# RSNA AI Data Repository and

# Medical Imaging and Data Resource Center

# Contributing Institution Agreement

This Contributing Institution Agreement (“Agreement”) by and between **[INSTITUTION INFORMATION]** (“Contributing Institution") and **The Radiological Society of North America** ("RSNA"), a non-profit organization having a principal place of business at 820 Jorie Boulevard, Suite 200, Oak Brook, IL 60523-2251 USA, is effective as of date of last signature ("Effective Date").

WHEREAS, the mission of RSNA is to promote excellence in patient care and health care delivery through education, research and technologic innovation;

WHEREAS, the aggregation and dissemination of relevant medical imaging and associated clinical data for research can foster innovation in the fight against the COVID-19 pandemic;

WHEREAS, the RSNA is a participant in the Medical Imaging and Data Resource Center (MIDRC), a multi-institutional initiative funded by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to foster innovation in the fight against COVID-19 through dissemination of imaging and associated clinical data for research;

WHEREAS, MIDRC is expected to foster development and implementation of new diagnostics, including machine learning algorithms, that will enable population-wide preventive and management strategies for COVID-19;

WHEREAS, RSNA is seeking to collect de-identified COVID-19-related medical imaging and associated clinical data for purposes that include, but are not limited to, combining, organizing, and labeling such data and making it available for purposes of education and research through MIDRC;

WHEREAS, Contributing Institution has decided to submit data to RSNA by delivering de-identified COVID-19-related medical imaging and associated clinical data to RSNA to make available through MIDRC;

NOW THEREFORE, in consideration of the recitals, covenants, conditions and promises herein contained, RSNA and Contributing Institutions agree as follows:

# DEFINITIONS

# “Aggregated Institution Materials” shall mean the aggregate set of Institution Materials submitted from all participating and contributing institutions, including Contributing Institution, for the Project.

# “Applicable Law” shall mean all Federal, state and local laws and regulations to the extent applicable to the terms of this Agreement, including without limitation HIPAA and the HITECH Act, in each case as the same may be amended or supplemented from time to time.

# “Contributing Institution” shall mean the healthcare institution identified above entering into this Agreement with the intention of providing Institution Materials to be incorporated in the Aggregated Institution Materials and used in the Project.

# “De-Identified” shall mean information which has been de-identified pursuant to the HIPAA Privacy Rule, (45 CFR 160 and 164).

# "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), Title XIII of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), and implementing regulations promulgated by the United States Department of Health and Human Services, including, but not limited to the Privacy, Security, Breach Notification and Enforcement Rules (45 C.F.R. Parts 160, 162 and 164), as may be amended from time to time.

# “Institution Materials” shall mean the De-identified imaging studies and related De-identified clinical information submitted by Contributing Institution for use in the Project.

# “Institutional Review Board” or “IRB” shall mean committee(s), including an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), designated to safeguard ethical conduct of studies using human subjects by monitoring and reviewing biomedical and behavioral research under certain national and international laws, regulations, codes and/or norms.

# “Intellectual Property” or “Intellectual Property Rights” shall mean any and all patentable inventions first conceived and first reduced to practice in performance of the Project shall be determined according to U.S. patent law and ownership will vest in the party to whom the inventor has an obligation to assign all right, title and interest in the invention.

# “MIDRC” shall mean the Medical Imaging and Data Resource Center, a multi-institutional initiative funded by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to foster innovation in the fight against COVID-19 through dissemination of imaging and associated clinical data for research.

# “Project” shall mean the activities set forth on Exhibit A, attached hereto and made a part hereof.

# “Purpose” shall mean use as part of and in furtherance of the Project and in all cases including research, educational use and quality improvement measures.

# “Research Data” shall mean the Aggregated Institution Materials which have been annotated as permitted under this Agreement and processed by RSNA or its affiliates in accordance with the standard procedures of RSNA or affiliates in effect at the time of collection, and which are ultimately published by RSNA pursuant to the Project.

# “Research Results” shall mean supplementary or derived information, such as annotations and overlays, outcomes and evaluations generated by third party researchers, including RSNA and any participating research organizations, using Research Data.

# GRANT OF RIGHTS; FEES

* 1. **License Grant.**
		1. **Contributing Institution Grant**. Subject to the terms and conditions of this Agreement, Contributing Institution hereby grants RSNA a perpetual, irrevocable, non-exclusive right and license to use the Institution Materials in connection with the Project to advance the objectives of the Project. For uses of Institution Materials that fall outside of the Project, an amendment to this Agreement will need to be reviewed and agreed upon by both parties, and subjected to IRB approval, if required by law or Contributing Institution’s policies. The Parties acknowledge and agree that the foregoing license shall permit RSNA to combine Institution Materials with other data and make the Aggregated Institution Materials, of which the Research Data is a derivative. Research Data will be made available both during and following the conclusion of the Project to registered users for purposes of commercial and non-commercial research and education similar to those contemplated by the Project.
	2. **Rights Reserved.** Rights not conferred are expressly reserved. All rights in Institution Materials not expressly granted to RSNA are reserved by Contributing Institution, including any right to sell, sublicense, or rent Institution Materials to third parties. Furthermore, notwithstanding Section 2.1, this Agreement does not constitute, grant nor confer any license under any patents of Contributing Institution to RSNA.
	3. **Costs.** Contributing Institution agrees to provide Institution Materials for use in the Project without cost.

# PRIVACY AND SECURITY

* 1. **Privacy Rule.** The Institution Materials may be used for the Project pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164 to the extent the Institution Materials constitute Individually Identifiable Health Information.
	2. **Privacy-Related Restrictions on Institution Materials Use.** RSNA agrees that it, its personnel, subcontractors or any third party acting for or on RSNA’s behalf or in conjunction with Project, including but not limited to third-party researchers or users of the platform upon which the Institution Materials may be made available shall not:
		1. use the Institution Materials to establish the individual identities of any of the subjects from whom the Institution Materials were obtained or Contributing Institution as the supplier of the Institution Materials
		2. publish any Institution Materials in a manner that wuld allow the subject to be directly re-identified or de-anonymized; or
		3. take any action with or make any use of the Institution Materials not otherwise permitted under Applicable Law or this Agreement.
	3. **Data De-identification.** Contributing Institution shall be responsible to ensure that Institution Materials are De-identified prior to submitting them to RSNA. Should RSNA inadvertently receive identifiable information or otherwise unintentionally identify a subject, RSNA shall promptly notify Contributing Institution and follow Contributing Institution’s reasonable written instructions, which may include return or destruction of the identifier such that remaining information shall meet the requirements of De-identification under HIPAA.

# Data Annotations. RSNA may make data annotations or overlays or otherwise supplement the Aggregated Institution Materials for purposes of furthering the aims of the Project. RSNA agrees not to supplement Institution Materials in any way that could result in the re-identification of a particular individual or contributing institution.

* 1. **Appropriate Security Safeguards.** RSNA will use appropriate physical, technical and administrative safeguards to prevent use or disclosure of the Institution Materials other than as provided for by this Agreement.
	2. **Industry Standards for Transmittal.** Contributing Institution represents to RSNA that Contributing Institution will use the standards generally accepted in the data processing industry to transmit the Institution Materials as required by this Agreement in a protected and secure manner.
	3. **Combining Data Sets.** RSNA may combine the Institution Materials with other Research Data for the purposes of achieving Project aims and as may be further agreed upon by both parties and approved by the IRB, if necessary. RSNA may not release, publish or make available combinations of data that could result in re-identification of individuals.

# INTELLECTUAL PROPERTY

* 1. **Ownership of Data; Ownership of Results.**
		1. All Institution Materials shall be owned exclusively by Contributing Institution. To the extent RSNA has or acquires any rights in or to the Institution Materials, RSNA and RSNA agents each hereby irrevocably assign, transfer and convey to Contributing Institution all of its right, title and interest in and to the Institution Materials, excluding any modifications, enhancements or derivative works developed by RSNA using the Institution Materials, including without limitation the Research Data.
		2. Research Data shall be the exclusive property of RSNA, subject to the terms of the license granted to RSNA by Contributing Institution for the elements of Institution Materials incorporated therein.
		3. Research Results shall be the property, or joint property as the case may be, of the respective party or parties who generated the subject data annotations, summaries, analyses and/or interpretations.
	2. **No Other Intellectual Property Rights.** Except as specifically provided in this Agreement, neither party shall have any right or license by virtue of this Agreement to use or exploit for commercial purposes any Intellectual Property Rights of the other party.

# PUBLICATION; PUBLIC DISSEMINATION

# It is the intent of RSNA and MIDRC to allow access to Aggregated Institution Materials and Research Data to registered users for purposes of commercial and non-commercial research and education similar to those contemplated by the Project.

# Contributing Institution may conduct research and publish Research Results derived from the Research Data in accordance with the access and approval procedures established by RSNA and MIDRC. Such use and access are outside the scope of this Agreement.

# CONFIDENTIALITY AND SECURITY

* 1. **Protection of Confidential Information.** “Confidential Information” shall mean proprietary and confidential information communicated by one party to the other in writing, marked as “Confidential” or, in the case of oral disclosures, identified at the time of such oral disclosure as confidential, and reduced to writing and identified as “Confidential” within thirty (30) days of disclosure. Except as permitted in this Agreement, and to the extent Confidential Information are required to be shared in order to fulfill the Purpose, each party agrees that it shall hold confidential all Confidential Information of the disclosing party and shall not use or disclose such Confidential Information, except as authorized in this Agreement, without the express written consent of the disclosing party. Each party shall take reasonable measures and efforts to provide protection for the disclosing party’s Confidential Information, including measures at least as strict as those the receiving party uses to protect its own Confidential Information of similar importance. The confidentiality obligations of the parties shall survive the termination or expiration of this Agreement.
	2. **Employees and Agents.** Each party shall have the right to disclose the other party’s Confidential Information to those of its employees and agents who have a need to know such Confidential Information in order to exercise the receiving party’s rights or perform the receiving party’s obligations pursuant to this Agreement.
	3. **Court Order.** If the receiving party receives a subpoena, court order or other validly issued administrative, regulatory or judicial notice requesting the disclosure of the disclosing party’s Confidential Information, the receiving party shall (to the extent legally permitted):
		1. promptly notify the disclosing party in writing to allow the disclosing party a reasonable opportunity to resist such disclosure and/or seek a protective order before the required time for disclosure; and
		2. receiving party shall not oppose disclosing party’s efforts in resisting the disclosure and/or seeking a protective order to govern the disclosure. The receiving party shall be entitled to comply with such subpoena, court order or notice, but shall in doing so make every reasonable effort to secure confidential treatment of any Confidential Information it is compelled to disclose and shall not disclose any more Confidential Information than is necessary to comply with the subpoena or other process.

# REPRESENTATIONS AND WARRANTIES

# Contributing Institution Representations. Contributing Institution represents to RSNA that:

# Contributing Institution has full power and authority to enter into this Agreement and grant the rights and licenses hereunder;

# Contributing Institution’s disclosure of Institution Materials will not knowingly violate any applicable law, rule or regulation;

# the execution, delivery and performance of this Agreement by Contributing Institution will not knowingly violate any applicable law, rule or regulation; and

# Contributing Institution will comply with, and will cause its staff, faculty, graduate students and research assistants to acknowledge and be aware of the applicable terms of this Agreement.

#  RSNA Representations

# that it has full power and authority to enter into this Agreement and grant the rights and licenses hereunder;

# RSNA’s use of Institution Materials will not knowingly violate any applicable law, rule or regulation; and

# it will perform, hereunder exceeding but in no event lesser than is consistent with commercially reasonable measures for an organization of similar size and circumstance and in all cases pursuant to Applicable Law.

# LIMITATION OF LIABILITY

* 1. **No Indemnity.** Each party shall be responsible for its own negligent acts or omissions and the negligent acts or omissions of its employees, directors, officers, and agents in the performance of the Project and the administration of this Agreement, to the extent allowed by law.
	2. **Limitation of Liability**. IN NO EVENT WILL ANY PARTY BE LIABLE TO ANY OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, OR DAMAGES OF ANY KIND OF ANY OTHER PARTY ARISING OUT OF ANY PERFORMANCE OF THIS AGREEMENT OR IN FURTHERANCE OF THE PROVISIONS OR OBJECTIVES OF THE PROJECT, OR FOR ANY LOSS OF PROFITS, LOSS OF REVENUE, LOSS RESULTING FROM INTERRUPTION OF BUSINESS OR LOSS OF USE OR DATA, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

# DISCLAIMER OF WARRANTIES

Except as expressly set forth in this Agreement, Institution Materials and Research Results are provided “AS IS” without representation or warranty of any kind, either express or implied, and the parties hereby disclaims any and all representations and warranties, including without limitation any representations or warranties of accuracy, non-infringement, merchantability or fitness for a particular purpose, and all warranties that may arise from course of dealing, course of performance, or usage of trade.

# RELATIONSHIP MANAGEMENT

* 1. **Contact Persons.** The Contributing Institution Contact Person(s) and RSNA Contact Person designated below will facilitate, coordinate, and oversee the performance of the parties’ respective obligations under this Agreement. Each party may replace its contact person by written notice to the other party.
	2. **Ongoing Adaptation.** Both parties agree to cooperate in good faith with each other on an ongoing basis to adapt the parties’ arrangements under this Agreement to accommodate future changes in applicable law, relevant technology, or other changes in the relevant industry or environment. The parties shall cooperate in good faith to make any conforming amendments or modifications to this Agreement to accommodate the provision of Institution Materials to RSNA.
	3. **Dispute Resolution.** In the event of a dispute arising out of or relating to this Agreement, the parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. Either party may, by written notice to the other party, refer the dispute to the other party for attempted resolution by formal good faith negotiation within thirty (30) days after such notice is received. If the dispute remains unresolved after the good faith negotiation period provided in the previous sentence, either party by written notice to the other party may have such issue referred for resolution to the Chief Legal Counsel for RSNA and the equivalent officer of the Contributing Institution (collectively, the "Executive Officers"). The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Executive Officers fail to resolve the dispute within thirty (30) days after it is referred to them, each party shall have the right to pursue any other remedies legally available to resolve the dispute, including the right to terminate the Agreement, and the matter may be brought by a party as a suit in a court of competent jurisdiction in accordance with Section 13.5 (Governing Law).
	4. **Remedies.** Each party shall be entitled to seek equitable relief, for the other party’s actual or threatened failure to abide by these provisions, in addition to all other rights and remedies available at law or in equity. Notwithstanding the procedure described in Section 10.3, each party shall be entitled to seek preliminary injunctive relief in any court of competent jurisdiction for the other party’s actual or threatened breach of this Agreement.

# PUBLICITY

Neither party will use the name or trademark of the other party in any publicity, advertising or announcement related to this Agreement or the Project without the prior written consent of the other party. Contributing Institution shall have the right to identify RSNA as a participant in MIDRC and to have publicly registered information about the Project appear on its research directory/website and for funding applications.

# TERM AND TERMINATION

# Initial Term; Renewal Term. This Agreement shall be effective from the Effective Date until December 31 of the calendar year in which the Effective Date occurs (the “Initial Term”), and shall be automatically renewed on an annual basis of term years of January 1 to December 31 (each, a “Term Year”) thereafter unless any Party provides the other(s) with a written notice of termination on or before sixty (60) days prior to the expiration of the Initial Term or any then-current Term Year. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of both parties. The Initial Term, along with any renewal term, shall be referred to as the “Term.”

* 1. **Term for Transfer of Institution Materials.** Contributing Institution will make the Institution Materials available to RSNA during the Term of this Agreement
	2. **Termination for Convenience.** Either party may terminate this Agreement for convenience with thirty (30) days’ written notice.
	3. **Termination for Cause.** Either party may terminate this Agreement by written notice if the other party has defaulted in any material obligation under this Agreement and failed to cure such default within thirty (30) days after written notice of the default from the terminating party, including, (i) breaches of its obligations under Section 2, 4, 5, 6, 8 or 9 of this Agreement, or (ii) violates any Intellectual Property Rights of the non-breaching party. Either party may terminate this Agreement immediately upon written notice if the other party becomes insolvent or if a court of competent jurisdiction enters an order or decree in respect of such party under any bankruptcy or similar law approving a petition for reorganization or appointing a custodian for all or substantially all its assets or ordering the liquidation of such party.
	4. **Discontinuation of Use.** The parties acknowledge and agree that termination shall not affect rights accrued and/or surviving, subject to the terms of this Agreement. Upon termination or expiration of this Agreement, RSNA may continue using the Institution Materials as permitted under this Agreement until the conclusion of the Project, at which time the Institution Materials will be made available for use in general research consistent with this Agreement as set forth on Exhibit A.
	5. **Effect of Termination. Expiration of License.** The Parties agree that it would be infeasible to return or destroy Institution Materials from which Research Data is derived, and that such return or deletion would materially interfere with the Purpose of the Project. With respect to Institution Materials, the License granted at Section 2.1(A) above continues in perpetuity. At the conclusion of the Project, the Institution Materials will be made available for use in general research consistent with this Agreement as set forth on Exhibit A.

# GENERAL PROVISIONS

* 1. **Authority.** Each party represents and warrants to other that it has the full power and authority to enter into and perform this Agreement and all necessary legal, corporate, contractual, and other power and authority to grant the rights contemplated by this Agreement.
	2. **All Notices.** All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All notices to RSNA are emailed or mailed to RSNA Contact Person:

RSNA

Department of Informatics

820 Jorie Blvd, Suite 200

Oak Brook, Illinois 60523

Attn: Christopher Carr

T: 1-630-571-2670

E-mail: informatics@rsna.org

All notices to Contributing Institution are e-mailed or mailed to Contributing Institution Contact Person(s):

**[INSTITUTION CONTACT 1]**

With a copy to:

**[INSTITUTION CONTACT 2]**

* 1. **Waiver, Amendment or Modification.** The waiver, amendment or modification of any provision of this Agreement or any right, power or remedy hereunder shall not be effective unless made in writing and signed by the Party against whom enforcement of such waiver, amendment or modification is sought. The terms of this Agreement shall not be added to, amended or modified by the terms of any purchase order, acknowledgement, or other form. No failure or delay by either party in exercising any right, power or remedy with respect to any of its rights hereunder shall operate as a waiver thereof.
	2. **No Implied Obligations**. Nothing herein shall obligate either party (or its respective representatives or appointees) to reach agreement on issues that are left open to the subsequent agreement of such party (or its respective representatives or appointees). In addition, neither party shall, by reason of any failure to reach agreement under the terms and conditions of this Agreement, be liable to the other for compensation, reimbursement or damages on account of any loss of prospective profits or on account of expenditures, investments, or other commitments made in connection with this Agreement or the anticipation of extended or expanded performance hereunder. Except as expressly provided, nothing in this Agreement is intended to prevent either party from entering into agreements with third parties.
	3. **Governing Law; Severability.** The parties agree to remain silent as to governing law and venue. If any provision of this Agreement or the application of any such provision shall be held by a tribunal of competent jurisdiction to be unenforceable or contrary to law, the remaining provisions of this Agreement shall continue in full force and effect.
	4. **Accrued Rights; Surviving Obligations**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either party prior to such termination or expiration, and shall not relieve either party from its obligations which are expressly indicated to survive expiration or termination of this Agreement.
	5. **Integration.** This Agreement, including the attached Exhibit A, supersedes all prior oral and written proposals and communications, if any, and sets forth the entire agreement of the parties with respect to the subject matter hereof, and may not be altered or amended except in writing, signed by an authorized representative of each party.
	6. **Headings.** No headings in this Agreement affect its interpretation.
	7. **Export Controls.** As applicable, the parties shall not violate the US Export Laws. “Export Laws” means the Export Administration Regulations of the U.S. Department of Commerce and the regulations and executive orders administered by the Office of Foreign Asset Control of the U.S. Department of the Treasury. In the event of a violation of Export Laws, either party may terminate this Agreement immediately if the violation is unable to be satisfactorily remedied.
	8. **Electronic Copy.** The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

[SIGNATURES CONTINUE ON NEXT PAGE]

The duly authorized party representatives execute this Agreement, including all its terms and conditions.

|  |  |
| --- | --- |
| [INSTITUTION] | RSNA |
| Signature | Signature: |
| Name:  | Name: |
| Title:  | Title: |
| Date:  | Date: |

I acknowledge that I have read this Agreement in its entirety and will use reasonable efforts to uphold my obligations and responsibilities under this Agreement.

|  |
| --- |
| [PRINCIPAL INVESTIGATOR] |
| Signature: |
| Name:  |
| Title:  |
| Date:  |

# Exhibit A

**Project**

Title of Project: **RSNA AI Data Repository and Medical Imaging Data Resource Center (MIDRC)**

**1. Introduction**

RSNA will compile de-identified images and correlative data from contributing institutions, practices and societies around the world to contribute to the Medical Imaging and Data Resource Center (MIDRC), a comprehensive source for COVID-19 general research and education efforts.

**2. Rationale**

The MIDRC image hosting, annotation and analysis framework will enable researchers from both academic institutions and commercial corporations to understand epidemiological trends and to generate new AI algorithms to assist with COVID-19 disease detection, prognosis and therapy planning.

**3. Scope of Activities**

Completion of this project requires the following:

(1) Data/Materials Collection:

Each contributing institution will select imaging studies and other relevant clinical information in accordance with the research data protocols provided by RSNA and de-identify this information in accordance de-identification protocols provided by RSNA and with relevant laws and industry best practices.

(2) Data/Materials Sharing:

The data and materials will be transmitted electronically to a data platform provided by the RSNA or its contracted agents for purposes of building the RSNA AI Data Repository and MIDRC. This data will be aggregated with similar data from other institutions. Users of the data will be required to register and to agree to limitations on their use of the data, including prohibitions against attempting to reidentify individual subjects and against any sale or transfer of the data to third parties.

**4. Collaborators and Responsibilities (location, names)**

(1) Contributing Institution:

 [contact info]

(2) The Radiological Society of North America (RSNA):

Christopher Carr

Project Director

RSNA

Department of Informatics

820 Jorie Blvd, Suite 200

Oak Brook, IL 60523

**5. Data Variables** (to be shared from Contributing Institution to RSNA)

Imaging examinations: Relevant imaging studies, including chest radiographs, chest CT examinations (axial series only, any protocol) and others of COVID-19 patients, as well as similar studies of non-COVID-19 patients for use as controls.

Correlative data variables for subjects of these imaging studies including, at minimum:

Age

Sex

COVID-19 positive confirmation testing method (PCR, serological, clinical)

At its discretion, Contributing Institution may submit additional correlative data as requested by RSNA and in accord with MIDRC clinical data protocols.

**6. Data Disposition Instructions (destroy, return) for Data:**

Data will be made available for use in general research. Once Data has been ingested and uploaded into the RSNA AI Data Repository and MIDRC, it cannot be destroyed and must be retained.

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