-identified, unless otherwise noted. The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) as of (formatting) the date specified on the final page hereof.

INTRODUCTION

RADIANT is a multi-center network which aims to define new forms of diabetes, and the unique mechanisms underlying atypical diabetes subgroups. This network aims to clinically and genetically characterize this unique population and recognizes that this data is a valuable scientific source for the greater scientific community. RADIANT data is maintained under the joint stewardship of University of South Florida, as well as the NIDDK (for materials in NIDDK repository).

To protect the confidentiality and privacy of the RADIANT Study participants and their families, investigators granted access to Data and Materials must adhere to the requirements of this DMDA. Failure to comply with this DMDA could result in its termination, denial of further access to RADIANT and other NIDDK resources, and may leave violators liable to legal action on the part of RADIANT participants and their families.

The undersigned parties entering into this DMDA include: the RADIANT Study Investigator, the Recipient and Recipient's Principal Investigator (defined in the next section) and University of South Florida, on behalf of the RADIANT Study and under the direction of the RADIANT Steering Committee.

DEFINITIONS

For purposes of this agreement:

"Genetic Analysis Data" refers to any and all information derived from genetic materials and any and all data derived from statistical analyses linking data from genetic materials with other study data.

"Data" refers to any and all study data, including laboratory, examination, and questionnaire results, and Genetic Analysis Data, or signal data and associated records either obtained directly from RADIANT participants or obtained from third parties as authorized by the participants pursuant to University of South Florida's contract with the NIDDK, as well as data provided to RADIANT by ancillary studies.

"Resultant Data" refers to data derived in whole or in part by Recipient from Data and/or Materials provided under this DMDA.

"Materials" refers to bio-samples, including but not limited to, urine and blood samples and products thereof, including but not limited to, monocytes and extracted DNA from said biosamples pursuant to the University of South Florida's contract with the NIDDK, as well as Materials provided to RADIANT by ancillary studies.

"Research Project" refers to the project described in the attached research application.

“Recipient” refers to either a RADIANT Study Investigator or the institution or other entity receiving access to RADIANT Data and/or Materials requested for the Research Project identified in section 3 below as described in the attached research application.

“Principal Investigator (PI)” refers to the Research Project director for the Recipient.

PROCEDURES FOR REQUESTING RAW RADIANT DATA

Association with study and data access

We define three (3) levels of association with the study: 1) RADIANT Study Investigators who are or have been supported by the current grant or contract for their role in study management, data collection, or operations; 2) Collaborators who have no formal role in the study, but who wish to utilize RADIANT data in their scientific research; and 3) Ancillary Study Investigators who utilize RADIANT participants or resources to collect additional data or reanalyze specimens or scans.

RADIANT Study Investigators may access and utilize RADIANT data in accordance with the Policy on the Release of RADIANT Data. Completion of this Data and Materials Distribution Agreement (DMDA) indicates agreement to abide by the requirements and rules of the Policy on the Release of RADIANT Data. Collaborators who fit the defined association levels 2 or 3 in the above paragraph who wish to access RADIANT study data need to team up with a RADIANT Study Investigator willing to sponsor their research. For all RADIANT Study Investigators (level 1) and Collaborators (levels 2 and 3), access is given only to the data required for a particular research project after approval of the proposed research project by the RADIANT Steering Committee and completion of this DMDA. Ancillary Studies require approval by the Steering Committee, and once new data are collected, they must be sent with appropriate documentation to the Coordinating Center for merging with other RADIANT data. In order to obtain biospecimens and data, an Ancillary Study investigator with an approved project needs to complete a DMDA, which requires IRB review at their institution.

Study Policies and Procedures for Release of (Raw) Data

It is not standard protocol for raw RADIANT data to be released for external analysis conducted outside of the Data Coordinating Center (DCC). However, in rare instances in which expertise on a specific statistical methodology is required outside of the Data Coordinating Center, a raw dataset may be requested and released. Data access is provided to RADIANT Study Investigators, Collaborators or Ancillary Study Investigators for scientific research upon completion of the following procedures.

1. Paper proposal

A manuscript proposal must be submitted to the Data Coordinating Center. It is reviewed by the Publications and Presentations (P&P) Committee and the Steering Committee for consistency with the goals of RADIANT, lack of overlap with other work, scientific integrity, and evidence of collaborative authorship, including junior investigators. All persons who will have access to study data need to be named on the proposal. The proposal plan must be clearly outlined and include the following: aims and hypotheses, the reason for requesting release of the raw dataset, the exact variables to be included in the dataset, a comprehensive analytical plan (including specific methodology and statistician’s name and curriculum vitae) and definitive timeline. If there is a change of analyst (someone new who will access the data), the name of the new analyst needs to be communicated to the DCC and P&P Chair for study records. The dataset for the manuscript proposal will be frozen as of the specified date and will not be updated, unless necessary due to an extenuating circumstance, such as identified error in dataset.

2. Data and Materials Distribution Agreement (DMDA)

A Data and Materials Distribution Agreement must be completed to obtain study data. If an Ancillary Study, this requires IRB review from the recipient investigator’s institution.

3. Data Request

Data may be obtained from the DCC by submitting a Data Request Form to our Data Manager. Data are stored on

database servers located in a locked room in the entry-secured Health Informatics Institute in Tampa, Florida. Access to RADIANT data by Data Coordinating Center personnel is limited to data sets with all personal identifiers removed, replaced by a study id number. Access to de-identified data by researchers outside the DCC is limited to data (relevant for project, paper proposal, or sample data) tailored to the research project for RADIANT Investigators. All study dates and personal dates (i.e. date of birth) are removed from the data before distributing and replaced with variables for “time on study” or “age at specified time”. In the rare instances when identifiable data have been approved for distribution, the data are encrypted prior to sending. The data manager keeps a record of data sets sent.

TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Materials. University of South Florida and NIDDK agree to transfer to the Recipient the Materials described below, including the types of samples, amount per sample, the number of individuals from whom samples are to be provided, and whether samples are nonrenewable or from a renewable for use by the Recipient's PI to conduct the Research Project as summarized in section 3 below.

2. Data. University of South Florida agrees to provide Recipient with Data described as follows:

University of South Florida will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data.

3. Research Project.

3.1 These Materials and Data will be used by Recipient's PI solely in connection with the Research Project, as named and described in the attached research proposal (insert Research Project name below):

3.2 If any aspect of the Research Project, e.g., biological assays and/or genetic analyses, is to be performed by an entity other than Recipient as permitted by section 4.2, such entity is to be named below:

3.3 This DMDA covers only the Research Project cited in section 3.1 of this DMDA. Recipient must submit a separate DMDA for each Research Project for which Data and/or Materials are requested. Any modification to the Research Project, described herein, requires submission to the RADIANT Publication and Presentation Committee/Steering Committee.

4. Non-transferability. This DMDA is not transferable.

4.1 Recipient and Recipient’s PI agree that substantive changes made to the Research Project, and/or appointment by Recipient of another Principal Investigator and/or transfer of Recipient’s PI to another institution or other entity to complete the Research Project, require execution of a separate DMDA. Except as provided in section 4.2 below, Recipient may not distribute Data or Materials to any other individual or entity, regardless of the intended use of such Data or Materials. However, nothing in this section precludes Recipient from publishing results of the Research Project through the usual channels of scientific publication once reviewed and approved by the RADIANT Publications Committee.

4.2 Recipient and Recipient's PI may transfer or cause to be transferred Materials to an institution or institutions or other entities not affiliated with Recipient but with which Recipient has either a fee-for-service or subcontract agreement or specific authorization from the NIDDK for performance of assays and/or genetic analyses for the Research Project as identified in section 3.2. A separate DMDA is not required if the derived data are either returned to the Recipient and Recipient's PI or are deposited for Recipient and Recipient's PI in a publicly accessible database authorized by the NIDDK upon completion of the assays. No Data are to be provided to such institutions or other entities unless a separate DMDA has been approved by University of South Florida and NIDDK.

5. Conduct of Research Project. Recipient's PI is responsible for the conduct of the Research Project and shall be responsible for assuring that any co-investigator(s) comply with the terms of this DMDA.

6. Publication. Prompt publication of the results of the Research Project is encouraged. The University of South Florida and NIDDK request that the Recipient's PI provide to RADIANT a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to permit review, comment, approval and ensure compliance with the **confidentiality** requirements of this DMDA.

7. Acknowledgments. Recipient and Recipient's PI agree to acknowledge the contribution of RADIANT staff in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials.

7.1 Collaborations. All manuscripts resulting from the Research Project will be reviewed and approved by RADIANT Publications and Presentations Committee.

7.1.a If the manuscript is approved by RADIANT, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

“The RADIANT Study is funded by U54 DK118638 and U54 DK118612 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).”

“This manuscript has been reviewed by the RADIANT Study for scientific content and consistency of data interpretation with previous RADIANT Study publications.”

7.2 Other Studies (after the close of the RADIANT Study and the data is available for public distribution). If the Research Project does not involve collaboration with Study Investigators, then the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

“The RADIANT Study is funded by U54 DK118638 and U54 DK118612 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).”

“This manuscript was not prepared in collaboration with investigators of the RADIANT Study and does not necessarily reflect the opinions or conclusions of the RADIANT Study or the NIDDK.”

7.3 Ancillary Study Investigator Acknowledgments. If Data include data provided to RADIANT by ancillary study investigators, Recipient and Recipient's PI also agree to acknowledge their contribution in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Data.

8. Non-Identification. Recipient and Recipient's PI agree that Materials and/or Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data and/or Materials were obtained or derived.

9. Use Limited to Research Project. Recipient and Recipient's PI agree that Materials, their progeny, or derivatives thereof, and Resultant Data will not be used in any experiments or procedures unless said experiments or procedures are disclosed and approved as part of the Research Project.

10. Use in Human Experimentation Prohibited. Recipient and Recipient's PI agree that Materials, their progeny, and derivatives thereof will not be used in human experimentation of any kind.

11. Compliance with Participants' Informed Consent. Recipient and Recipient's PI agree that Data and/or Materials, their progeny, and derivatives thereof will not be used for any purpose contrary to a participant's applicable signed informed consent document(s). Recipient and Recipient's PI agree to consult with RADIANT Study Investigators and ascertain, specifically and in detail, the terms and conditions applicable to the RADIANT Study informed consent documents.

12. No Distribution; Avoidance of Waste. Recipient and Recipient's PI agree to retain control over Data, Materials and their progeny, and derivatives thereof. Recipient and Recipient's PI further agree not to transfer Data, Materials and their progeny, and derivatives thereof, with or without charge, to any other entity or individual, except for Data and/or Materials as provided for in section 4.2 above. Recipient and Recipient's PI agree to make reasonable efforts to avoid contamination or waste of Materials.

13. Resultant Data to be Provided to the University of South Florida and NIDDK. Recipient and Recipient's PI agree to provide the University of South Florida with a report every twelve (12) months during the term of this DMDA. The report shall include a description of the activities performed and Resultant Data obtained during the twelve (12) months before the reporting date. Recipient and Recipient's PI agree that the University of South Florida and NIDDK, in accordance with the [NIH Data Sharing Policy](#), may distribute all such Resultant Data through established NIDDK procedures to all institutions requesting access for their identified qualified scientific investigators to such Resultant Data and that submit to NIDDK a signed DMDA comparable to this DMDA. Recipient and Recipient's PI will provide all Resultant Data in the precise electronic format specified by the University of South Florida. If errors in family structure, especially paternity, are identified, Recipient and Recipient's PI agree to contact the University of South Florida's RADIANT Research Coordinator, at the time such errors are identified, to receive detailed instructions as to how to provide such information and to whom. Recipient and Recipient's PI further agree to refrain from any disclosure of such identified errors to anyone other than individual(s) specifically identified and authorized by the University of South Florida.

14. Costs/No Warranties. Cost for Materials distribution will be determined on a case by case basis. Costs are subject to change following written notification from University of South Florida with the approval of NIDDK. **NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/OR DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS AND/OR DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.**

15. Recipient's Responsibility for Handling Materials. Recipient and Recipient's PI acknowledge that Materials may carry viruses, latent viral genomes, and other infectious agents. Recipient and Recipient's PI agree to treat Materials as if they were not free of contamination, and affirm that Materials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Materials, Recipient assumes full responsibility for their safe and appropriate handling. All usable residual material will need to be repackaged and returned to the RADIANT repository; otherwise unusable waste will need to be disposed of according to standard protocol.

16. Non-Endorsement, Indemnification. Recipient and Recipient's PI agree not to claim, infer, or imply United States Government endorsement of the Research Project, the entity, or personnel conducting the Research Project, or any resulting commercial product(s) except as described in section 7. Recipient and Recipient's PI agree to hold harmless the University of South Florida and all investigator(s) who generated Data and Materials, and the agents and employees of each of them for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose. Except where prohibited by law, Recipient agrees to defend and indemnify the University of South Florida and all investigator(s) who generated Data and Materials, and the agents and employees of each of them for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

17. Accuracy of Data. Recipient agrees that the University of South Florida is not responsible for the accuracy of Data or the provenance or integrity of Materials provided.

18. Recipient's Compliance with Recipient IRB's Requirements. Recipient certifies that the conditions for use of the Data and/or Materials in conjunction with the Research Project have been approved by the Recipient's Institutional Review Board (IRB), OHRP, or similar human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipients agree not to contact or make any effort to identify individual, families, communities, tribes or populations which are or may be the source of the Materials or Dataset(s). Recipient agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the University of Utah's Institutional Review Board (IRB). Recipient agrees to report promptly to the University of South Florida any unanticipated problems or proposed changes in the Research Project. Recipient also agrees to report to Recipient's IRB any unanticipated problems or changes in the Research Project that involves additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

19. Recipient's compliance with applicable laws. Recipient acknowledges that they are responsible for complying with all applicable local, state and federal laws, as well as any relevant institutional policies in all their uses of the Data and/or Materials in conjunction with the Research Project.

20. Recipient's Responsibility to follow Data Security Best Practices. Recipient is aware of computer and data security best practices and will follow them for receipt, storage and use of Data and Resultant Data. An example of best practice guidelines can be found in http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf.

21. Intellectual Property (IP). In the spirit of achieving maximum public benefit from the results of the Research Project that is the subject of this DMDA, the University of South Florida urges Recipients to avoid making any IP claims on the Materials and Dataset(s) and their analyses with the understanding that conclusions derived from there will remain freely available without requirements for licensing. However, the University of South Florida encourages practices consistent with recommendations cited in NIH's Best Practices for Licensing of Genomic Inventions and in the NIH Research Tools Policy.

The determination of the rights of ownership of research results, including, but not limited to inventions resulting from the performance of the research under this agreement, as well as the administration of such inventions, shall be in accordance with the NIH policy. The parties will insure that the NIH policy is applicable to all persons who perform any part of the work under this agreement.

Subject to the above paragraph, the ownership and user rights to background and results are agreed upon as follows:

Background means any information, in whatever form, including but not limited to any intellectual property rights of a Party participating in the project, or a third party working for that Party, has created outside this agreement which is needed and used to perform the project. Background is the property of the owning Party. Unless otherwise informed in writing by the owning Party, a Party has free of charge right to use the other Party's background for project purposes during the time of this agreement. The right to use background for other purposes or after the Project is concluded shall be negotiated and agreed upon separately.

Results mean any information in whatever form, including but not limited to any intellectual property rights, created by a Party or by a third party working for that Party, during or otherwise in connection to this project. Results shall be the property of the Party carrying out the work leading to such results and the Party has sole discretion to decide whether and on what conditions it shall use and give rights to the results unless otherwise provided in this agreement.

All the Parties to this agreement have free of charge right to use any results generated during the term of this agreement and thereafter for non-commercial research and education purposes. Right to use for commercial purposes and business activities shall be negotiated and agreed upon separately. It is further stipulated that all Parties

to this agreement will promptly disclose all intellectual property generated during the course of this agreement to RADIANT.

22. Amendments. Amendments to this DMDA must be made in writing and signed by authorized representatives of all parties.

23. Termination. This DMDA shall terminate at the earliest of: the completion of the Research Project; five (5) years after the effective date of this DMDA; abandonment of the Research Project; or violation by Recipient of any provisions of this DMDA not remedied within 30 days after the date of written notice by NIDDK and/or the University of South Florida of such violation. Upon termination of this DMDA, recipient agrees to destroy all copies of all Data received from the University of South Florida and consult with the University of South Florida and the NIDDK regarding the disposition of all remaining Materials. Recipient will verify that the RADIANT data have been destroyed in a written or electronic communication to the University of South Florida /RADIANT.

24. Disqualification, Enforcement. Failure to comply with any of the terms of this DMDA may result in disqualification of Recipient from receiving additional Data and/or Materials. The University of South Florida may have the right to institute and prosecute appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this DMDA, the limitations on the use of the Data or Materials provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient's PI acknowledge and agree that a breach or threatened breach of the confidentiality requirements or use limitations of this DMDA may subject Recipient and Recipient's PI to legal action on the part of RADIANT participants, their families, or both.

25. Representations. Recipient and Recipient's PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

26. Prior Distribution Agreements. By execution of this DMDA, Recipient certifies its good faith belief that it is in compliance with the terms and conditions of all its existing DMDAs with the University of South Florida and/or the NIDDK.

Required Signatures begin on the next page

RECIPIENT'S AUTHORIZED REPRESENTATIVE OR RADIANT STUDY INVESTIGATOR:

Name and Title of Recipient's Authorized Representative

Affiliation of Recipient's Authorized Representative

Signature and Date of Recipient's Authorized Representative

RECIPIENT'S RADIANT STUDY INVESTIGATOR SPONSOR (if applicable):

Name and Title of Recipient's Investigator Sponsor

Affiliation of Recipient's Investigator Sponsor

Signature of Recipient's Investigator Sponsor and Date

This Distribution Agreement is entered into as of: _____ (effective date)