

## **CancerLinQ Discovery<sup>®</sup> Data Access Policy** (May 27, 2020)

### **I. Introduction**

CancerLinQ LLC (“CLQ”) is committed to conquering cancer through appropriate, secure, and ethical usage of health information entrusted to CLQ. CLQ believes that the ability to learn from every patient will accelerate progress against cancer and will give patients and physicians more comprehensive information to make decisions about cancer prognosis and treatment.

CancerLinQ Discovery<sup>®</sup> is a cancer information resource containing clinical and related data that has been de-identified as to patient and provider. CancerLinQ Discovery is derived from CancerLinQ<sup>®</sup>, CLQ’s learning health system that is designed to help oncology professionals monitor, coordinate, and improve the quality of care they provide to cancer patients. Participating healthcare organization, practices and professionals (“Subscribers”) have given CLQ permission to de-identify the registry-type data they share with CLQ. This secondary information, provisioned in CLQ’s secure cloud environment with approved analytic tools, is expected to also have utility in a range of applications, such as updating and developing quality benchmarks and clinical guidelines, research, hypothesis generation, identification of signals, and provision of reports.

CancerLinQ Discovery offers an active and responsive data access program. Any non-commercial individual or entity with a legitimate interest in CancerLinQ Discovery data or reports (“Researcher”) may submit a request to CLQ, using the data access request form available on the CancerLinQ website or through CLQ’s CancerLinQ Discovery Platform, a secure hosted environment and software system licensed by CLQ from the American Heart Association (the “CancerLinQ Discovery Platform”). Requests will be evaluated by CancerLinQ staff in accordance with this Data Access Policy. Requests for commercial uses of CancerLinQ Discovery data may be submitted to authorized licensees of CLQ, or if submitted to CLQ, will be referred to such licensees for fulfillment.

### **II. Glossary of Terms Used**

**Authorized User:** Any individual who is a Researcher or a representative of a Researcher who has been provided authorized access to Discovery Data on behalf of a Researcher subject to a Data Access Agreement.

**Data Access Agreement:** A written agreement signed by CLQ and the Researcher that sets out the permitted uses of Discovery Data and other responsibilities of Researchers and Authorized Users. A Data Access Agreement may be part of a larger agreement between a Researcher and CLQ. Where a Limited Data Set is involved, a Data Access Agreement will be a HIPAA-compliant Data Use Agreement.

**De-Identified Data:** Health information: (a) that has been redacted or otherwise revised to exclude all identifiers specified in 45 CFR § 164.514(b)(2) and with respect to which no actual knowledge exists that the information could be used alone or in combination with other information to identify any individual who is a subject of the information; or (b) that an appropriately qualified professional has determined does not constitute Individually Identifiable Health Information in accordance with 45 CFR § 164.514(b)(1).

**Discovery Data:** De-Identified Data, anonymized as to health care providers, that is derived from the CancerLinQ Subscriber registry and made available as a secondary data resource to Researchers via the CancerLinQ Discovery Platform. Discovery Data may refer to a core data repository, pre-selected subsets of that core, or subsets of that core that are provisioned by CLQ and contain data necessary to address a particular Research question or carry out a Researcher's queries.

**Limited Data Set:** Protected health information that excludes the following direct identifiers of the individual, or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images. Disclosure of a limited data set may only be for the purposes of research, public health, or health care operations, and must be accompanied by a fully executed data use agreement. 45 C.F.R. § 164.514(e).

**Publication:** An abstract, manuscript, slide set, poster, filing, or publishable report based on Discovery Data.

**Research:** A systematic investigation designed to develop or contribute to generalizable knowledge, or other study or analysis approved pursuant to this Policy. Research includes development of Research projects or preparation for Research.

**Report:** A document or dashboard that provides information and analyses gleaned from a review or analysis of Discovery Data, including summary data, that has been carried out by a Researcher or by CLQ on a Researcher's behalf.

### III. General Policies

- A. CancerLinQ Discovery is intended to further the charitable purpose of disseminating oncology information, facilitating collaboration among those involved in oncology, and promoting high quality cancer care. This means, among other things, that all uses of Discovery Data should have the effect of enhancing Discovery Data and the CancerLinQ registry, and the understanding of their potential uses, for the benefit of all.

- B.** CLQ (including leadership, workforce, advisors, and volunteers) and Authorized Users, will follow ethical guiding principles of stewardship, protection, transparency, and accountability when making decisions regarding CancerLinQ Discovery data.
- C.** CLQ and Authorized Users will comply with all applicable laws, regulations, and contractual obligations, including but not limited to HIPAA, Subscriber Participation Agreements, the Data Access Agreements, and Business Associate Agreements, securities laws, and antitrust laws.
- D.** Discovery Data will remain within a CLQ-controlled environment, where they can be accessed in a secure and approved way by Authorized Users. Only Reports, not the underlying data, may be exported by Authorized Users. CLQ does not sell Discovery Data. For the purposes of this subsection, the CancerLinQ Discovery Platform constitutes a CLQ-controlled environment.
- E.** Authorized Users are not authorized to access any data that is identifiable to an individual patient, provider, or oncology practice. Authorized Users will not attempt to re-identify any patient, provider, or oncology practice via CancerLinQ Discovery data, alone or in combination with other data sources, including other CancerLinQ Discovery data sets. Analyses resulting in a cohort of fewer than 10 patients, providers, or practices are not permitted.
- F.** CancerLinQ Discovery is a non-exclusive resource. CLQ may, at its option, permit multiple unrelated, but similar or identical, requests or analyses by different Researchers.
- G.** CLQ has the responsibility and authority to review Discovery Data access requests, Research requests, and publications resulting from CancerLinQ Discovery Research.
- H.** Enhancement and enlargement of the data set available for CancerLinQ Discovery is ongoing. However, CancerLinQ Discovery is provided “as is,” and neither CLQ nor ASCO gives any assurance about Discovery Data’s accuracy, completeness, or fitness for purpose. CLQ does not guarantee the availability or quality of data or other resources to support requests or reports to fulfill requests. CLQ will make reasonable efforts to, but retains sole discretion whether to, fulfill requests for which data are available and of sufficient quality.
- I.** All learning about Discovery Data is intended to enhance the resources of CancerLinQ and CancerLinQ Discovery. Data curation, data mapping, and other enhancements to Discovery Data, if any such activities are performed, will feed back into the broader data sets for the benefit of all.
- J.** CLQ is committed to transparency about the uses of Discovery Data. This Policy will be made public. CLQ reserves the right to make periodic reports to Subscribers and the public about the uses of Discovery Data. Researchers and Projects will be identified within

such reports unless specifically prohibited by an agreement between CLQ and the Researcher.

K. Except for work done by CLQ, CLQ does not endorse any Research, Report, or Researcher.

#### **IV. Data Access Requests**

A. Individuals and entities requesting access to Discovery Data or Reports must submit a Request Form and provide all required information.

B. IRB approval, if necessary, must accompany requests for access to Discovery Data. CLQ reserves the right to require IRB approval for certain requests.

C. CLQ may assess fees, which may vary depending on the scope and nature of the request.

D. A list of approved software will be made available to researchers. Use of any unapproved software will be subject to prior approval by CLQ.

#### **V. Request Approval Criteria**

A. CLQ will evaluate a Researcher's request to determine whether:

- i. The project is consistent with ASCO's mission, the goal of improving quality of care, or identifying practice trends or clinical endpoints;
- ii. CLQ is likely to have data relevant to the project;
- iii. The Researcher's analytic team or the CLQ analytic team appears to have the qualifications and resources appropriate to conduct the analyses;
- iv. Analytic tools and methodologies proposed by Researcher are compatible with CancerLinQ Discovery and this Policy;
- v. The proposed project is consistent with CLQ's privacy and security policies; and
- vi. A plan exists for disseminating the results of the Research.

B. CLQ may ask Researchers to supplement the application or may iterate with Researchers during the review process so as to develop a request that is appropriate for approval.

C. Researchers whose requests are denied may seek reconsideration by CLQ, but CLQ reserves the right in its sole discretion to approve or decline any request.

#### **VI. Data Access and Use**

A. If a request is approved, the Researcher's Authorized Users will be granted access to Discovery Data to the extent necessary to carry out the proposed Research.

- B. Requestors and Authorized Users are legally bound by the terms of the Data Access Agreement, which must be signed prior to awarding Data access to Authorized Users.
- C. A Researcher's use of a Discovery Data set must be related to the scope of the Researcher's requests and permitted by the Data Access Agreement.
- D. Researchers are specifically prohibited from linking Discovery Data with any other dataset, public or private, including other CancerLinQ Discovery datasets.
- E. Researchers may not attempt to re-identify any individual in a Discovery Data set.

## **VII. Publication Review**

- A. Researchers must have an intention to publish the results of their Research, as articulated in their data access requests. Publications resulting from the Research or based on Discovery Data may be reviewed and approved by CLQ before they are submitted to a congress or journal or otherwise released beyond the Researcher.
- B. CLQ will review the Publications to assure that they are consistent with the approved requests, that they accurately characterizes Discovery Data, that CancerLinQ Discovery is acknowledged as the source of the data, that authorship is appropriately acknowledged, that no confidential or proprietary information of CLQ is included within the Publications, and that there is no express or implied CLQ endorsement of an external Researcher's work or product.
- C. A CLQ disclaimer may be required to be included with the Publication.
- D. CLQ review does not assess or validate research methods, quality, or results. CLQ review is not a substitute for peer review, which is independently performed by relevant associations, congresses, and journals.
- E. CLQ approval of a Publication does not assure acceptance of the Publication by any ASCO meeting or journal. ASCO educational programs and publications are independent and peer reviewed and have sole discretion over the work accepted.

## **VIII. Miscellaneous Provisions**

- A. The specific terms of written agreements between Researchers and CLQ may supersede portions of this Policy and normal workflow. This includes but is not limited to access timelines, application fees and review timelines.
- B. CLQ reserves the right to audit any Research or Report.

- C. After a project or license is concluded, the Researcher's access to the corresponding Discovery Data will be terminated. CLQ will use reasonable efforts to provide access to a copy of the Research data set to the extent required by a journal, funding source, or regulatory body and if CLQ is given adequate notice of the requirement.
- D. CLQ will review requests for installation of unapproved software. CLQ may require Researchers to execute a software agreement prior to the installation of unapproved software.
- E. This Policy may be amended, modified, or revised by the affirmative supermajority vote of the CLQ Board of Governors, in its discretion.

*Approved by the CancerLinQ Board of Governors on December 13, 2016*

*Adopted by ASCO Board of Directors in its capacity as sole corporate member of CancerLinQ on December 14, 2016*

*Revisions approved by the ASCO Board Executive Committee May 21, 2020*

*Revisions approved by the CancerLinQ Board of Governors May 27, 2020*