

## **CARRA Registry TERMS OF USE AGREEMENT**

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### **Purpose:**

The Childhood Arthritis and Rheumatology Research Alliance (“CARRA”) is a North American organization of pediatric rheumatologists who are committed to advancing the health and quality of life of children living with rheumatic disease, and who have joined together to answer critical clinical research questions. The mission of the alliance is to prevent, treat and cure rheumatic diseases in children and adolescents through fostering, facilitating, and conducting high-quality research.

Duke University (“Duke”) was awarded a grant from National Institute of Arthritis and Musculoskeletal Diseases and Skin Diseases (“NIAMS”) under the American Recovery and Reinvestment Act of 2009 (“ARRA”). Specific aims under this NIAMS grant include establishing the Childhood Arthritis and Research Alliance Network (“CARRANET”) and developing and implementing an informatics infrastructure enabling observational, disease-related data capture across investigative sites in the major pediatric rheumatic diseases (“CARRANET Registry”). Through funding from Duke’s NIAMS grant, Children’s Hospital Corporation d/b/a Children’s Hospital Boston (“CHB”) has designed and developed the CARRANET Registry, a self-scaling registry software platform that enables CARRANET investigators at each participating CARRANET registry site (“Registry Site”) to access the data that they and other Registry Site investigators (“Site Investigators”) contributed through participation in the CARRANET Registry coordinated by Duke (“Registry Data”). CHB will host CARRANET Registry and allow access to Registry Data to those users appointed by and authorized at each Registry Site (“User”). Access will be through CHB’s Virtual Private Network remote access (“VPN”). By entering into the CARRANET Registry and by accessing Registry Data in accordance with the terms herein, “You” are an authorized User from a Registry Site.

### **Scope of Agreement:**

This Terms of Use Agreement, as may be modified from time to time (“Agreement”), constitutes legally binding terms and applies to Your use of CARRANET Registry. By accessing and/or using CARRANET Registry, You (i): agree to be bound by this Agreement and all applicable laws, rules and regulations, including but not limited to (“HIPPA”) as defined in 45 Code of Federal Regulations (CFR) § 164.514(e)(2) (“Applicable Law”); (ii) certify that You are the permitted User, as authorized by the Registry Site’s Institutional Review Board (IRB) and the Registry Site’s Site Investigator; (iii) certify that You have been given the proper authorization to access CARRANET Registry and (iv) agree that You shall use CARRANET Registry solely for the purpose of acquiring and analyzing Registry Data as contemplated by the CARRANET Network Participation Agreement (“Participation Agreement”) and Registry Site Agreement (“Registry Agreement”) executed between your Registry Site and Duke.

You also certify that you have read and agree to the guidelines for publication as outlined in the Participation Agreement and the CARRA Publication Policy guidelines ([http://www.carragroup.org/content\\_dsp.do?pc=Policies](http://www.carragroup.org/content_dsp.do?pc=Policies)) by which Registry Data may be shared and disclosed (“CARRA Guidelines”) and accept that they may be amended from time to time without prior notice.

CHB reserves the right to modify this Agreement at any time and from time to time and each such modification shall be effective upon approval by the CARRANET Registry Executive Committee and posting on the CARRANET Policies webpage

([http://www.carragroup.org/content\\_dsp.do?pc=Policies](http://www.carragroup.org/content_dsp.do?pc=Policies)). All material modifications will apply prospectively only. Your continued use of CARRANET Registry following any such modification constitutes Your agreement to be bound by and Your acceptance of this Agreement as so modified. It is therefore important that You review this Agreement with each use of the CARRANET Registry. If You do not agree to be bound by this Agreement and to abide by all Applicable Law, You must discontinue use of the CARRANET Registry website immediately.

**1. In order to access CARRANET Registry and CHB VPN, You agree to the following:**

- a) Access. CHB grants You CARRANET Registry access through VPN based solely on Your representations to CHB when granted such access. You certify that all such representations are complete and accurate.
- b) Remote Access Policy. When accessing the CARRANET Registry through VPN, You agree to adhere to all CHB security policies and guidelines for computer use and may be held accountable for any security breach to the supported system or other CHB computer resources caused by your accessing the CARRANET Registry. You agree to abide by the “Children’s Hospital Boston, The information Services Policy and Procedure Manual: Remote Access Policy” (“CHB Remote Access Policy”) (<https://www.carranetwork.org/projects/carranet-registry/i2b2-information-and-documents/CHB%20Remote%20Access%20Policy%20with%20Related%20Content.pdf/view>).
- c) For purposes of this Agreement, You understand that (i) Registry Data itself does not comprise CHB’s data, including CHB Protected Health Information; and (ii) rights to the Registry Data stored and transmitted over CARRANET Registry are subject to NIH Data Sharing Policies [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/) and the requirements set forth in the Participation Agreement; (iii) Registry Site Registry Data stored and transmitted over CARRANET Registry will not affect Duke’s status as the “Covered Entity” (as the phrase is defined in the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”)) responsible for protecting disclosure of the Registry Data; and (iv) each Registry Site shall retain rights to use its own Registry Data for internal educational, research and clinical purposes.
- d) CARRANET Registry Safeguards. You agree to take appropriate safeguards to prevent use of or access to CARRANET Registry and/or the VPN by anyone who is not an authorized User and has not been granted VPN access by CHB.
  - i. Should access or use other than by permitted Users be required by government request, requirement, order or law, CHB and Duke shall be informed immediately as set forth in Section 1.d.ii and Section 1.d.iii, respectively.
  - ii. CHB Reporting: You understand and agree that any other information You may obtain via access to VPN, excluding Registry Data and related information, comprises CHB information. If You or another user obtains unauthorized information, it must be destroyed immediately and You must promptly notify CHB by contacting Craig Bennett, HIPAA Manager, by telephone at 857-218-4680 or via email to: [craig.bennett@childrens.harvard.edu](mailto:craig.bennett@childrens.harvard.edu)

- iii. Duke Reporting: If You or an unauthorized user obtain unauthorized access to the CARRANET Registry or the Registry Data, You must immediately destroy all unauthorized hard copies and electronic copies of Registry Data, other data or any other unauthorized information and immediately notify Duke's Office of Research Administration in writing and via telephone to: Duke's Office of Research Administration, ATTN: John Minchnowicz, Executive Director, 2200 West Main Street, Suite 820, Durham, North Carolina 27705 (e-mail copy of same to: john.michnowicz@duke.edu), 919-664-2241

**2. In accessing the Registry Data, You agree to the following:**

- a) Use of Data. You agree that You shall use Registry Data accessed on CARRANET Registry as allowable and set forth in Participation Agreement and Registry Agreement and exclusively and only for the purposes mutually agreed upon by CARRA, CARRANET, and Registry Site's IRB and subject to any subsequently amended and mutually agreed purposes.
- b) Other Use or Disclosure. You agree that You will not disclose, or allow access to Registry Data to anyone other than other authorized Users except as required by law. For the subset of Registry Data which pertains exclusively to Registry Site's own subjects ("Subjects"), that site retains all rights to use its own Subject's Registry Data as it sees fit and according to all applicable Registry Site guidelines and restrictions for such data use, including adherence to all restrictions imposed by the Registry Site's IRB and applicable law.
- e) Registry Data Safeguards. You agree to take appropriate safeguards to prevent use of, access to or disclosure of Registry Data to anyone other than as provided by the CARRANET Participation Agreement, Registry Agreement, CARRA Guidelines, and Registry Site's IRB. If Registry Data is accessed or used by anyone other than a permitted User or if disclosure of Registry Data is required by government request, requirement, order or law, Duke and CHB shall be informed immediately as set forth in Section 1.d.ii and Section 1.d.iii, respectively.
- c) Contact/Identification. Except for Subjects at Your Registry Site for which the Registry Site already possesses coded identifiers under the Registry Site's IRB authorization, You shall refrain from (1) any manipulation of Registry Data that enables You or others to identify Subjects whose information is included in Registry Data and (2) any use or attempted use of Registry Data to enable contact with any individual who is a Subject of Registry Data or his/her relatives, employers or household members.
- d) Publication. Publications by You regarding Registry Data shall be governed by the terms outlined in the Participation Agreement and in accordance with the CARRA Publication Policy guidelines ([http://www.carragroup.org/content\\_dsp.do?pc=Policies](http://www.carragroup.org/content_dsp.do?pc=Policies)), subject to any further limitations imposed by Your Registry Site's IRB or Site Investigator. In all publications resulting directly from use or analysis of Registry Data, You must cite NIAMS funding support under Grant No. RC2AR058934 and ARRA.

Further, You agree to provide appropriate acknowledgement under CARRA Guidelines where so specified, or if not so specified then as per the most recently released version of "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" guidelines produced by the International Committee of Medical Journal Editors.

**3. Other:**

- a) Liability. Except to the extent permitted by law, You assume all liability from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from Your use of CARRANET Registry and Registry Data, except when caused by the gross negligence or willful misconduct of CHB.
- b) Disclaimer. All CARRANET access is provided on an "as is" and "as available" basis. CHB does not provide any express warranties or representations either guaranteeing access to the CARRANET Registry or Registry Data or regarding to the content of the Registry Data.
  - i. Specifically, CHB and CARRANET do not guarantee that the services it provides will operate without interruption or errors in functioning.
  - ii. CHB and CARRANET do not guarantee the substance or usefulness of any Registry Data.
- c) Termination. You must terminate this Agreement if You are no longer a permitted User. CHB may terminate this Agreement immediately in the event that the You are no longer a permitted User or You are in material breach of the terms of this Agreement, CARRA Guidelines, or the CARRANET Participation Agreement or Registry Agreement.
- d) Massachusetts Law. All disputes arising out of this Agreement shall be governed by Massachusetts law regardless of otherwise applicable Choice of Law standards.
- e) Severability. If any provision of this Agreement is found by a court of competent jurisdiction or arbitrator to be illegal, void, or unenforceable, the unenforceable provision will be modified so as to render it enforceable and effective to the maximum extent possible in order to effect the intention of the provision; and if a court or arbitrator finds the modified provision invalid, illegal, void or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement will not be affected in any way.
- f) Entire Agreement. You agree that this Agreement constitutes the entire, complete and exclusive agreement between You and CHB regarding access to CARRANET Registry and Registry Data therein and supersedes all prior agreements and understandings between You, Your Registry Site and CHB, whether written or oral, or whether established by custom, practice, policy or precedent, with respect to the subject matter of this Agreement.