**­USCLC CUTANEOUS LYMPHOMA REGISTRY SITE AGREEMENT**

This Cutaneous Lymphoma Registry Site Agreement (this “Agreement”) is entered into and made effective as of [\_\_\_\_], by and between United States Cutaneous Lymphoma Consortium, a District of Columbia corporation with offices at Association Management Executives, Inc., 6134 Poplar Bluff Circle, Suite 101, Norcross, GA 30092 (“USCLC” or “Sponsor” and \_\_\_\_\_\_, [insert name of University, Practice, or other entity], a [nonprofit] [insert state of incorporation] corporation with its principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“Site”). Sponsor and Site are each a “Party” and are referred to collectively herein as the “Parties,” for the purpose of participating in the Registry (as defined below).

WHEREAS, Sponsor is developing a clinical data registry containing information relating on cutaneous lymphoma cases and research projects (“the Registry”); and

WHEREAS, Site has expressed an interest in participating in the Registry in accordance with Sponsor requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the Parties hereto agree as follows:

# **THE REGISTRY**

## Site agrees to participate in the Registry through one or more of its investigators (“Investigator”) submitting data and other information (including each subject’s signed informed consent and authorization form (“ICF”), confirmation of Institutional Review Board (“IRB”) approval/waivers, and if necessary, source documents and/or other reports necessary for regulatory approval or tracking), such data and information to be collectively referred to herein as (“Data” or “Site Data”) that shall be collected at and under the direction of the principal Investigator (“Principal Investigator”) at each site in strict accordance with (1) the protocol previously furnished to Site by or on behalf of Sponsor, as amended from time to time (the “Protocol”), a copy of which is attached hereto as Exhibit A and incorporated by reference herein, (2) the written instructions of Sponsor or its representatives, and (3) all applicable laws, rules, regulations, guidelines and industry standards (“Applicable Law”). Each Investigator must be a member in good standing of the Sponsor in order for such Investigator to participate in the Registry on behalf of a Site. If any Investigator fails to maintain membership in Sponsor, such Investigator may no longer participate in the Registry. Any changes to the Protocol must be agreed upon in advance by Sponsor. Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the Protocol.

## Site shall use best efforts to submit Data to the Registry in a timely manner and otherwise comply with the rules and schedules reasonably established by the Sponsor.

# **REPRESENTATIONS AND CERTAIN COVENANTS**

## Site hereby represents: (i) that it has the legal authority to enter into this Agreement and participate in the Registry and (ii) that the terms of this Agreement do not conflict with and would not result in a breach under any agreement to which Site is a party that would have a material adverse effect on its ability to perform its obligations under this Agreement.

## Site agrees and acknowledges that failure to submit Data to the Registry, or its submission of Data to the Registry that does not comply with Sponsor’s requirements, may result in Site’s failure to receive one or more reports generated by the Registry and/or disqualification from future participation in the Registry.

## Site agrees and acknowledges that the Data captured by the Registry will include certain entity, physician, and patient-identifying information (which shall be encrypted during transfer and at rest in the Registry software system). Site agrees that it is the Site’s and Investigators’ responsibility to obtain any authorizations, consents, or permissions required in order to submit such Data for inclusion in the Registry.

## Site hereby represents that in the course of participating in the Registry and in connection with all activities hereunder, Site will adhere to Applicable Law. Site certifies that in the course of performing its obligations hereunder, Site will not use in any capacity the services of any person who has been debarred or disqualified by the OIG, GAO or the FDA pursuant to the Generic Drug Enforcement Act of 1992 or any other equivalent or successor statutes, rules or regulations.

2.5 Site hereby represents:

1. that, to the best of its knowledge, all Data submitted for inclusion in the Registry will be accurate and complete, and acknowledges that such Data may be subject to independent audit in accordance with terms and conditions mutually agreed upon by the Parties. Site will use its best efforts to address any Data or related deficiencies identified by Sponsor, and agrees to cooperate with and assist Sponsor and its designees in connection with the performance of any independent audit of the Site’s Data submissions or Data submission process;
2. it will obtain from each patient whose Data is submitted to the Registry a signed ICF form, the template for which has been provided by the Sponsor and approved by the IRB associated with Site in accordance with the Protocol and with 21 CFR Part 50 and/or the ICH Guidelines for Good Clinical Practice, as applicable, and to the extent, if any, that such ICF differs from that provided by the Sponsor, then provide copies of such ICF to the Sponsor for approval prior to commencement of use of such form; properly perform and direct the Registry in accordance with the Protocol, Applicable Law and good clinical practice;
3. it will assist and cooperate with Sponsor in its efforts to conduct the Registry;
4. it will review all data entry on the electronic case report forms (as defined in the Protocol) to assure their accuracy and completeness, and reasonably assist the Sponsor’s representatives upon request in promptly resolving any discrepancies or errors in case report forms and in performing random audits on patients’ records, laboratory reports, or other raw Data sources underlying Data recorded in the case report forms; and
5. it will submit all Site Data, and undertake all reasonable activities, so that the time schedules set forth in the Protocol and this Agreement are strictly met or as otherwise reasonably requested by the Sponsor.

# **GENERAL BENEFITS TO SITES**

## Sponsor will provide Site with the opportunity to participate in the Registry; a secure platform and forms for which to enter data; the ability to review and use Site’s Data for its own purposes so long as it does so in compliance with the terms of this Agreement; periodic reports and analyses from the Registry, of both Site Data and Registry Data, without charge; and appropriate acknowledgement in publications related to Site’s Data as determined by USCLC Registry Committee in accordance with its guidelines on publications.

# **CONSENT AND REVIEW**

## Investigators at each site shall obtain the informed consent and authorization of the subjects participating in the Registry in accordance with the Common Rule at 45 CFR Part 46 (the “Common Rule”) and the applicable regulations issued under the Health Insurance Portability and Accountability Act of 1996 at 45 CFR Part 160 and Subparts A and E of Part 164, as amended, (“HIPAA”), respectively, as well as any other Applicable Law. The relevant IRB shall review and approve the Protocol and any amendments thereto, including the ICF, in accordance with Applicable Law. Site will use the ICF template that has been approved by Sponsor’s central IRB with modifications as necessary to meet the local IRB’s specifications, subject to Sponsor review and approval of such changes. However, the data sharing portions of the ICF must remain the same at all sites. The original of the fully-executed consent form should be kept on file at the Site. The HIPAA-compliant authorization shall permit Site to submit each individual’s Protected Health Information (as defined by HIPAA) to the Registry and allow the Registry to share certain information including slides and de-identified photographs with other sites participating in the Registry. Site agrees to supply Sponsor or Sponsor’s designee with written evidence of local IRB approval, a copy of the fully-executed ICF which is IRB and Sponsor-approved, a copy of any modified ICF later approved by the local IRB and Sponsor and used by Site, and a copy of signed ICF for each subject. Only the information of subjects, from whom informed consent and authorization has been properly obtained and who meet the enrollment criteria set forth in the Protocol or otherwise provided by Sponsor, shall be included in the Registry.

# **RECORD KEEPING, REPORTING AND ACCESS TO RECORDS**

## Site agrees to maintain adequate and accurate records as required under Applicable Law relating to the Registry. Site specifically agrees to timely prepare and maintain complete and accurate records, notes, reports, and data required in connection with the Registry for each subject, as provided in the Protocol and this Agreement. Site agrees to permit Sponsor or its representatives, the FDA, or any other applicable regulatory authority, access to the records maintained pursuant to this Section 5 upon request at reasonable times for purposes of source Data verification, auditing or inspection. Site agrees that it will not destroy any such records without Sponsor’s prior written consent.

# **CONFIDENTIALITY**

## Site agrees that all proprietary and confidential information received from Sponsor, including but not limited to the Protocol, the Registry Data (as defined in Section 7.3 herein) and reports of Registry Data are Sponsor’s “Confidential Information” and shall remain the sole and exclusive property of Sponsor during the term of this Agreement and thereafter. Sponsor Confidential Information shall also include, without limitation, patent applications, technology, business plans or the Protocol and all information relating thereto; all proprietary biological, chemical or other materials; applications, formulas, manufacturing processes, basic scientific data, study data and Registry Data, prior clinical data, and formulation information. Site agrees not to disclose Sponsor’s Confidential Information to any person or entity (except any employee or agent directly involved in the Registry so long as the same are bound to confidentiality obligations no less onerous than these or as required by Applicable Law) without the prior written consent of Sponsor and further agree to take all reasonable precautions to prevent the disclosure by any employee or agent of Confidential Information to any third party or otherwise into the public domain. Site agrees that neither it, nor any employee or agent involved in the Registry, will be permitted to make any use of Confidential Information except in the conduct of the Registry and evaluation of its results. The provisions of this Section 6 do not apply to any information which (i) was known to Site prior to receiving that information either directly or indirectly from Sponsor, as demonstrated by competent written records; (ii) is generally known to the public or which becomes generally known to the public through no act or omission on the part of Site; (iii) is disclosed to Site at any time by a third party not under an obligation of confidentiality to Sponsor and who had legal right to disclose it; or (iv) is required by Applicable Law to be disclosed, provided that Site shall give Sponsor prior notice of any such legally-required disclosure and shall use reasonable best efforts to seek confidential treatment or a protective order.

## Any and all Confidential Information received by Site, or any of its employees or agents, in whatever form, including all copies or duplicates made or retained by Site or any of its employees or agents, shall be promptly returned to Sponsor upon written request by Sponsor or disposed of in accordance with the written instructions of Sponsor. The obligations of this Section 6 shall survive the termination or expiration of this Agreement.

# **INTELLECTUAL PROPERTY AND PUBLICATION**

## It is agreed and acknowledged that all Data submitted for inclusion in the Registry by or on behalf of Site are and shall remain Site’s proprietary information, and may be used by Sponsor and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Site with respect thereto.

## Site hereby agrees that all Data submitted by or on behalf of Site to Sponsor or Sponsor’s designee for purposes of inclusion in the Registry may be used by Sponsor as a part of the Registry and any subset thereof that Sponsor may choose to create and use as it sees fit for the purposes of promoting Site’s and other Registry sites’ health care operations (including without limitation quality improvement), medical research (as defined by the Common Rule and HIPAA) by Sponsor and others authorized by Sponsor, and the other interests of the Registry (including, without limitation, publication of such Data); provided, however, that no such Data shall be used and disclosed in such a way as to identify Site or any individual physician or physician group, unless and until Site advises Sponsor in writing that it has authorized and/or secured appropriate consent for such disclosure. Sponsor will not share PHI with third parties except as otherwise authorized under this Agreement, the Common Rule, and HIPAA.

## Site acknowledges that Sponsor is and shall be deemed the owner of all rights to the Registry including but not limited to the aggregate data contained therein and subsets thereof; all data fields, data elements, datasets, databases (including databases created to maintain Site’s Data in the Registry), and data dictionaries developed by and for the Registry; any and all reports based on the Registry Data, and all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts) (collectively “Registry Data”); and all trademarks, trade secrets and all other intellectual property arising from or reflected in the Registry, with the exception of Site’s Data (collectively, with Registry Data, “Sponsor Intellectual Property”).

## Site will not use, share with third parties, or publish Registry Data without Sponsor’s prior written approval. In addition to Sponsor’s prior written approval, Site may not conduct research on Registry Data without separate IRB approval of the protocol and consent form for such research at their site.

## In order to prevent duplication of effort or publication, Site agrees that it will not submit its Data to any other entity or person for research or publication purposes without first informing the USCLC in writing of its purpose and nature. Further, Site may only share its Site Data with third parties for such purposes that have entered into a Site or data use agreement with Sponsor.

## Sites shall ensure that all proposed publications (including manuscripts and abstracts for presentations) arising from the use of Site’s Data provided pursuant to this Agreement are submitted to Sponsor for review and comment at least thirty (30) days prior to submission for publication or making public any information that has been derived utilizing Site’s Data. Sites will incorporate any reasonable revisions requested by the Sponsor relating to the characterization of Site’s Data and/or agree to delay proposed publications as reasonably necessary to allow coordination with Sponsor publications relating to the same Data. Site agrees to acknowledge the contribution made by the Sponsor in all publishable work arising from research on Site’s Data, except in the instance where Sponsor and Site cannot agree on Sponsor’s requested changes to a publication, in which case Sponsor may require Site to insert a disclaimer in the publication stating that Sponsor does not support the analysis, results, and/or conclusions of the publication based on Site’s Data. If Sponsor staff or volunteer leaders collaborate with Site on any publication, such individual or individuals will be listed as a co-author.

## Registry results are expected to be published and presented on an annual basis and potentially more frequently as Data permit. The Registry Committee will be responsible for defining the content of scientific publications and presentations, identifying target journals and medical meetings and determining authorship including the order of authors for any such publication or presentation of Registry Data. In making determinations of authorship, the criteria set forth by the International Committee of Medical Journal Editors (Uniform Requirements for Manuscripts Submitted to Biomedical Journals) will serve as a guide. If desired, a medical writer will be hired to assist with manuscripts and/or oral and poster presentations.

# **INDEMNIFICATION; LIMITATION OF LIABILITY**

Site shall , indemnify and hold harmless Sponsor, its directors, officers and employees, from and against any and all costs, expenses (including reasonable attorney’s fees), actions, liabilities or demands (including those based on injury to or death of any person or damage to property) related to third-party claims and arising out of, or resulting from, any material breach, negligence or willful misconduct of Site, its Investigators, or its agents related to its obligations and activities conducted under this Agreement.

Sponsor shall , indemnify and hold harmless Site, its directors, officers and employees, from and against any and all costs, expenses (including reasonable attorney’s fees), actions, liabilities or demands (including those based on injury to or death of any person or damage to property) related to third-party claims and arising out of, or resulting from, any material breach, negligence, or willful misconduct of Sponsor, or its agents related to its obligations or activities conducted under this Agreement.

This Section 8 shall survive the expiration or sooner termination of this Agreement.

Under no circumstances will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

# **INSURANCE**

# At all times during the term of this Agreement, Site shall maintain insurance with coverage and limits reasonably sufficient to cover its obligations hereunder and shall provide proof of such insurance to Sponsor upon Sponsor’s request. Site may satisfy the foregoing requirement through an appropriate self-insurance program, but must provide Sponsor with proof of such insurance upon Sponsor’s request.

# **USE OF NAME**

# Any use by Sponsor of the name of Site or Investigators will be limited to identifying Site or an Investigator as a participant of the Registry. Neither Sponsor nor Site shall use the name, trademarks, or logos of the other Party for promotional purposes without prior written consent of the other Party.

# **TERM AND TERMINATION**

This Agreement will be in force from the Effective Date for as long as the Registry continues to operate unless terminated earlier in accordance with the provisions of this Section 11. Sponsor may terminate this Agreement without cause upon thirty (30) days’ notice to Site. Either Party may terminate this Agreement for a material breach by the other Party upon ten (10) days’ notice if the breach has not been cured within such notice period. Site shall promptly return Registry Confidential Information upon the termination or expiration of this Agreement. In addition, upon termination, Site shall return any fees or funds advanced by Sponsor to the extent they are unearned. Site agrees and understands that it will not be feasible for Sponsor to return the Data submitted by Site upon termination or expiration of this Agreement; however, Sponsor will protect such Data in accordance with the terms of this Agreement as long as it possesses or controls such Data.

# **NOTICES**

All notices and demands of any kind or nature which any Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., Federal Express or DHL) to the following addresses:

If to Site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attn:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If to Sponsor: Elise Olsen, MD

USCLC Registry Committee Chairman

Box 3294 DUMC

Durham, NC 27710

Tel: 1-919-971-2203

Email: USCLCRegistry@gmail.com or elise.olsen@gmail.com

and Association Management Executives, Inc.

6134 Poplar Bluff Circle, Suite 101

Norcross, GA 30092

Tel: 404-310-5866

Attn: Alyson Conley

Email: alyson@theassociationcompany.com

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any Party hereto may, from time to time, by notice in writing served upon the other Party(ies), designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

# **MISCELLANEOUS**

## Independent Contractors. Site and Sponsor are acting hereunder as independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers. Site may not subcontract any of the services to be performed by it under this Agreement without prior written consent from Sponsor. Nothing contained herein shall be construed to create an employer/employee relationship between Sponsor and Site.

## Equitable Relief. The Parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that emergency injunctive relief shall be available as a potential remedy for any such breach by any other Party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching Party (ies).

## Compliance with Applicable Law. Site shall comply in all material respects with all Applicable Law regarding the privacy of individually identifiable health information, including but not limited to, HIPAA and any other applicable statutes or regulations concerning patient privacy and data security. Sponsor agrees to collect, use and disclose Data collected or produced in connection with the Registry which identifies or could be used to identify Participant’s patients only in accordance with the informed consent(s) and authorizations obtained from each subject as part of the Registry, and for the purpose of complying with Applicable Law. Sponsor will use all reasonable efforts to protect the privacy and security of subject Data and will also require its business partners to do the same. Sponsor will not initiate contact with any subject.

## Headings. The headings of the various sections hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify or place any construction upon any of the provisions of this Agreement.

## Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

## Survival. The provisions of Sections 2, 5, 6, 7, 8, 9, 10, 12, 13.2, 13.3, 13.6, 13.7, 14 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.

## No Assignment. Except in connection with the sale of all or substantially all the assets, stock or business of Sponsor relating to the Registry (by merger or otherwise), any attempted assignment of rights or delegation of duties under this Agreement shall be void without the prior written consent of the non-assigning or non-delegating Parties. All transferred rights and duties shall inure to the benefit of and be binding on the Parties’ successors and permitted assigns.

## Waiver. No waiver, expressed or implied, shall be a continuing or subsequent waiver of the particular right or obligation.

## No Third Party Beneficiaries. Except as explicitly stated in this Agreement, this Agreement shall not confer any rights or remedies upon any person or entity other than the Parties and their respective successors and permitted assigns.

## Counterparts. This Agreement may be executed in counterparts and by electronic mail and/or facsimile signatures. This Agreement is entered into effective as of the date first written above.

## Authority. The persons executing this Agreement represent and warrant that they have the full power and authority to enter into this Agreement on behalf of each respective Party.

## Entire Agreement. This Agreement (a) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the Parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the Party against whom enforcement is sought.

# **REGULATORY INSPECTION**

Site shall notify the Sponsor immediately by telephone or telefax of any inquires, correspondence, or communications with or from the FDA or any other governmental or regulatory authority, including without limitation requests for an audit of the Registry by the FDA or any other governmental agency. Sponsor shall have the right (but not the obligation) to be present at any such inspections of the Site’s facilities or operations or of the study location, and shall have the opportunity to provide, review, and comment on any responses that may be required.

**IN WITNESS WHEREOF,** the Parties hereto have executed this Agreement as of the date first above written.

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| --- | --- |
| **SPONSOR**  By:  Name:  Title:  Date: | **SITE**  By:  Name:  Title:  Date: |

**EXHIBT A**

**PROTOCOL**