

**THE CANCER IMAGING ARCHIVE
DATA SUBMISSION AGREEMENT**

This Data Submission Agreement (this "Agreement") is made as of the last signature below (the "Effective Date") by and between the Board of Trustees of the University of Arkansas acting for and on behalf of the University of Arkansas for Medical Sciences, 4301 W Markham #860, Little Rock, AR 72205 ("UAMS") and:

ORGANIZATION NAME ("ORGANIZATION")
ORGANIZATION ADDRESS

UAMS operates The Cancer Imaging Archive ("TCIA") to facilitate submission of healthcare data and imaging from medical centers around the world for the purpose of research. This Agreement sets forth the terms by which UAMS will facilitate the Organization's participation in submission activities for TCIA research and publication programs.

Now, therefore, the Parties agree to the following:

1. **Purpose.** The purpose of this Agreement is to document the submission of imaging and related data by Organization to TCIA for curation and publication of high-quality, de-identified datasets for use in research.
2. "**Submission Data**" means the data collection as further described in Exhibit A. Subject to and in accordance with terms set forth in this Agreement, Organization shall provide and UAMS shall process, use, and publish Submission Data according to the submission, acceptance, and use policies ("Policies") set forth on TCIA's website (available at <https://www.cancerimagingarchive.net>), which are subject to change in the sole discretion of UAMS. Organization certifies that the Submission Data was collected in compliance with applicable international, national, state, tribal, and local laws and regulations, including any laws and regulations governing the use of human and animal subjects in research and privacy or data protection. If applicable, Organization further certifies that the Submission Data was collected under consent, or appropriate waiver of consent, for research use of the Submission Data in de-identified form consistent with the purpose of TCIA. Organization may optionally code the data for re-identification purposes, but under no circumstances shall Organization share the key codes with UAMS.
3. "**Curated Submission Data**" means Submission Data that has been confirmed by UAMS to be fully de-identified pursuant to TCIA's Policies and this Agreement and is in a form suitable for publication by TCIA.
4. **Provision of the Submission Data.** Organization and UAMS agree to collaborate on the provision and curation of the Submission Data; this process is outlined in the Policies and is summarized as follows:
 - 4.1. Organization submits a proposal to TCIA requesting permission to publish a new dataset.
 - 4.2. TCIA Advisory Group (which is composed of staff from the National Cancer Institute and Frederick National Laboratory for Cancer Research who are experts in cancer imaging,

informatics, and related technologies) reviews the proposal at its next monthly meeting and decides whether to accept the dataset in TCIA.

- 4.3. UAMS will assist Organization in performing an initial de-identification pass by providing NIH-approved open-source software tools and technical support for DICOM de-identification before the Submission Data leaves the Organization and is transmitted in an encrypted state to UAMS.
 - 4.4. Once the Submission Data is received by UAMS, the UAMS quality control and curation staff will work with Organization to ensure the Submission Data are complete, fully de-identified, and meet TCIA's standards for Curated Submission Data.
 - 4.5. UAMS will assist Organization in creating a summary page for the Curated Submission Data and in providing auxiliary information useful to downstream users.
 - 4.6. UAMS will publish the Curated Submission Data and announce its publication via appropriate channels.
 - 4.7. If Organization is from a member country of the European Economic Area ("EEA") or the United Kingdom ("UK") and, therefore, subject to the EEA's or UK's General Data Protection Regulation ("GDPR"), Organization further agrees to the certification contained in Exhibit B.
5. **Use of Submission Data.** Organization understands that the primary purpose of TCIA is to assist academic research institutions in de-identifying Submission Data and publishing the Curated Submission Data. In handling Organization's Submission Data, UAMS will:
 - 5.1. Disclose Submission Data only to UAMS employees who are directly responsible for the activities related to TCIA;
 - 5.2. Use appropriate safeguards to prevent use or disclosure of the Submission Data; and
 - 5.3. Not re-disclose PHI contained within the Submission Data;
 - 5.4. Use the Submission Data in accordance with all applicable federal, state, and local laws and regulations, including the U.S. Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA").
 6. **No Re-Identification of Study Subjects.** UAMS and its employees will not identify or attempt to identify the individual(s) to whom the Submission Data pertains or contact or attempt to contact the individual(s) that UAMS believes to be the subject of any Submission Data. UAMS certifies that this restriction is currently applicable, and will continue to be applicable in the future, to downstream users of the Curated Submission Data by virtue of the Policies. In the event of a breach of this Section, UAMS will notify the Organization.
 7. **License.** Organization retains ownership of the Submission Data. Organization hereby grants to UAMS a non-exclusive, royalty-free license to the Submission Data for internal purposes of the operation of TCIA and for research purposes. Organization hereby grants to UAMS a non- exclusive, sub-licensable, worldwide, perpetual, irrevocable, royalty-free license to the Curated Submission Data for purposes of making the Curated Submission Data freely available for all purposes. In addition, Organization grants to UAMS all further rights necessary for UAMS to make Curated Submission Data available to the public (i) pursuant to the Creative Commons Attribution 4.0 International License, which is incorporated herein by reference, or (ii) pursuant to such other licenses as may be appropriate for a limited access collection. If the Curated Submission Data results in a limited access collection, which requires restriction upon redistribution, the limited access collection may be made available under a TCIA limited access license in a manner consistent with TCIA's mission to curate and publish high quality, de-identified datasets for use in research. (A non-

limiting example of a limited access collection would be a Curated Data Submission that includes facial imaging that is capable of being re-faced.) Organization certifies that it has the right to grant UAMS a license to publish and otherwise use the Submission Data and Curated Submission Data in accordance with the terms of this Agreement.

8. **Responsibility.** Except where there is negligence or willful misconduct on the part of the UAMS or its representatives, or a breach of any applicable federal, state, or local law by UAMS or its representatives, Organization shall be responsible for actual damages arising from the work performed under this Agreement due to the negligence or willful misconduct on the part of Organization or its employees or agents, or a breach of any applicable federal, state, or local law by Organization or its employees or agents.
9. **Flow-Down Provisions.** TCIA is funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. 75N91019D00024. Organization acknowledges and agrees that the U.S. Government may have rights in the Submission Data and Curated Submission Data.
10. **No Use of Marks.** Neither party may use the name, trademark, trade name, logo, symbol, or other image or trade name of the other party or its employees, students, or agents in any advertisement, promotion, publicity, news release, or in any other way that implies endorsement without the prior written approval of an authorized representative of the party whose name is being used. Notwithstanding the foregoing, UAMS shall have the right to identify the Organization as the site at which the Curated Submission Data was generated. Each party retains the right to use the other's name, and a summary of the Curated Submission Data, in support of future funding applications.
11. **Term.** This Agreement shall commence on the Effective Date and shall continue in force until the publication of the Curated Submission Data by TCIA. The terms of Sections 5 (Use of Submission Data), 6 (No Re-Identification of Study Subjects), 7 (License), 9 (Flow-Down Provisions), and 10 (No Use of Marks) shall survive expiration of this Agreement.
12. **Assignment.** Except as otherwise provided in this Agreement, Organization and UAMS shall not assign or transfer any rights or obligations hereunder, or any part hereof, without the prior written consent of the other Party, except as a transfer of substantially all assets of such party (e.g., merger, acquisition, etc.).
13. **Relationship.** Nothing in this Agreement shall be considered to create a partnership, employment relationship, work made for hire, or any other type of joint venture. The Parties shall be considered independent contractors.
14. **Governing Law.** The parties agree to remain silent on governing law. This Agreement shall be construed using the English language.
15. **Notices.** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is: (i) delivered by hand; (ii) received by registered or certified mail, postage prepaid, return receipt requested; (iii) confirmed as received if by facsimile; or (iv) received by nationally recognized, overnight courier, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

15.1. If to UAMS:

ATTN: University of Arkansas for Medical Sciences
Research Contracts Attorney
4301 West Markham St. #860
Little Rock, AR 72205

With a copy to: University of Arkansas for Medical Sciences
ATTN: The Cancer Imaging Archive
4301 W Markham #782
Little Rock, AR 72205

15.2. If to Organization:

ORGANIZATION
ATTN
ORGANIZATION NOTICE ADDRESS
CITY/STATE/ZIP
PHONE
FAX
EMAIL

- 16. Entire Agreement.** This Agreement constitutes the entire agreement and understanding between the Parties and supersedes any prior or contemporaneous negotiations, agreements, understandings, or arrangements of any nature or kind with respect to the subject matter herein. This Agreement may not be amended except by written instrument signed by both parties.
- 17. Counterparts.** This Agreement may be executed simultaneously in any number of counterparts (including scanned copies of signatures in portable document format ("PDF") and delivered via electronic mail), each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this Agreement in multiple counterparts as of the date last executed below by their duly-authorized officers.

The Board of Trustees of the University of Arkansas acting for and on behalf of the University of Arkansas for Medical Sciences	ORGANIZATION
UAMS AUTHORIZED SIGNATURE	ORGANIZATION AUTHORIZED SIGNATURE
UAMS AUTHORIZED SIGNATORY NAME	ORGANIZATION AUTHORIZED SIGNATORY NAME
UAMS AUTHORIZED SIGNATORY TITLE	ORGANIZATION AUTHORIZED SIGNATORY TITLE
UAMS AUTHORIZED SIGNATURE DATE	ORGANIZATION AUTHORIZED SIGNATURE DATE

Read and Acknowledged by TCIA Principal Investigator:	(If required by Organization) Read and Acknowledged by Organization's Principal Investigator:
UAMS PI SIGNATURE	ORGANIZATION PI SIGNATURE
UAMS PI SIGNATURE DATE	ORGANIZATION PI SIGNATURE DATE

EXHIBIT A
DESCRIPTION OF SUBMISSION DATA

PLEASE DESCRIBE IN DETAIL THE SUBMISSION DATA (e.g., number and modality of images; imaging locations; number of subjects; data elements and number of cases for supporting clinical, proteomic, or genomic data; and associated analyses, etc.):

EXHIBIT B**STATEMENTS AND ADDITIONAL SAFEGUARDS APPLICABLE TO SUBMISSION DATA
FROM THE EEA GDPR OR UK GDPR JURISDICTIONS**

1. For purposes of the Agreement and this Exhibit B, GDPR means “Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)” or the equivalent Article or Section of UK Data Protection Laws (“UK GDPR”).
2. Organization certifies that it has reviewed TCIA’s Submission and De-identification Overview (<https://wiki.cancerimagingarchive.net/display/Public/Submission+and+De-identification+Overview>).
3. Organization certifies that it has reviewed TCIA’s Data Usage Policies and Restrictions (<https://wiki.cancerimagingarchive.net/display/Public/Data+Usage+Policies+and+Restrictions>).
4. Organization certifies that it has reviewed TCIA’s (i) Legal Framework and Ethical Use of this Resource and (ii) User Registration Privacy Act Notification Statement (<https://www.cancerimagingarchive.net/disclaimer/>).
5. Organization acknowledges that the intent of TCIA is to publish Curated Submission Data for use in research.
6. Organization acknowledges that TCIA uses a standards-based approach for de-identification of images stored in the Digital Imaging and communications in Medicine (DICOM) format. DICOM Standard PS3.15 2016a - Security and System Management Profiles defines how to correctly de-identify DICOM objects. TCIA incorporates the “Basic Application Confidentiality Profile,” amended by inclusion of profile options: Clean Pixel Data Option, Clean Descriptors Option, Retain Longitudinal With Modified Dates Option, Retain Patient Characteristics Option, Retain Device Identity Option, and Retain Safe Private Option. DICOM is ISO 12052:2017.
7. Organization certifies that the Submission Data has been collected in a lawful manner and that Organization has the right and authority to provide the Submission Data to TCIA for TCIA’s purpose of publishing the Curated Submission Data in accordance with TCIA’s mission and policies.
8. Organization certifies that the Submission Data is anonymized as that term is understood in the Organization’s home country, or the Submission Data is otherwise not personal data subject to the GDPR.
9. Organization agrees that once the Submission Data is provided to UAMS, Organization will destroy any mapping or linkage documentation that it may possess related to the Submission Data to prevent re-identification of any person. Accordingly, Organization acknowledges that UAMS will not be able to associate any subset of Submission Data with a particular person, and, therefore, UAMS will not be able to withdraw specific Submission Data if so requested by Organization or the subject of the Submission Data.