**LEO Cohort: Policy on sharing of data, biospecimens and other resources**

**12/1/2020**

**Principles and Overview**

The Lymphoma Epidemiology of Outcomes (LEO) cohort is a prospective cohort study of newly diagnosed non-Hodgkin lymphoma (NHL) patients for use by researchers (internal and external to LEO) to advance the study of NHL prognosis and survivorship. To achieve this objective, LEO promotes the sharing of data, biospecimens and other resources with internal and external investigators. LEO Investigators are committed to the key principles outlined in the *Final NIH Statement on Sharing Research Data*, NOT-OD-03-032, dated February 26, 2003, and we reaffirm our support for the concept of data sharing.

**Access to LEO Resources**

LEO data capture forms, questionnaires, manuals/standard operating procedures, and other study materials and resources are freely available to the public from the LEO website ([www.LEOcohort.org](http://www.LEOcohort.org)).

**Open Source Data Projects**

Open source data projects are supported through dbGAP (<https://www.ncbi.nlm.nih.gov/gap/>). Phenotypic data from the underlying cohort will be added in waves, while genomic and other data generated from projects using LEO biospecimens will be added as those projects are published. All data will be submitted as de-identified (according to HIPAA) dataset(s) to dbGAP. Application for use of these data is coordinated through dbGAP, and no contact with LEO Investigators is expected or required, no LEO approval is needed, and there is no expectation of authorship. We plan to upload data to dbGaP in waves (current plan is Year 3 and Year 5 of the proposed renewal funding period 2020-2025) as follows:

Wave 1 (by Year 3 Q2 of grant):

* *Baseline Clinical Data* (abstracted data on LEO WHO diagnosis, age, gender, stage, height/weight, HIV status, performance status, B-symptoms, hemoglobin, WBC, LDH, International Prognostic Index score, treatment class)
* *Baseline Enrollment Questionnaire* (self-reported demographics, anthropometrics and health history, quality of life, and frailty)
* *Hematologic Malignancies Questionnaire* (self-reported demographics, family history, medications, physical activity, smoking, alcohol use, supplement use, menstrual and reproductive history)
* *Outcome Data File* (survival time, with validated disease recurrence/progression, death and cause of death)

Wave 2 (by Year 5 Q3 of grant):

* *Follow-up 3 Questionnaire* (self-reported physical activity and physical function, smoking, alcohol use, psychosocial function, social support, survivorship care, fertility)
* *Outcome Data File* (update survival time, with validated recurrence/progression, death and cause of death)

**Collaborative Projects**

Projects by internal and external investigators that desire collaboration with LEO investigators and/or that require biospecimens or LEO data not available on dbGAP (e.g., HIPAA-defined limited dataset, EHR data, scans, pathology slides or reports, specialized abstraction, etc.) are submitted and reviewed through the same approval process. In this scenario, one or more of the LEO team members will need to be engaged in the project development and implementation, and while we encourage full collaboration in this context with one or more LEO investigators (e.g., inclusion as a co-investigator on the project or grant; co-author on manuscripts; etc.) this is not required.

Collaborative projects for data and/or biospecimens from either internal or external investigators are directed to the LEO Administrative Core for initial review, and ultimately the LEO Steering Committee for approval. An initial feasibility inquiry can be submitted through the “Resource Request Form” on LEO Cohort Website ([www.leocohort.org](http://www.leocohort.org)) or contacting one of the LEO PIs [Drs. James Cerhan (cerhan.james@mayo.edu) or Christopher Flowers (CRFlowers@MDAnderson.org)]. This initial inquiry can be just a brief description of the project (300 words or less) or a more formal letter of intent (outlined in the *Guidelines for Collaboration*). We will respond to initial project inquiries within 2 weeks to help external investigators decide if they would like to proceed with a formal letter of intent. Requests from lymphoma patient advocacy groups, individuals, or others interested in LEO data for patient education without the intent of publication can also use this approach.

The LEO Steering Committee will review, discuss, and formally vote on approval of letters of intent and written proposals. Proposals are approved by a simple majority of Steering Committee members, and approval or disapproval will be recorded in our proposal tracking database. There is also an appeals process.

Data and biospecimens are shared under the LEO Memorandum of Understanding (MOU), which follows a data enclave model, such that the dataset is stripped of identifiers prior to release for sharing and users commit to: (1) providing a detailed summary of the proposed research project, including a complete list of data requested; (2) using the data only for research purposes; (3) maintaining confidentiality of the data and not identifying any individual participant; (4) securing the data summary statistics using appropriate computer technology; and (5) destroying or returning the user data after analyses are completed and the manuscript is published.