LEO

SOP Manual

Revised 9.2025

Subject Enrollment

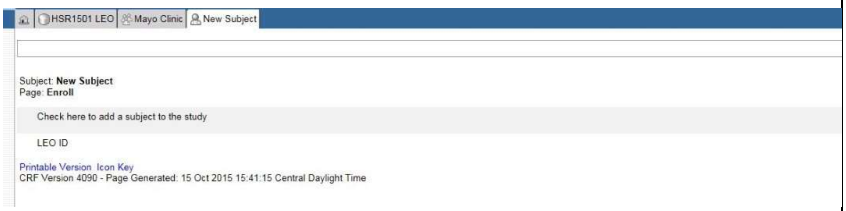
RAVE Database-Enrollment

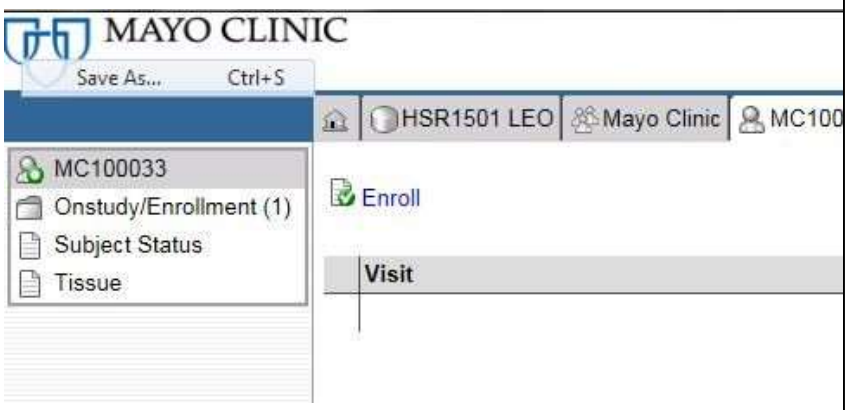
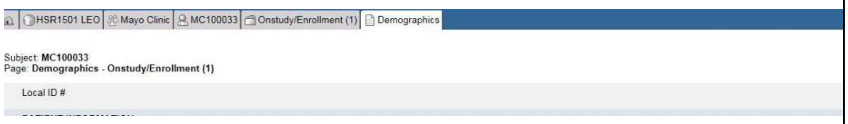
Purpose: To outline process for adding new participant to LEO RAVE database during enrollment
Responsibility: LEO Center coordinator responsible for adding new participants to RAVE

Demographics form is to be completed within 24 hours of patient consent.
Enrollment Questionnaire is to be completed *within 90 days* from consent date.

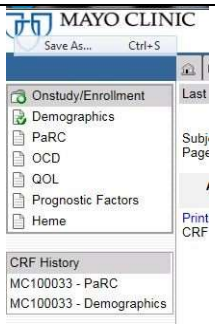
General RAVE Data Entry Notes: Use tab to move from question to question, use space bar to select radio button, use arrow keys to navigate between radio button answers. Dates are in Month/Day/Year format

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Sign on to RAVE	1. https://login.imedidata.com/login?show_new_reset_token=true	
2	Select LEO database	1. Select HSR1501 LEO database 2. If applicable, select role	
3	Add subject	1. Select "Add Subject"  2. Select the checkbox for "check here to add a subject to the study" 3. Select "save"  4. LEO ID will appear in top tab/top left hand corner  	Subjects are eligible for LEO if they have a new diagnosis of Lymphoma within the last 183 days and no prior history of Lymphoma or CLL.

4	Enter Onstudy Information	1. Select “onstudy/enrollment” folder  2. Enter local ID *(can be any identifier of the center’s choosing)*  3. Select Save	
5	Complete Demographics CRF	1. **Enter data in all applicable fields of the CRF from the baseline enrollment forms (patient provided) and from medical record where necessary. – Consent address cannot be modified once form is saved. If changes needed, contact the site data manager. – Current address can be left blank until consent address changes. 2. Dates Questionnaires Returned section a. Enter date enrollment questionnaire is returned (should be the same as consent date) b. When returned, enter date the risk factor questionnaire was returned 3. Ineligibility section *(only complete if patient is ineligible for LEO)* a. Enter reason for ineligibility if LEO participant entered does not fit LEO enrollment criteria	1.Required field: Consent date **If baseline questionnaire is captured via electronic data capture, enter current address, dates questionnaire returned

6	Complete PaRC (patient reported comorbidities) CRF	1. Select PaRC on upper left hand corner of database	

		 2. Select appropriate answer for any comorbidities based on questions answered in the Enrollment form. a. Yes: If any comorbidity question (including organ transplant and immune disorder) on Enrollment form is marked Yes b. No: if all questions on comorbidity are answered No or left blank 3. Enter Save 4. If Yes is selected on the front page (before saving), answer all questions according to patient provided information in Baseline Enrollment Form. For items left blank on the questionnaire select "unconfirmed" or "not provided"	
7	Complete OCD (other cancer diagnosis) CRF	1. Open the OCD CRF 2. Answer the "do you currently or have you had another type of cancer" question based on the enrollment form. If left blank by patient, answer "unconfirmed". 3. If Yes a. Complete the additional information provided by the participant on the enrollment form	
8	Complete the QOL (quality of life) CRF	1. Open the QOL CRF 2. Enter date questionnaire was completed *Note: questions will not appear until date is entered and CRF is saved. If completion date not provided by patient, subtract 5 days from date received, and enter that date.* 3. Complete CRF based on information provided in the Baseline Enrollment Form	
9	Complete QOL part 2 CRF	1. Open the QOL part 2 CRF 2. Complete CRF based on information provided in the Baseline Enrollment Form	

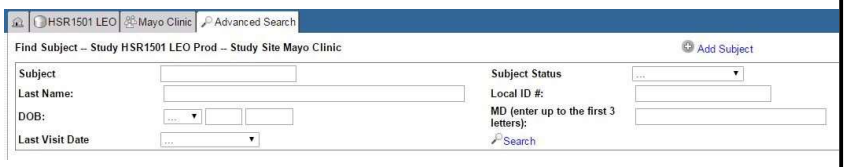
Duplicate Patient

Purpose: To describe the process on how to handle patients who are possible duplicates, being seen at multiple LEO Centers.

Responsibility: LEO Coordinators and Statistical Core

Coordinator identifies duplicate patient

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
	Identify Duplicate Patient	1. Coordinator identifies patient that has been seen at another LEO Center	
	Duplicate patient communication	1. LEO Center identifying patient should contact LEO Center with potential duplicate patient 2. LEO Center identifying potential duplicate patient to email the following patient information to other LEO center: a. DOB month/year b. First initial/last initial c. Treating MD at other LEO Institution	* no other information should be given as it is PHI
	Duplicate patient confirmation	1. The LEO Center contacted should search RAVE to see if there is a duplicate patient based on the information provided above 2. Use Advanced Search Option 	
	Determine LEO Center to perform all follow-up	1. Centers should work together to determine which center will follow the patient.	
	Assure patient is only active at ONE LEO Center	1. The center NOT following the patient should enter the patient as ineligible in the Demographics screen a. Reason: Other – DUPLICATE patient 	

Statistical Core identifies duplicate patient

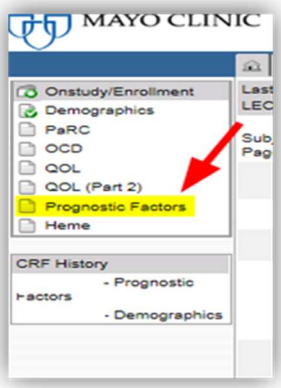
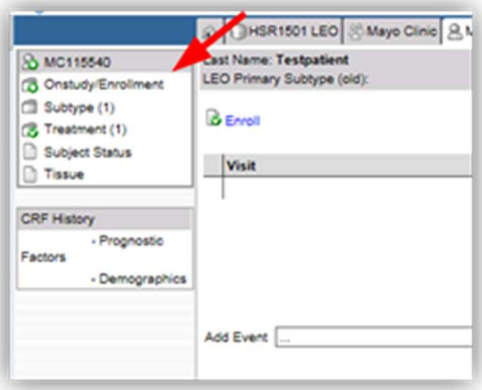
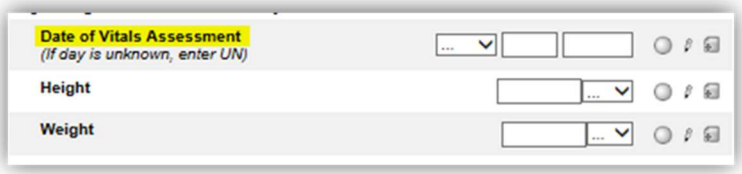
Instructions

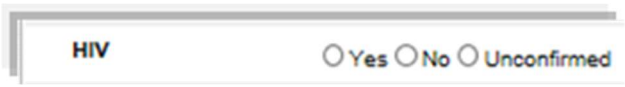
STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Identify Duplicate Patient	1. Statistical Core will run periodic automated checks for duplicate patients between LEO centers. 2. If duplicate patient identified, statistical core will send LEO IDs to LEOcohort@mayo.edu for distribution to centers affected	
2	Notification of stats identified duplicate patient	1. LEO cohort will notify both centers of duplicate patient by email 2. Email will contain the following: a. LEO IDs from each center with duplicate patient	
3	Determine LEO Center to perform all follow-up	1. Each center should verify through the medical record if patient plans to return to LEO center for all follow-up or will have majority of treatment administered	
4	Assure patient is only active at ONE LEO Center	1. The center NOT following the patient should enter the patient as ineligible in the Demographics screen a. Reason: Other – DUPLICATE patient 	

Prognostic Factors Clinical Abstraction

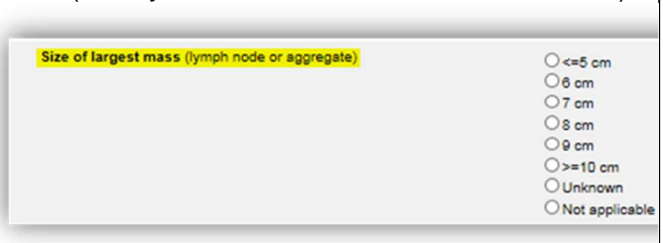
Purpose: To provide a guide for the entry and abstraction of data in the Prognostic factors form in RAVE

Responsibility: LEO Center coordinators responsible for data abstraction into RAVE
****NOTE: Data should be abstracted at initial lymphoma diagnosis.**

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Sign on to RAVE	1. https://login.imedidata.com/login?show_new_reset_token=true	
2	Select LEO database	1. Select HSR1501 LEO database 2. If applicable, select role	
3	Open Form	1. Select Prognostic Factors form from Onstudy/Enrollment Folder  	
4	Date of Vitals Assessment (height/ weight) **Abstracted from the patient's clinical notes or vital signs section of the**	1. **Date of Vitals Assessment –** enter the date the vitals were measured at diagnosis 2. **Height –** Enter height at diagnosis and select unit of measurement (cm or in) 3. **Weight –** Enter weight +/- 28 days from diagnosis date and select unit of measurement (kg or lbs) 	*Weight measurement must be collected **+/- 28 days** from diagnosis date and **prior to treatment** initiation. If multiple measurements, use closest measurement to diagnosis date.* *Height can be pulled from any adult clinic note if not available within*

	electronic medical record.		*28 days of diagnosis* *Date of vitals measured should reflect date of documented weight if height and weight are pulled from separate dates*
5	HIV Status **Abstracted from the patient's clinical notes or Laboratory sections section of the electronic medical record.**	1. Select the HIV status of the patient at diagnosis a. **Yes** = HIV positive b. **No** = HIV negative c. **Unconfirmed** = HIV testing is unavailable or not performed. 	
	Splenic Involvement **Abstracted from the patient's baseline PET/CT scan, clinical notes, or biopsy information section of the electronic medical record.**	1. Select the status of lymphoma involvement of the spleen a. **Yes-Biopsy Proven**-if biopsy of spleen is performed, and the biopsy is positive for lymphoma b. **Yes-Imaging Only**- if spleen is positive for lymphoma on CT or PET and no biopsy was performed c. **No**-if biopsy is performed and spleen is negative for lymphoma OR if no biopsy performed and spleen is negative for disease on CT or PET d. **Unconfirmed**- If diagnostic biopsy or radiologic studies are not available OR biopsy/radiologic studies are indeterminate  **PET/CT Scan Helpful hints** hypermetabolic / FDG avid/ Hypermetabolism / metabolic activity / SUV are all words used to describe **potential lymphoma involvment** Physiological uptake, reactive, normal, post-surgical changes and inflammation means **normal uptake/no indication of cancer**.	*If splenic involvement is not mentioned as having any FDG avidity or intensity in the CT or PET scan, this is considered not involved unless documented by a clinician.* ***Any*** *splenic FDG activity and intensity per CT and PET scan indicates positive per imaging, even if there is no splenomegaly.* *If both imaging and biopsy are available, document biopsy results*

<table>
<tr>
<td>7</td>
<td>Size of largest mass

Abstracted from the patient's baseline PET/CT scan or clinical notes section of the electronic medical record.</td>
<td>1. Select size of larges lymphoma mass per radiologic measurements or as clinically indicated
a. <=5 cm
b. 6 cm
c. 7 cm
d. 8 cm
e. 9 cm
f. >=10 cm
g. Not applicable – select if patient only has circulating disease (ie. only blood and/or bone marrow involvement)
 

h. Unknown- select if size of largest mass is unknown or not transcribed</td>
<td>Use largest reported measurement in any one direction and round up or down per standard rounding rules.

Do not count entire size of an enlarged spleen as this measurement. Only splenic lesions can be counted for this measurement</td>
</tr>
<tr>
<td>8</td>
<td>Clinician Reported Performance Status at time of Diagnosis

Abstracted from the patient's clinical notes section of the electronic medical record.</td>
<td>1. Indicate the patient's ECOG status at time of diagnosis as documented in baseline clinician note
0- Fully active, able to carry on all pre-disease performance without restriction (Karnofsky or Lansky 90-100)
1- Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (i.e. light housework, office work) (Karnofsky or Lansky 70-80)
2- Ambulatory and capable of all self-care but unable to carry out any work activities; up and about (Karnofsky or Lansky 50-60)
3- Capable of only limited self-care, confined to bed or chair more than 50% of waking hours (Karnofsky or Lansky 30-40)
4- Completely disabled; cannot carry out any self-care; totally confined
Not provided – ECOG score is not documented and cannot be determined

This can be referred to as ECOG / Performance Score / Performance Status in the clinical notes.</td>
<td>Convert Karnofsky and Lansky scores to this ECOG score

If ECOG performance score is not specifically listed: gather description of daily activities in clinical notes, the LEO coordinator is able to assign performance status in LEO database.

If a range is documented (ie. 0-1) use higher score</td>
</tr>
<tr>
<td>9</td>
<td>Stage

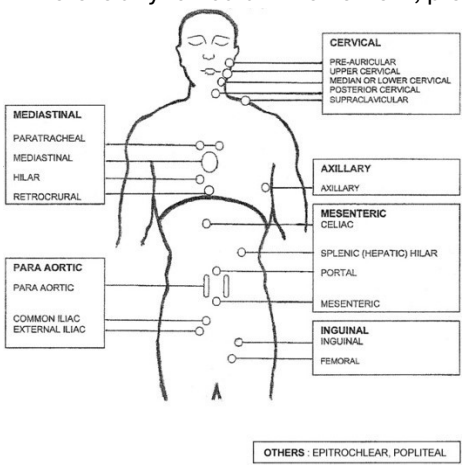
Abstracted from the patient's baseline PET/CT scan, clinical notes and/or biopsy results section of the electronic</td>
<td>1. Indicate the highest documented stage per physician note at diagnosis

Staging Reference Table:
<table>
<tr><th>Stage</th><th>Involvement</th></tr>
<tr><td>Limited</td><td></td></tr>
<tr><td>I</td><td>One single lymph node or extranodal lesion</td></tr>
<tr><td>II</td><td>Two or more nodal groups on the same side of the diaphragm (including bilateral nodal involvement)</td></tr>
<tr><td>Advanced</td><td></td></tr>
<tr><td>III</td><td>Lymph nodes on both sides of the diaphragm <u>OR</u> Lymph nodes above the diaphragm with spleen involvement</td></tr>
<tr><td>IV</td><td>Extensive or diffuse nodal or extranodal involvement</td></tr>
</table></td>
<td>ALL staging questions/ clarifications go to the LEO center PI. If staging is absent from the clinical notes, the LEO coordinator can assign stage based on provided information in the EHR

Any nodal site >1cm = lymphomatous involvement - even if the stage is different</td>
</tr>
</table>

	medical record.	**<u>Staging Notes:</u>** • Circulating lymphoma cells (blood) / Sezary Syndrome / bone marrow involvement = stage IV • Extranodal organ involvement: ○ If no other site of disease **<u>AND</u>** is a single lesion that is <5cm, considered stage IE ○ Otherwise, stage IV • Any radiographic mention of “extensive”, “bulky” and/or multiple extranodal lesions (even within a single extranodal organ) = stage IV **Reference: Cheson et al. Recommendations for Initial Evaluation, Staging, and Response Assessment of Hodgkin and Non-Hodgkin Lymphoma: The Lugano Classification. JCO September 20, 2014 vol. 32 no. 27 3059-3067.**	*than indicated in clinic notes* *If staging includes, "A" or “B”, “A” indicates the absence of B symptoms, while "B" indicates their presence.*
	Bone Marrow (BM) Involvement by PET **Abstracted from the patient’s baseline PET/CT scan section of the electronic medical record.**	1. Select answer regarding bone marrow involvement by PET imaging only at diagnosis a. **Positive**- Histological confirmation on PET scan b. **Negative**- PET was performed but was negative. Not histologically involved c. **Indeterminate-** PET was performed, but imaging is not clear or was inconclusive regarding involvement. This is applicable if marrow involvement cannot be excluded. d. **Not Done**- PET was not performed/not done 	*Do not document bone marrow involvement in the extranodal section* *If bone marrow is not specifically mentioned in the PET report and there is no language similar to: “no other FDG avid disease”, indicate as indeterminate.*
	Bone Marrow (BM) Involvement by Biopsy **Abstracted from the patient’s baseline clinical notes or biopsy results.**	1. Select answer regarding bone marrow involvement by biopsy only a. **Positive**- bone marrow biopsy positive for lymphoma b. **Negative**- Biopsy was performed but was negative per pathology report c. **Indeterminate**- Biopsy was performed, but pathology is not clear or was inconclusive regarding involvement. d. **Not Done**- Biopsy was not performed/not done	*Do not document bone marrow involvement in the extranodal section*

	Nodal Involvement **Abstracted from the patient's baseline PET/CT scan, clinical notes or biopsy results section of the electronic medical record.**	1. Select whether or not lymph nodes are positive for lymphoma, or if lymphoma in any lymph nodes were clinically indicated a. **Yes**-there are one or more lymph nodes involved by lymphoma b. **No**- lymph nodes are not involved by lymphoma c. **Unconfirmed**- it is unknown or unclear if lymph nodes are involved List of lymph nodes are available in Appendix for reference **Terms used in clinical notes and Radiology (PET-CT scan) notes that indicate nodal involvement: Nodal / Lymph node / nodule / adenopathy / lymphadenopathy**	*Note that per Lugano classification, Tonsils, and Waldeyer's ring are considered nodal tissue.* *Any lymph nodes >1cm = lymphomatous involvement* *"mesenteric mass" = nodal*
13	Extranodal Site Involvement **Abstracted from the patients baseline PET/CT scan, clinical notes or biopsy results section of the electronic medical record.**	1. Select whether or not there are any extranodal sites positive for lymphoma a. **YES** - if area or organ is indicated as being positive for lymphoma on final path report / PET/CT scan / clinical note AND organ or area is NOT a lymph node, bone marrow or spleen. i. Indicate all areas of involvement listed under "Site". If area/organ is not listed, select other and enter specifics in comment field. b. **NO** - if there is no lymphoma involvement of sites that are not lymph nodes OR if the only non-lymph node sites are bone marrow and/or spleen. c. **Unconfirmed** – if radiologic imaging, clinical notes, or pathology reports are unclear/unavailable for extranodal involvement  *Extranodal site = lymphoma positive anatomic sites other than lymph nodes, spleen, thymus and the pharyngeal lymphatic ring. *REFER TO APPENDIX 6 FOR NODAL/EXTRANODAL CODING	*Per interpretation of radiologic studies: if reference in report from radiologist considered to be accurate and called involved—study coordinators should check with LEO Center PI if unclear.* *Bone marrow is not captured in this extranodal section.* *Note that per Lugano classification, Tonsils, Waldeyer's ring, and spleen are considered nodal tissue* *Orbital involvement does not equate CNS involvement.* *Kidney lesion= kidney involvement.*

14	B-Symptoms **Abstracted from the patient's baseline clinical notes.**	1. Fever: a. **YES:** Select if unexplained persistent fever of more than 100.4 * / 38C in the month prior to diagnosis b. **NO:** Select if no fever was present in the **month prior to diagnosis** c. **Unconfirmed:** It is unclear or unknown if fever was present. 2. Night Sweats a. **YES**: Select If recurring, drenching night sweats occurred in the month prior to diagnosis b. **NO:** Select if night sweats were not reported. c. **Unconfirmed:** Select if it is unclear or unknown that night sweats were present 3. Weight Loss a. **YES:** Select if unexplained weight loss ≥10% of body weight was reported in the **6 months prior to diagnosis.** b. **NO:** Select if unexplained weight loss <10% of their body weight, or no weight loss was reported. c. **Unconfirmed:** It is unclear, or unknown if weight loss occurred within 6 months of diagnosis. The presence or absence of B symptoms has prognostic significance and is reflected in the staging of these lymphomas	*B symptoms are so called because lymphoma staging includes both a number (I-IV) and a letter (A or B). "A" indicates the absence of systemic symptoms, while "B" indicates their presence.* *Sweats can be noted as "soaking bed sheets, NS or bed clothes" Drenching sweats occurring during the day will also be counted as a night sweat.*
Follicular Patients Only			
15	Number of Nodal Groups Link to FLIPI paper **Abstracted from the patient's baseline PET/CT scan, clinical notes or biopsy results.**	*Refer to NLCS Nodal Chart for FL* 1. Select the number of nodal groups positive for lymphoma disease a. **≤ 4-**Four or less nodal groups (as defined on Nodal Group Chart- Attachment 1a) indicated positive for disease on final path report. b. **≥ 5-**Five or more nodal groups (as defined on Nodal Group Chart-Attachment 1a) indicated as positive for disease on path report or physician note. c. **Unconfirmed** - if radiologic imaging, clinical notes, or pathology reports are unclear/unavailable for nodal involvement If there is any follicular involvement, please complete this section.  	*Nodal groups are NOT equivalent to INDIVIDUAL lymph nodes. Individual lymph nodes make up FLIPI nodal groups.* *Bilateral Involvement of Cervical, Axillary, Inguinal and Hilar are counted as **TWO** separate Nodal Groups.* *For FLIPI, spleen is not counted as a nodal*

16	Are there >2 nodal areas with >3 cm affected? Link to FLIPI2 paper	1. Select if 3 or more nodal areas are positive for lymphoma ***AND*** the longest measurement in any 1 direction for each nodal area is >3cm a. **YES** - if there are three or more nodal areas with 3cm or greater area affected (Listed on CT or PET Report) b. **NO -** If there are two or less nodal areas or if the areas affected are less than 3cm. (listed on CT or PET Report) c. **Unconfirmed -** if radiologic imaging, clinical notes, or pathology reports are unclear/unavailable for nodal involvement	
CLL Patients Only			
17	RAI Stage Classification[1] (select one) For CLL patients ONLY	**0=Stage 0**- Lymphocytosis greater than 5,000 cell/mm and greater than 40% of cells in the bone marrow **1=Stage 1-**Lymphocytosis with large lymph nodes **2=Stage 2-**Lymphocytosis with enlargement of spleen and/or liver **3=Stage 3**-Lymphocytosis and marrow replacement resulting in anemia **4=Stage 4**-Lymphocytosis and low platelet due to marrow replacement **9=Missing**-data Is unable to be abstracted	*Do not enter RAI stage for SLL diagnosis, only CLL*
18	17p deletion	1. Yes-if 17p deletion is noted in pathology report 2. No-if 17p deletion is noted as not present in pathology report 3. Unconfirmed-if no mention of 17p deletion is pathology report a. % mutated (if yes above)-enter mutation % from pathology report	
19	TP53 mutation	1. Yes-if TP53 mutation is noted in pathology report 2. No-if TP53 is noted as not mutated in pathology report 3. Unconfirmed-if TP53 is not noted in the pathology report	
20	IGHV	1. Mutated-if IGHV mutation is noted on pathology report 2. Unmutated-if IGHV is noted as unmutated on pathology report 3. Unconfirmed-if IGHV mutation is not noted in pathology report	

Problem cases should always be addressed with your center PI or you can email the LEOcohort email with questions and the Prognostic Factors Content Expert will contact you back and they can offer assistance.

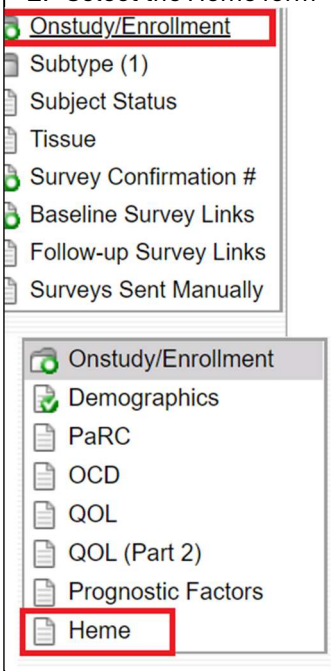
Heme Values

Purpose: To describe the process for entering baseline lab values for newly accrued LEO participants

Responsibility: Coordinator responsible for abstracting clinical data and entering into RAVE database

General Heme Form Notes: This form contains 2 separate sections of information:

1.) **Research Sample** – data specific to the LEO blood sample that is collected, processed, and sent to Mayo.
   a. This data is unrelated to the abstracted lab values in section 2
2.) **Clinical Hem Lab Values** – abstracted lab values from the EHR.
   a. Select values based on date closest to diagnosis date and prior to receiving any lymphoma directed treatment. Values can be taken from different draws within 28 days from the diagnosis date (+/-28 days)

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Sign on to RAVE	1. https://login.imedidata.com/login?show_new_reset_token=true 2. Select patient to complete abstraction	
2	Open Heme form	1. Select the Onstudy/Enrollment Folder from the left-hand navigation pane 2. Select the Heme form 	
Section 1: **RESEARCH SAMPLE** *(Date of collected sample for study research)*			
3	Date of Research Sample Drawn	1. Enter the date the LEO research blood sample was drawn from patient	*This is **NOT** the date of the abstracted lab values on this form.*

			This is the collection date of the research blood sample that is processed and sent to Mayo.
4	Baseline Research Sample Timing	1. Select the timing of the LEO research blood draw a. **Prior to any lymphoma treatment** – LEO research blood sample was collected before any lymphoma directed treatment was initiated (ie. pre-treatment) b. **Lymphoma treatment initiated prior to research draw** - LEO research blood sample was collected after lymphoma directed treatment was initiated c. **Timing of treatment unknown**	*This information pertains to the collection of the research blood sample that is processed and sent to Mayo.* ***NOT*** *the abstracted lab values.*
Section 2: **<u>CLINICAL HEM LAB VALUES</u>** *(Clinical lab values are +/- 28 days from the diagnosis)*			
5a	CBC	1. Enter the values from the CBC with differential panel at diagnosis i.	
5b	White Blood Cell Count	1. Enter white blood cell count by $x10^9$/L or K/mm^3 a. **Missing/Not Done**: select if white blood cell count value is unable to be obtained within the specified parameters, or if the lab was not drawn	*WBC*
5c	Hemoglobin	1. Enter hemoglobin value by g/dL a. **Missing/Not Done**: select if hemoglobin value is unable to be obtained within the specified parameters, or if the lab was not drawn	*Hgb*
5d	Platelet count	1. Enter platelet count value by $x10^9$/L a. **Missing/Not Done**: select if platelet count is unable to be obtained within the specified parameters, or if the lab was not drawn	*Plt*
5e	Absolute lymphocyte count	1. Enter absolute lymphocyte count by $x10^9$/L a. **Missing/Not Done**: select if absolute lymphocyte count is unable to be obtained within the specified parameters, or if the lab was not drawn	*ALC* *If both automated and manual counts are available – use automated count.* *If absolute counts are not available but lymphocyte % is available, convert the % to decimal and multiply by the WBC count to determine differential counts.*
5f	Absolute monocyte count	1. Enter absolute monocyte count value by $x10^9$/L a. **Missing/Not Done**: select if absolute monocyte count is unable to be obtained within the specified parameters, or if the lab was not drawn	*AMC* *If both automated and manual*

			counts are available – use automated count. *If absolute counts are not available but monocyte % is available, convert the % to decimal and multiply by the WBC count to determine differential counts.*
5g	Absolute neutrophil count	1. Enter absolute neutrophil count value by $x10^9$/L a. **Missing/Not Done**: select if absolute neutrophil count is unable to be obtained within the specified parameters, or if the lab was not drawn	*ANC* *If both automated and manual counts are available – use automated count.* *If absolute counts are not available but neutrophil % is available, convert the % to decimal and multiply by the WBC count to determine differential counts.*
6a	Other	1. Enter the values form the complete metabolic panel and other individual lab tests	
6b	Bilirubin, total	1. Enter total bilirubin value by mg/dL a. **Missing/Not Done**: select if total bilirubin is unable to be obtained within the specified parameters, or if the lab was not drawn	*Tbili*
6c	Creatinine (age-adjusted)	1. Enter creatine serum value by mg/dL a. **Missing/Not Done**: select if total bilirubin is unable to be obtained within the specified parameters, or if the lab was not drawn	*creat*
6d	LDH	1. Enter LDH value by U/L a. **Missing/Not Done**: select if LDH is unable to be obtained within the specified parameters, or if the lab was not drawn	*Lactate dehydrogenase*
6e	LDH – institutional upper limit of normal	1. Enter posted institutional upper limit of normal by U/L	*Lactate dehydrogenase ULN*
6f	Beta-2 microglobulin	1. Enter Beta-2 microglobulin by mcg/mL a. **Missing/Not Done**: select if B2M is unable to be obtained within the specified parameters, or if the lab was not drawn	*B2M*
6g	Beta-2 microglobul	1. Enter posted institutional upper limit of normal by mcg/mL	*B2M ULN*

	in – institutional upper limit of normal		
6h	Serum albumin	1. Enter serum albumin value by g/dL a. **Missing/Not Done**: select if albumin is unable to be obtained within the specified parameters, or if the lab was not drawn	*alb*
6i	Calcium	1. Enter calcium value by mg/dL a. **Missing/Not Done**: select if calcium is unable to be obtained within the specified parameters, or if the lab was not drawn	*Ca*
	Erythrocyte sedimentation rate	1. Enter Erythrocyte sedimentation rate value by mm/hr a. **Missing/Not Done**: select if Erythrocyte sedimentation rate is unable to be obtained within the specified parameters, or if the lab was not drawn	***HODGKIN PATIENTS ONLY*** *ESR*

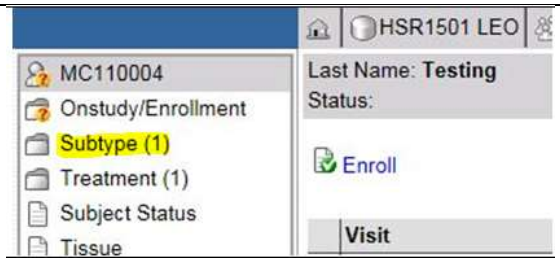
Subtype Clinical Abstraction

Purpose: To describe process for abstracting subtype information from clinical note

Responsibility: Coordinator responsible for abstracting clinical information from the medical record

General Subtype Notes: Enter one subtype form per subtype/diagnosis date

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Sign on to RAVE	1. https://login.imedidata.com/login?show_new_reset_token=true	
2	Open Subtype Form		
3	Date of Diagnosis	1. Enter date of first *definitive* lymphoma diagnosis regardless of where biopsy occurred (LEO Center or outside institution).	REQUIRED FIELD *After saving the form, this date will appear in parenthesis by the form name* ***Do not include biopsies stating "suspicious for lymphoma" when determining date of diagnosis***
4	Baseline Clinical	*Note* up to four subtypes can be entered per timepoint if applicable-Clinical diagnosis should be taken from the clinical note 1. Clinical Primary Subtype-Select subtype from list a. Subtype should be determined from impression/report/plan section of clinical note b. See Subtype Reference sheet in Appendix 2. Select subclassification from list (if applicable) a. See Subtype Reference sheet in Appendix	*Note that multiple biopsies may be performed in the initial work-up to definitively determine subtype. Do not include the initial NOS subtype if a definitive subtype is determined from a subsequent biopsy from the same clinical work-up.* *However, note that some patients with aggressive B-cell will have a low-grade*

		3. Clinical Secondary-Select subtype from list. a. See Subtype Reference sheet in Appendix 4. Select subclassification from list (if applicable) a. See Subtype Reference sheet in Appendix	*NOS in the bone marrow. This should be coded.* *Subtypes requiring subclassification: Anaplastic Large Cell Lymphoma (ALCL), Follicular Lymphoma, Post-transplant Lymphoproliferative Disorder (PTLD), Mycosis Fungoides, Hodgkins Lymphoma, Enteropathy Associated T-cell Lymphoma (EATL)*
5	LEO Pathology Contacts	1. For all pathology related questions please contact the LEO cohort email at LEOCOHORT@mayo.edu 2. Lindsey En PH: 507-422-5000; en.lindsey2@mayo.edu 3. Sara Borgschatz PH: 507-266-5038; borgschatz.sara@mayo.edu 4. Rachel Benson PH: 507-266-6695; benson.rachel@mayo.edu 5. Tanner Reicks (Program Manager) PH: 507-266-2656; reicks.tanner@mayo.edu	

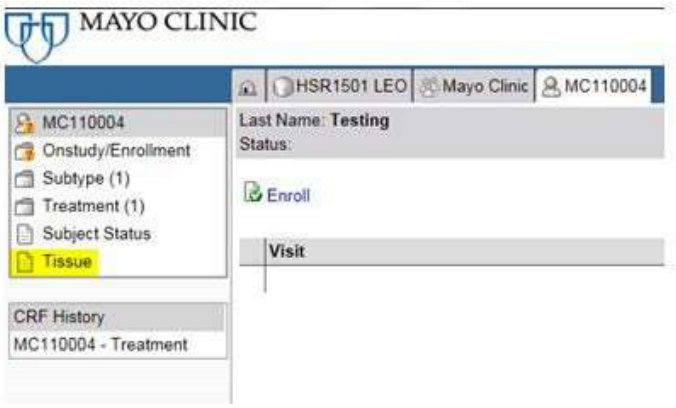
Tissue Clinical Abstraction

Purpose: To describe the process for abstracting biopsy information from the pathology report for entry into the tissue form.

Responsibility: Coordinator responsible for abstracting clinical data

General Tissue Notes: This is a virtual repository for all lymphoma tissue collected on LEO Participants. Each Tissue form contains information on a single biopsy. For multiple biopsies, create a new tissue form for each biopsy.

Instructions

STEP	TITLE	PURPOSE/ DESCRIPTION	GUIDELINES
1	Sign on to RAVE	1. https://login.imedidata.com/login?show_new_reset_token=tr ue	
2	Open Tissue Form		
3	Timepoint	1. Select when the biopsy was performed a. Baseline-select if the biopsy occurred within the window of diagnosis* b. Re-biopsy/Relapse-select if biopsy occurred after initial diagnosis	REQUIRED FIELD *Baseline (up to the first treatment for non- observation participants)* *If patient had multiple biopsies to confirm diagnosis, select baseline for those biopsies.*
4	Sample Type	1. Select biopsy type 1. Excisional Biopsy 2. Core Needle Biopsy 3. Skin 4. Fine Needle Aspiration (FNA) 5. Bone Marrow 6. Blood 7. Pleural Fluid 8. CSF 9. Other (specify)	REQUIRED FIELD *Choose samples using the following hierarchy for review*

5	Biopsy Date	1. Enter date of biopsy from pathology report	REQUIRED FIELD
6	Internal Accession Number	1. If case is internal enter accession number assigned at LEO Center	
7	External Accession Number	1. Enter external accession number (if applicable)	
8	Location of Block	1. Select the location where the biopsy was performed a. LEO Center b. Outside Institution i. External Name ii. External Address iii. External Fax iv. External Phone	REQUIRED FIELD *Completing outside information will assist in future FFPE pulls*
9	Submitting Subtype 1	1. Select subtype a. Listed in Appendix	REQUIRED FIELD
10	Tumor %	1. If multiple subtypes in one biopsy, enter tumor % as reported in pathology report	
11	Submitting Subtype 2	1. Select subtype if applicable a. Listed in Appendix	
12	Tumor %	1. If multiple subtypes in one biopsy, enter tumor % as reported in pathology report	
13	Submitting Subtype 3	1. Select subtype if applicable a. Listed in Appendix	
14	Tumor %	1. If multiple subtypes in one biopsy, enter tumor % as reported in pathology report	
15	Anatomic Sampling Location	1. Select place on the body where the biopsy was performed a. Node b. Extranodal (except spleen or bone marrow) c. Spleen d. Bone Marrow e. Other (specify)	
16	Nodal/Extra nodal Location	1. Select nodal or extranodal location a. See Appendix – Nodal/Extranodal Reference Sheet	
17 FYI	LEO Pathology Contacts	6. For all pathology related questions please contact the LEO cohort email at LEOCOHORT@mayo.edu 7. Lindsey En PH: 507-422-5000; en.lindsey2@mayo.edu 8. Sara Borgschatz PH: 507-266-5038; borgschatz.sara@mayo.edu 9. Rachel Benson	

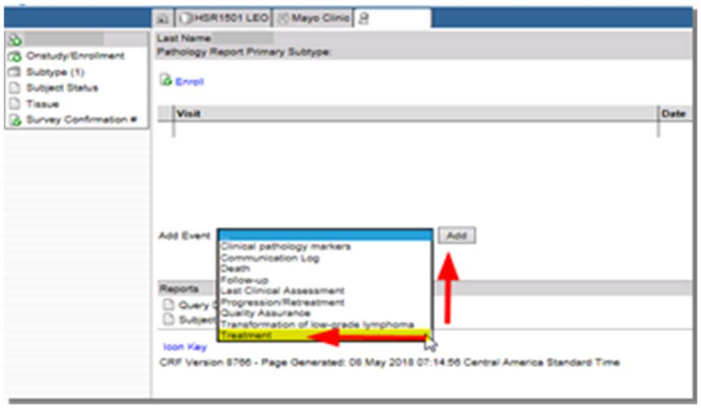
		PH: 507-266-6695; benson.rachel@mayo.edu 10. Tanner Reicks (Program Manager) PH: 507-266-2656; reicks.tanner@mayo.edu	

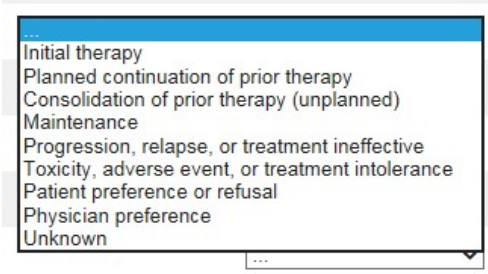
Treatment

Purpose: Description of data entry and clinical abstraction to complete treatment documentation.

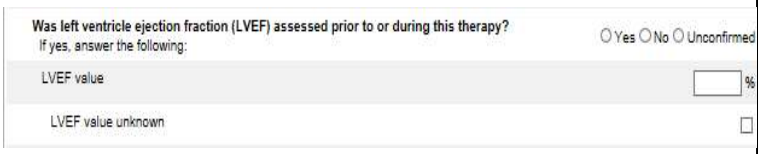
Responsibility: LEO Research Team Member/Coordinator assigned subject data entry tasks.

Instructions for Patient data entry of Treatment for Lymphoma into RAVE for LEO subjects

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1.	Open Treatment Form	1. Open the "Add Event" Drop down on the patients main page in RAVE. 2. Select "Treatment" 3. Select "Add" 	
2.	Refused Treatment	1. If patient refused treatment, select the "Refused Treatment" option at the top of the Treatment form 	
3	Treatment Reason	1. Choose reason for treatment from the drop down menu. 	**REQUIRED FIELD** **Note: Select Initial Therapy for the first line of treatment for all patients**

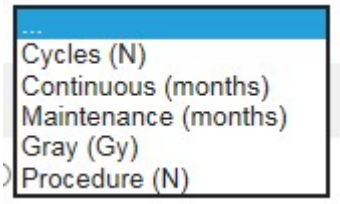
		 Definitions: **Initial Therapy:** The first treatment that the patient receives to treat lymphoma **Progression, relapse, or treatment ineffective:** Relapse after any response. Response to previous therapy is stable disease or progression.	**Treatment changes due to planned consolidation, toxicity, adverse events, or patient/physician preference will be captured in the same line. New lines of treatment are entered when a LEO defined event occurs (relapse, treatment ineffective, and progression)**

4	Treatment Location	1. LEO Center-Select if majority of treatment would occur at the LEO center entering data 2. Other Institution-Select if majority of treatment will be given at institution other than LEO center. 3.	**REQUIRED FIELD** **if treatment at multiple locations, select location where majority of treatment was given.* For tracking purposes, if treatment is elsewhere, this is a flag to get outside records.
5.	Is this treatment part of a clinical trial?	1. **Yes**: Select if the treatment is part of a clinical trial a. **If YES,** Enter Protocol Number & study identifier if known: 2. **No:** Select if treatment is standard of care and not a clinical trial 3. **Unconfirmed:** If you are unsure if the therapy is a part of a clinical trial	**REQUIRED FIELD** *This helps with tracking and clean up to provide a reference.* *Comment: Identifiers include ECOG/Alliance/SWOG trial number (eg. E4494) or clinicaltrials.gov identifier (e.g. NCT02285062)*

			
6.	Left Ventricle Ejection Fraction (LVEF)	Select if Echocardiogram was assessed prior to or during this therapy 1. Locate Echo Report in medical record 2. Select answer a. **Yes:** select if pre-treatment echocardiogram was done and LVEF was recorded b. **No:** select if documented that no echocardiogram was performed c. **Unconfirmed:** select if it is not clear if echocardiogram was or was not performed 3. LVEF Value: Enter LVEF % from echocardiogram report 4. LVEF Date: Enter date the echocardiogram was performed 	**REQUIRED FIELDS** *LVEF date should be no more than 4 months prior to start of therapy* *If there is a range, calculate average andround to nearest whole number per simple math.* *MUGA can be used as source documentation for LVEF data.*
7.	Therapy (1, 2, 3, 4)	 1. When documenting therapies, list medications in their acronym forms, Example: RCHOP instead of listing out all 5 of the different medications. 2. Choose therapy from the drop-down menu. 3. Choose additional therapies if needed. a. If documenting different modes of therapy line (example: 6 cycles of RCHOP follow by 12 Gy of radiation), list the initial started therapy first (RCHOP), followed by the secondary planned therapy (Radiation).	NOTE: When documenting treatment all agents used for the line of therapy should be placed on one treatemnt form. A line of therapy is defined as the complete administration of planned therapy or until there is an unexpected event that causes a change in therapy.

			This section includes chemotherapy, immunotherapy, radiation, transplant, antibiotic, topical steroids, surgery and observation.

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
		4. ****REFER TO appendix 11 – LEO Treatment Information for complete list of treatments***	Observation = watchful waiting, surveillance. Surgery will **only** be listed as a therapy if it was used for curative intent. Example: splenectomy for Splenic MZL. If surgery was done for diagnostic purposes (e.g. biopsy), this is not considered as a therapy.
8.	Start Date treatment Initiated	1. Enter the first date treatment was initiated (ex. Cycle 1 Day 1) a. Enter start date for each therapy agent listed	Observation initiated date should be the date of the clinical note defining observation as the plan.
9.	Stop Date of Last Dose/Cycle	1. Enter the date of the last dose of treatment within planned regimen a. Enter stop date for each therapy agent listed	*Leave blank if date not available Leave blank if line of treatment is still ongoing at time of data entry. Do not add planned or expected completion dates

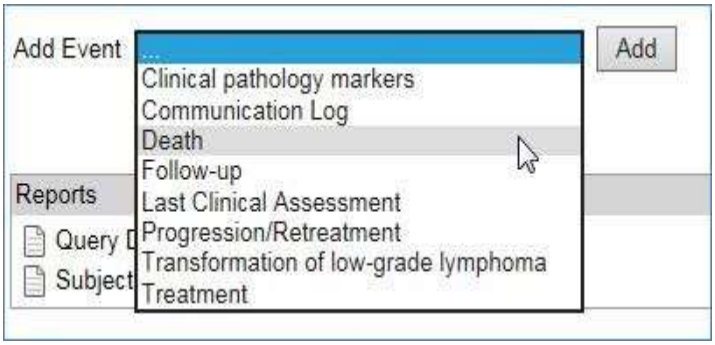
10.	Dose Mode	1. Select appropriate mode of treatment from the drop down menu a. Cycles (N)-select if treatment given in cycles (example: RCHOP) b. Continuous (Months)- select if mode of treatment is continuous (example: oral therapies) c. Maintenance (Months)- select if treatment if listed as maintenance d. Gray (Gy)- select if radiation is given e. Procedures- (N)- select if treatment is given via procedures (example: splenectomy, surgery, transplant) 	Please note: Some institutions document radiation in cGy (centigray). This will require a conversion on your part. **1 Gy = 100 cGy**
11.	Dose Amount	1. Enter in dosing amount- number of treatments a. Cycles (N)- enter number of cycles given for this treatment b. Continuous (Months)- if treatment is continuous, enter number of total months treatment is received c. Maintenance (Months)- enter total number of months maintenance therapy received d. Gray (Gy)- If radiation, enter the GY amount from radiation report if available e. Procedure (N)- enter number of procedures for treatment	In documenting Maintenance therapy, please document the total amount of time that therapy was received. Example: If patient got treated every three months for 8 doses of Maintenance therapy, you would enter 24 months as the maintenance amount. Leave blank if at time of data entry treatment is still ongoing. Do not enter planned or expected dose amounts

12	Adding additional lines of therapy	1. Identify if an additional line of treatment needs to be added. If yes- follow steps below a. Open treatment form b. Add new log line c. Follow steps 3-11 for each line of treatment patient receives	When completing LCAs, data validation, data queries and any review of the chart document subsequent lines of treatment

Cause of Death Abstraction

Responsibility: LEO center coordinator and LEO site PI

Note: Ensure Subject Status form is also updated to "Deceased"

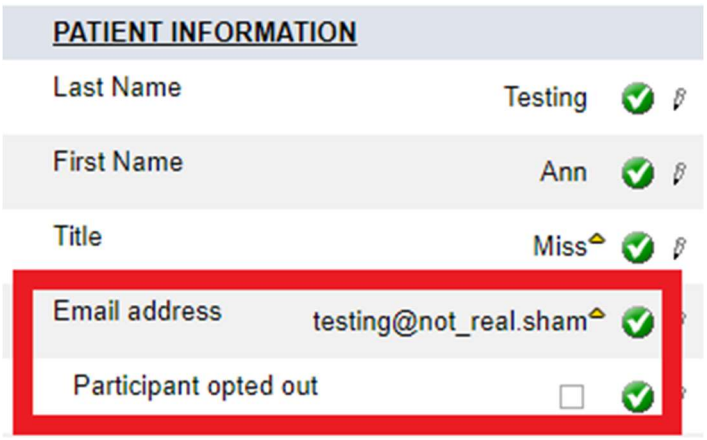
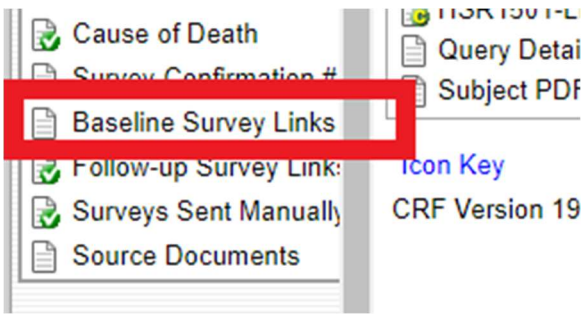
STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Sign on to RAVE	1. https://login.imedidata.com/login	
2	Select LEO database	1. Select HSR1501 LEO database 2. If applicable, select role	
3	Add Cause of Death Form	1. Select Cause of Death form from Add Event drop down box and click Add 	
4	Open Cause of Death form	1. On the left-hand side navigation page select "Death" to open death form	
5	Date of Death	1. Enter date the patient died.	Coordinator may document using the death certificate, medical record, online obituary or via family member
6	LEO Physician COD Review Performed?	1. Select the status of the LEO PI review: a. **No** – PI has not review COD form b. **Pending** – Data is waiting to be reviewed by PI c. **Yes** – PI has completed COD review and all data on COD form is accurate per LEO site PI	All forms in a status of "No" or "Pending" will populate on the Monthly Data Validation Report and will continue to show until the form is moved to "Yes"
7	Underlying Cause of Death (ICD-10 Code)	1. LEO Site PI to determine the underlying cause of death a. The specific diagnosis that led to the patient's death	If patient does not have sufficient records at LEO institution, coordinator should request records

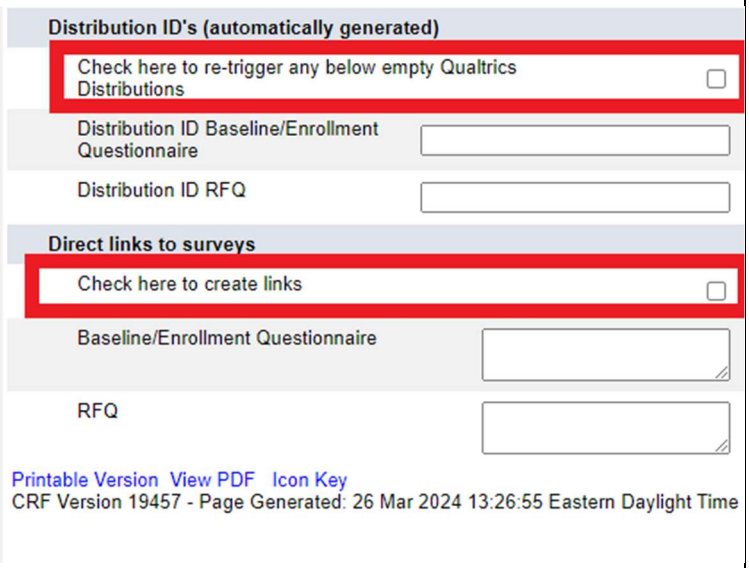
		b. Identify the ICD-10 code for the specific diagnosis using: https://www.icd10data.com/ICD10CM/Codes	from the patient's outside institution prior to the LEO site PI reviewing this data. The Web's Free 2024 ICD-10-CM/PCS Medical Coding Reference (icd10data.com)
8	LEO Cause of Death (LEO MD choose best answer)	1. LEO site PI to select the COD that best aligns with patient's primary COD a. **Due to this disease (ie. Progressive lymphoma)** – patient died from their lymphoma b. **Due to therapy – infection** – patient died due to an infection that resulted from lymphoma-directed therapy c. **Due to therapy – cardiac** – patient died due to a cardiac complication cause by lymphoma-directed therapy d. **Due to therapy – other** – patient died due to complications cause by the lymphoma-directed therapy that were not cardiac-related or infection e. **Due to therapy – secondary malignancy** – patient died due to a secondary malignancy (not lymphoma) that was caused by the lymphoma-directed therapy f. **Due to a secondary malignancy (not due to therapy)** – patient died from another malignancy that was not lymphoma (and not a therapy-related malignancy). i. Secondary malignancy includes malignancies diagnosed both prior to and after patient's lymphoma diagnosis g. **Due to Other Causes** – patient died from something that does not fit in any of the above categories h. **Unable to Obtain Records** – cause of death cannot be determined due to lack of records	This should be the LEO site PI's final determination of the patient's COD from their medical opinion. Once the LEO site PI has confirmed data on this form, be sure to update Step 6 to "Yes" so that this falls off of next month's Data Validation report.

Follow Up Questionnaires

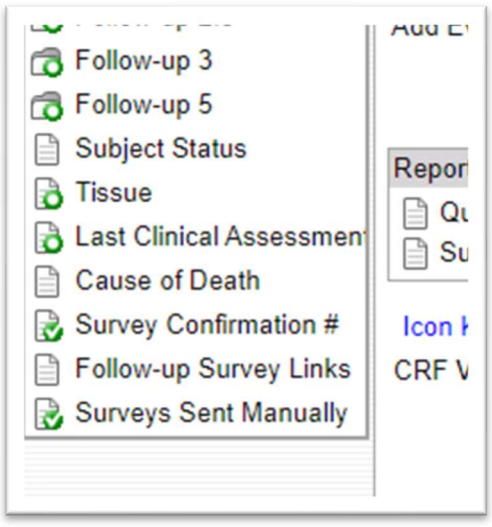
Obtaining Individualized Electronic Links

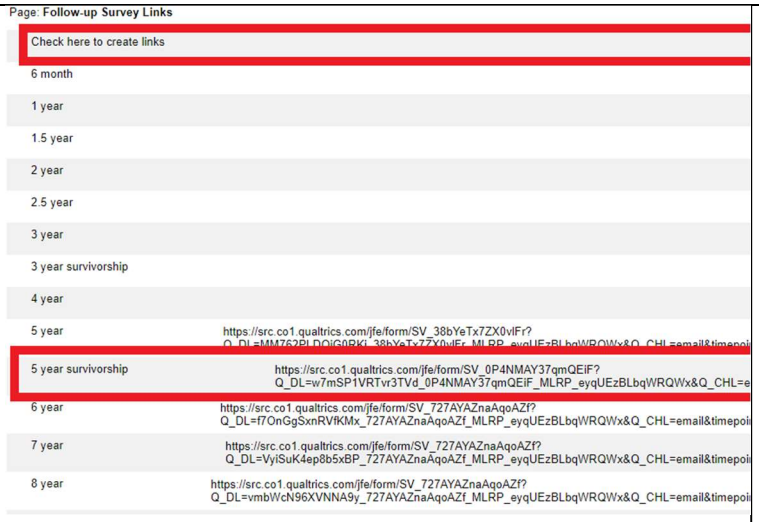
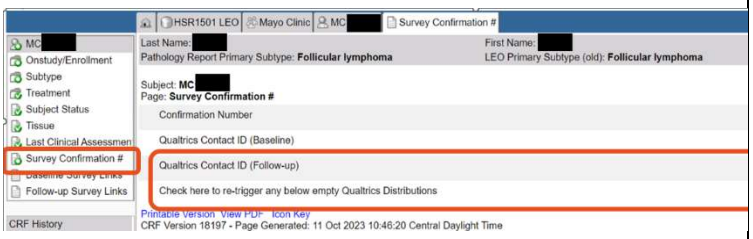
Note: Electronic Baseline and RFQ surveys are not automatically sent out to participants. The LEO coordinator must email these out to specified participants.

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Requirements for generating individualized links	1. Navigate to the Onstudy/Enrollment page and ensure the following fields are up-to-date: a. **Email address:** contains patient's up-to-date email address where they wish to receive LEO questionnaires b. **Participant opted out:** box must be unchecked 	
2	Obtain Baseline or RFQ survey link(s)	1. Select "Baseline Survey Links" on the left-hand navigation pane 2. Copy & Paste link(s) into browser 	*If using personalized links, patient does not need to enter LEO/Local ID into survey.* *If the patient is marked as Spanish-Speaking on the Onstudy/Enrollment form, the patient's survey will be toggled to Spanish.*

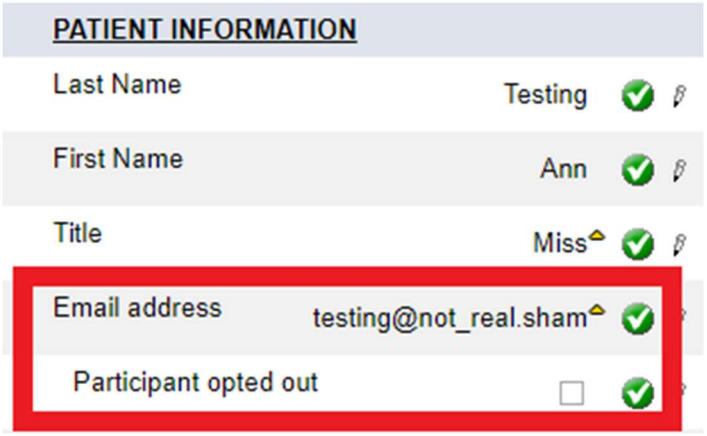
		3. If links are not readily available a. Check the boxes: i. "Check here to re-trigger any blow empty Qualtrics Distributions" ii. "Check here to create links" b. Save the form  	*The Spanish version is available via toggle for anyone*

[Text Wrapping Break]

1	Obtain Follow Up Survey link(s)	1. Select "Follow-Up Survey Links" on the left-hand navigation pane 2. Copy & paste link(s) into browser  3. If links are not readily available a. Check the box "Check here to create links" b. Save the form	*There are separate links for the 3/5-year follow-ups and 3/5-year survivorship booklets*

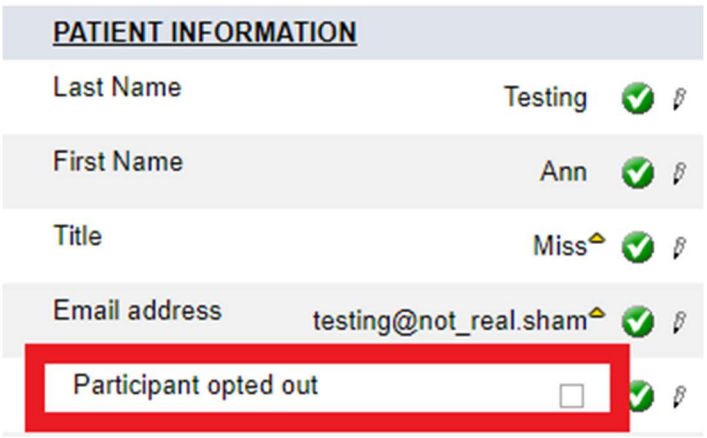
			
2	Troubleshooting	1. Select “Survey Confirmation #” on left-hand navigation pane 2. Check the “Check here to re-trigger any below empty Qualtrics Distributions” 3. Save form 	

Enrolling Patient in Automatic Follow-Up Surveys

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Update Onstudy/ Enrollment form	1. Navigate to the Onstudy/Enrollment page and ensure the following fields are up-to-date: a. **Email address:** contains patient's up-to-date email address where they wish to receive LEO questionnaires b. **Participant opted out:** box must be unchecked  2. The questionnaires are sent out, and when the patient completes it, the data is automatically uploaded to Rave. 3. There is an email notification sent to the leocohort@mayo.edu for verification purposes.	
2	Update Abstracted Subtype Form	1. Complete Diagnosis Date	
3	Process is Centralized at Mayo	1. The questionnaires are automatically sent out to the email address on file once the patient hits a follow-up timepoint. 2. When the patient completes the questionnaire, the data is automatically uploaded into Rave	

Note: Once the appropriate fields in Rave are updated to indicate automatic follow-up survey enrollment, there is no further steps the coordinator needs to take to ensure the follow-up surveys get sent out for each timepoint.

Opt Out of Automatic Electronic Questionnaires

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Participant opted out	4. Navigate to the Onstudy/Enrollment page and ensure the following fields are up-to-date: a. **Email address:** remove any entered email address if applicable b. **Participant opted out:** box must be checked 	*Patient's who opt out of electronic questionnaires must receive a paper questionnaire from the LEO site coordinator. This process is not centralized.*

Follow-up†	PaRE, PaRC, OCD	QOL	Financial Toxicity	Survivorship Booklet
6 months	X			
12 months	X	X	X	
18 months	X			
24 months	X	X	X	
30 months	X			
3 year *(2 separate questionnaires)*	X	X	X	X
4 year	X			
5 year	X	X	X	X

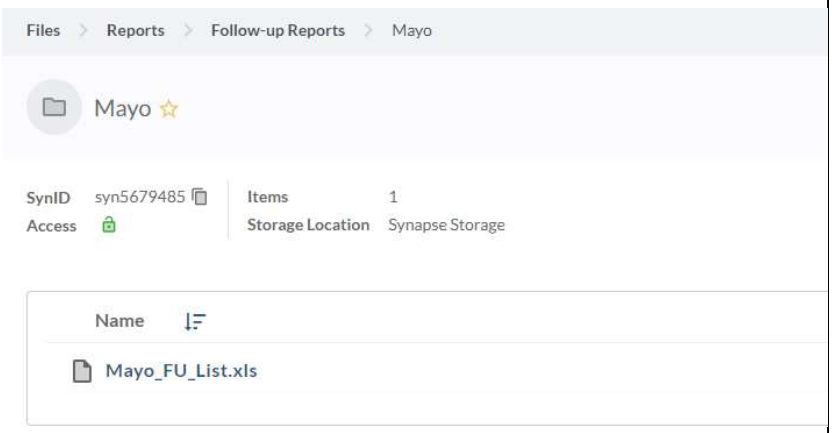
(2 separate questionnaires)				
Annual	X			
†From date of diagnosis, ±4 weeks				

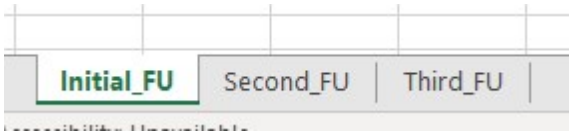
"Short" questionnaire: PaRE, PaRC, and OCD

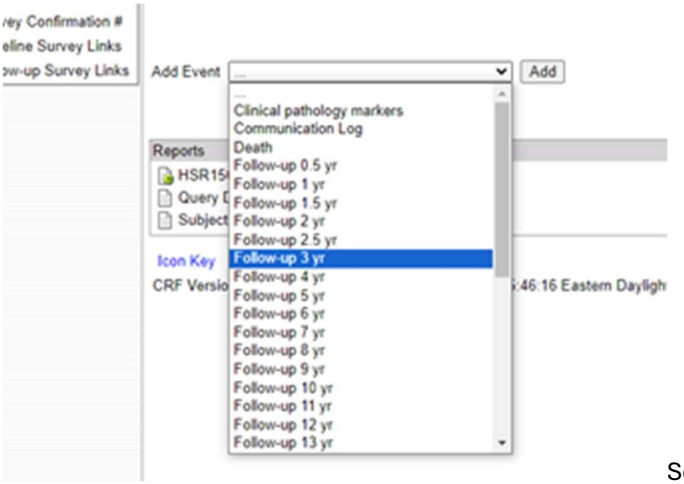
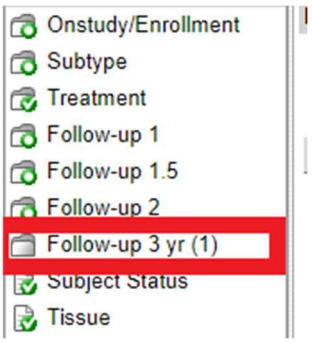
"Long" questionnaire: PaRE, PaRC, OCD, QOL, and Financial Toxicity

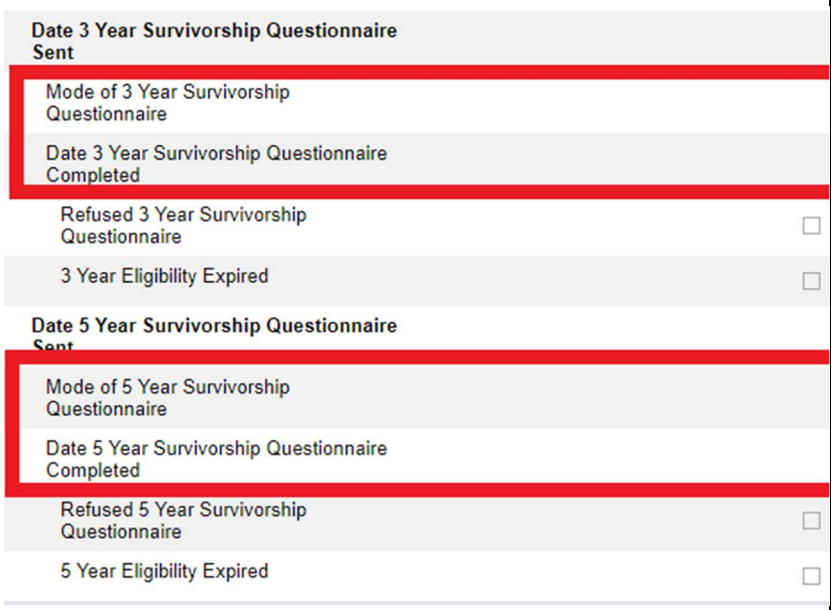
NON-Automated (Opted Out) Follow-Up Questionnaire Process

Note: Site Coordinators are responsible for downloaded and managing their Follow-Up report on a weekly basis

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Download Weekly Follow-Up Report	1. Login to Synapse 2. Files > Reports > Follow-up Reports > *SITE* > ***SITE*_FU_List.xls** 	*File updates every Monday and does not aggregate patients from previous week*
2	Review Follow-Up Report	1. File contains 3 tabs a. **Initial_FU** – the first attempt to capture follow-up questionnaire that is due. i. Only contains subjects not enrolled in automatic follow-up and require a mailed paper questionnaire b. **Second_FU** – the second attempt to capture follow-up questionniare that due.	

		i. Only contains subjects that are not enrolled in automatic follow-up and did not respond to the first attempt ii. Require a mailed paper questionnaire c. **Third_FU** – Final attempt to capture follow-up questionnaire that is due. i. Follow-up questionnaire expires in 14 days. ii. Contains both subjects enrolled on automatic follow-up and those not enrolled in automatic follow-up that have not responded to the first 2 attempts. iii. Coordinators should call patients on this list to gain an up-to-date email or mailing address and/or complete questionnaire over the phone. 	
3a	Initial_FU & Second_FU tabs: Prepare Mail Outs	1. All subjects on Initial_FU and Second_FU tab require a paper questionnaire mailed to them 2. Follow the Mail Merge SOP to create the appropriate cover letters and questionnaires 3. Follow Mail Merge SOP to create envelopes addressed to the patient 4. Pack each follow-up packet a. Each patient should receive a personalized cover letter indicating the survey timepoint of their questionnaire b. A follow-up questionnaire (+/- survivorship booklet if needed) with a "last timepoint completed" date and LEO ID noted on questionnaire c. A pre-stamped, pre-addressed envelop to mail back the completed questionnaire to your respective LEO site.	
3b	Third_FU tab	1. Call each patient: a. Remind them to complete follow up questionnaire if patient indicates they have the email or paper survey **OR** b. Complete survey with paper over the phone and enter responses directly into Rave **OR** c. Resend questionnaire to patient via mail or email with an updated address	*If patient does not complete questionnaire over the phone, they must complete questionniare within 14 days.*

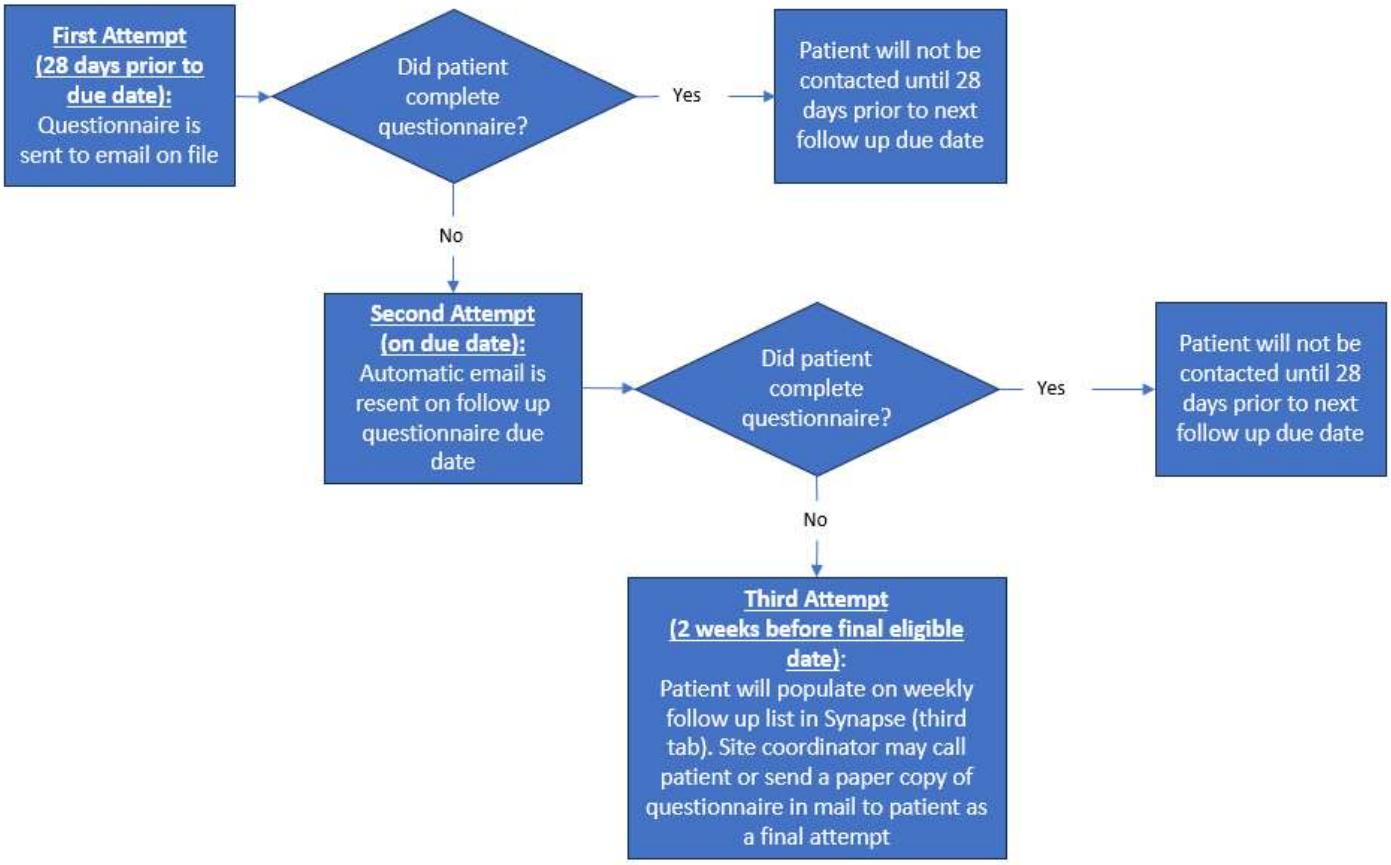
4	Enter Survivorship Send Out Date & Mode	****ONLY COMPLETE THIS STEP FOR 3-year and/or 5-year survivorship questionnaires**** 1. Login to Rave 2. On the Onstudy/Enrollment form à Demographics scroll to the bottom and complete the following: a. **Date 3 Year Survivorship Questionnaire Sent** b. **Mode of 3 Year Survivorship Questionnaire Completed**	
5a	Enter Paper Follow-Up Questionnaire Responses in Rave Upon Receipt	1. Once a patient completes a paper questionnaire and sends it back, you must enter survey responses in Rave 2. Login to Rave  3. Select questionnaire timepoint from Add Event dropdown list and click Add 4. Select the questionnaire form on the left-hand navigation pane  5. Complete the questionnaire forms in Rave exactly as the patient indicated on the paper form	*Do not make corrections to the patient's responses. Enter the responses exactly as the patient indicated even if they seem "incorrect".*
5b	Enter Date of Completion of Survivorship booklet and Scan and	Once a patient completes the paper survivorship booklet (3yr or 5yr) 1. Login to Rave 2. Select the Onstudy/Enrollment form 3. Scroll to the bottom of the page 4. Enter "Date 3/5 Year Survivorship Questionnaire Completed"	

	Upload to Synapse	5. Enter/Update “Mode of 3/5 Year Survivorship Questionnaire” to reflect the mode in which the patient completed the questionnaire  6. Scan the booklet into your computer a. Make sure the LEO ID and Local ID are visible on the booklet before scanning 7. Upload scanned booklet to Synapse a. Files à Questionnaires à Questionnaire Upload àCenter Name à Current Year Upload à Month of Upload  b. Select “Upload or Link to a File” c.  Drag and drop or upload file	

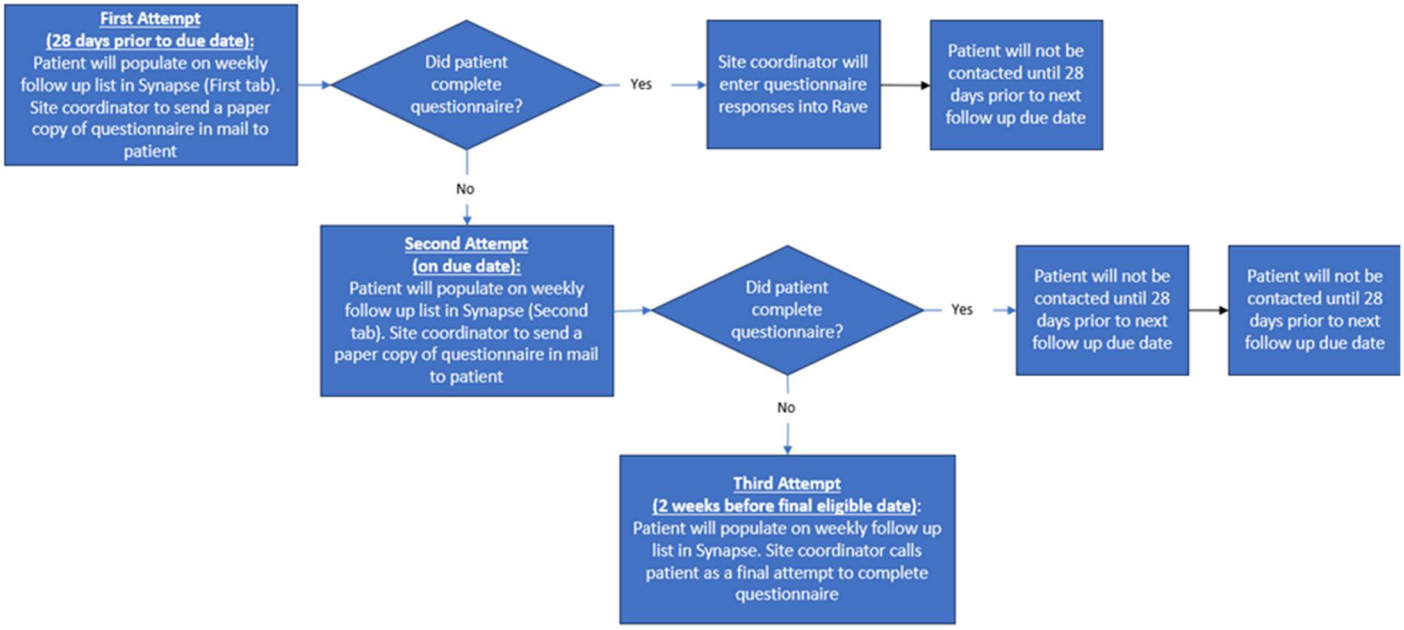
Universal Survey Links for Enrollment, RFQ, Survivorship, and PARE/PARC Follow-up

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Univeral or generalized links. Baseline Enrollment Risk Factor Questionnaire PARE/PARC Follow-up Survivorship Surveys	Contact leocohort@mayo.edu for permission and instructions on how to use the generalized links. Note: The universal links were the custom links' predecessor. The universal links are electronic links that require the participant to enter either their LEO_ID, LOCAL_ID, confirmation number, or time point information into the survey. These links are clunky to use but are still useful in certain situations. For example, if a custom link expires the universal link can still be used.	*These links are not part of the standard operating procedure.* *Please ask for permission from the LEO Cohort to use the universal survey links.* 

Automated Electronic Follow-Up Questionnaire Process



Opt Out of Automatic Electronic Questionnaires Process



Pathology and Specimen Handling

Formalin Fixed Paraffin Embedded (FFPE) Slide Handling/LEO Pathology Review

Purpose: To describe the process of list communication, obtaining slides for LEO Center Pathology Review

Responsibility: The individual responsible for obtaining slides and the review of each case at each LEO center

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1 FYI	Frequency of review	1. Review frequency: Monthly, unless otherwise specified. a. Center dependent, can be more frequent	
2	Receive manifest of cases to be reviewed by LEO Center Pathologist	1. Two manifests will be generated monthly for center review a. DLBCL/MCL/FL/TCL/MZL b. Other NHL 2. Manifests (Excel) will be uploaded into Synapse FFPE - Monthly folder. a. Synapse → FFPE → Mayo → Monthly → Mayo_DLBCL_FL_MCL_TCL_slide_manifest.xls b. Mayo_OtherNHL_slide_manifest.xls 3. Open manifest and save to local drive *Manifest will contain the following information (pulled from RAVE Tissue Screen and LEO Enrollment Subtype Screen) 1. Local ID 2. LEO ID 3. First/Last Name 4. Date of Birth 5. Lymp DXDT (Biopsy date) 6. Consent Date 7. Abstracted Clinical Primary Subtype 8. Histology sample type (Excisional, Core, Fine Needle, Bone Marrow, Skin, Blood, CNS, Pleural Fluid, Other) 9. Histology Accession 10. Histology External Accession 11. Histology Location (Other Institution/LEO Center) 12. Location Other Institution (if applicable) 13. Location Other Address (if applicable) 14. Location Other Fax (if applicable) 15. Location Other Phone (if applicable) 16. Anatomic Sampling Location (Nodal, Extranodal, Spleen, Bone Marrow, Other) 17. Extranodal/Nodal Location (where on the body)	

3	Obtain slides	1. Follow LEO center procedure for obtaining specific cases listed on manifest a. Refer to LEO tissue request fax template in Synapse (syn4214479) 2. If more than one biopsy is listed, please request in the following order: a. Excisional Biopsy b. Core Needle Biopsy c. Skin d. Fine Needle Aspiration (FNA) e. Bone Marrow f. Blood g. Pleural Fluid h. CSF i. Other (Specify) 3. Record outcome of slide request in Rave Tissue Screen 4. Outcome description below: **5. External center refused to send** ii. **N/F – Not yet in file** iii. **Tissue Exhausted** iv. **Included in shipment** v. **Requested** **6.** If doing a Pathology Report Review only, select box in LEO Enrollment Subtype Form	**Use LEO Center FedEx Account to obtains slides for review* ***3 attempts to receive slides before proceeding with Pathology Report Review*
4	LEO Center Coordinator Preps Cases for review	1. Print the LEO 2.0 Review Sheet a. Coordinator to fill in the following fields on review sheet: i. Sample Date ii. Internal/External Accession # iii. Location Institution iv. Baseline Clinical Primary Subtype v. Clinical Subtype Subclassification (if applicable) vi. Applicable Clinical Markers 2. Print pathology reports for all samples that will be reviewed 3. Arrange cases in slide flats for pathology review	**Always chose the higher % when enter pathology markers* ***TCL Markers abstracted by pathologist at all centers*
5	LEO Center Pathologist Review	1. LEO Center Pathologist will review each case a. Pathology Report Primary Subtype b. Block selection/ranking (Rank up to 4 blocks) for all subtypes including too smalls c. Problem cases identified (Ex: mismatch with clinical dx) *i. Will require clinical/path discussion quarterly* d. LEO Final Subtype (correlation between path & clinical) call e. Clinical Markers/Clinical Marker Review	**The WHO5 classification should be used for all cases diagnosed starting on or after 1/1/2025.*

6	Record outcome in LEO Center Tissue Review Form in RAVE	1. Record outcomes for all cases in LEO Center Tissue Review form in RAVE - use drop down selections only. *If outcome does not match listed, contact LEO FFPE Lead Coordinator* (listed in step 8) a. LEO Center Pathology Review Date b. LEO Project i. LEO TMA/Other, specify c. Sample Reviewed (# from Tissue Form) d. Sample Accession # (from Tissue Form) e. Outcome description below: i. ***Too Small – Tissue was insufficient for coring*** ***ii. Problem Case – Needs further review*** ***iii. Sufficient for coring*** f. Block Rating - 1-4 i. For all cases, sufficient and too small g. LEO Tissue Primary Subtype (subclassification if applicable)	
7	LEO Enrollment Subtype Form in RAVE	1. Record outcome of Pathologist review a. ICC discrepancy b. Problem Case Indicator c. LEO Primary Final Subtype (subclassification if applicable)	
8 FYI	Review Timeline/ Deadlines	1. Reference Outlook Calendar for all reminders and deadlines	
9 FYI	LEO Pathology Contacts	11. For all pathology related questions please contact the LEO cohort email at LEOCOHORT@mayo.edu 12. Lindsey En PH: 507-422-5000; en.lindsey2@mayo.edu 13. Sara Borgschatz PH: 507-266-5038; borgschatz.sara@mayo.edu 14. Rachel Benson PH: 507-266-6695; benson.rachel@mayo.edu 15. Tanner Reicks (Program Manager) PH: 507-266-2656; reicks.tanner@mayo.edu	

Formalin Fixed Paraffin Embedded (FFPE) Tissue Microarray (TMA) Block Handling/Processing

Purpose: To describe the process of list communication and sending TMA blocks to Mayo Clinic for central TMA Build and coring for future DNA/RNA extraction

Responsibility: The individual responsible for obtaining and sending paraffin tissue blocks at each LEO center

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Manifest Uploaded to Synapse	7. All block manifests will be pulled from RAVE based on LEO Center pathologist review. Manifests will be uploaded to Synapse. a. Synapse → FFPE → (Your LEO Site) → Quarterly → Mayo_DLBCL_block_manifest.xls	**Outlook calendar will have reminder*
2	Obtain blocks	1. Follow LEO center procedure for obtaining specific cases a. Refer to LEO tissue request fax template in Synapse (SYN4214479)	**Use LEO Center FedEx Account to obtain blocks for sending*
3	Record block outcome in RAVE and in manifest	1. Record outcome of block request for all cases in RAVE Tissue Screen a. Outcome description below: i. ***Included in Shipment***-slides/block obtained and will be shipped to Mayo Clinic ii. ***(NIF) Not yet in file-***case is still with pathology for clinical review and unable to be called for research iii. ***Tissue Exhausted-***All blocks associated with case are depleted iv. ***External center refused to send-***External center refuses to send both slides and blocks* 2. Update block manifest reflecting only what will be included in the shipment to Mayo a. If blocks are not included in shipment, delete that case from manifest.	**If center will not release block, do not include case in shipment-mark as "External center refused to send"*
4	Block Manifest	1. LEO Center will upload block shipping manifests from local drive into Synapse (**only include blocks shipped to Mayo**) a. Files are to be uploaded and saved in the Quarterly folders: DLBCL/FL/MCL/TCL/MZL 2. LEO Centers coordinator assures all blocks on shipping manifest are included in shipment a. If shipping manifest does not match blocks in hand, update on manifest and LEO Center Review outcome in RAVE	

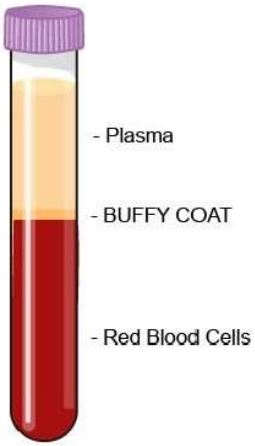
5	Ship Blocks	1. Package all blocks by subtype in the provided boxes a. Blocks should be lined up to correspond with the order of the path reports and in order of manifest 2. Package all path reports by subtype a. Center path report and outside path report if applicable b. De-identify personal identifiers (this does **not** include the accession number) c. LEO Center ID visible on path report 3. Ship by date reflected on your outlook calendar a. Earliest date and latest date **4. **Be sure to ship with cool packs**** 5. Ship via FedEx (2-day) Ship to: Lindsey En (LEO Pathology Coordinator) Bio Business 5-78 200 1st Street SW Rochester, MN 55901 (507) 422-5000	*Manifest must be uploaded to Synapse by the date of shipping of blocks *Each center to use their own FedEx account
6 FYI	Block Outcome	2. Mayo will record in the block outcome in LEO Central Pathology Review a. Block number reviewed b. Outcome of review c. Tumor % d. Tissue sufficient for TMA/RNA/DNA e. TMA Name f. (N) of RNA/DNA extracted g. (N) of TMA Cores 3. Mayo will upload the TMA maps and DNA results into Synapse a. Synapse → FFPE → TMA Maps b. Synapse → FFPE → FFPE DNA Results	
7 FYI	Block Return	1. Blocks will be returned within a **firm** 45 days of receipt at Mayo Clinic	
8 FYI	LEO Pathology Contacts	16. For all pathology related questions please contact the LEO cohort email at LEOCOHORT@mayo.edu 17. Lindsey En PH: 507-422-5000; en.lindsey2@mayo.edu 18. Sara Borgschatz PH: 507-266-5038; borgschatz.sara@mayo.edu 19. Rachel Benson PH: 507-266-6695; benson.rachel@mayo.edu 20. Tanner Reicks (Program Manager) PH: 507-266-2656; reicks.tanner@mayo.edu	

LEO Baseline Blood Draw and Sample Processing

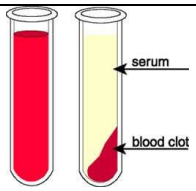
Purpose: Describe tubes needed for LEO Baseline Blood Draw and Processing Procedure post draw

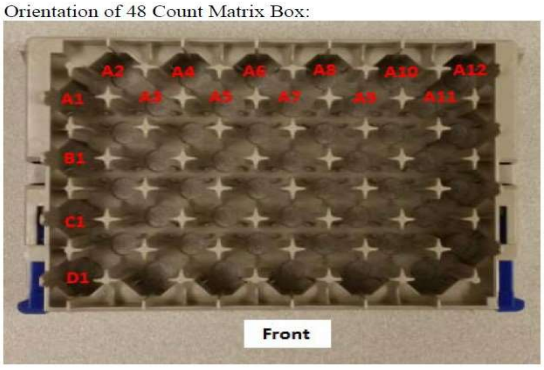
Responsibility: LEO Coordinator/Lab Staff responsible for "setting up" blood draw procedure, blood draw and blood processing

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Obtain tubes for baseline draw	1. 1x 10mL EDTA (purple top) 2. 1x 10mL No Add (red top) 3. 2x 10mL Streck	*sites provide collection tubes
2	Draw participant blood	1. Send to central venipuncture lab for draw 2. If coordinator obtaining draw a. Follow site venipuncture protocol	
3	Process EDTA	1. Centrifuge whole blood for 10 minutes at 1350g/2500rpm 2. Remove supernatant at top 3. Place into 15mL centrifuge tube 4. Centrifuge additional 10 minutes at 1350g/2500rpm 5. Aliquot 1mL plasma at top into 1.8mL matrix tubes (max=4) 6. Label tube-1inch x 1inch labels a. Sample ID (Site specific, max 10 characters) b. LEO ID c. Plasma  d. Draw Date 7. Place all aliquots (1.8mL matrix tubes) in matrix box provided by Mayo Clinic 8. Aliquot from each EDTA remaining buffy coat (up to 1mL) into 1.8mL matrix tube (max=2) a. Aliquot does not need to contain the full 1mL. Save as much sample as you can and estimate amount in partial aliquots. (make sure to indicate estimated amount on manifest)	*If possible, use printer for labeling tubes, not handwritten **there is NO lysis step when processing EDTA** **Buffy Coat will contain some plasma and some red blood cells** 

		9. Label tube (not handwritten) a. Sample ID (Site specific, max 10 characters) b. LEO ID c. Buffy Coat d. Draw Date 10. Place both aliquots (1.8mL matrix tubes) in matrix box provided by Mayo Clinic	

4	Process No Add	1. Allow blood to clot at room temperature 2. Centrifuge clotted blood at 1350g/2500rpm for 10 minutes 3. Remove serum 4. Aliquot 0.75mL into 1.8mL matrix tubes (max=6) a. Aliquot does not need to contain the full 0.75mL. Save as much sample as you can and estimate amount in partial aliquots. (make sure to indicate estimated amount n manifest) 5. Label tubes-1inch x 1inch labels a. Sample ID (Site specific, max 10 characters) b. LEO ID c. Serum d. Draw Date 6. Place all serum tubes in matrix box next to the WBC/white cell fraction aliquots for same participant 7. Assure all blood product (plasma, buffy coat, serum) from same patient are placed next to each other in matrix box 8. Store in -80 freezer until shipping	
5	Process Streck	1. Label each sample collection sheet and the corresponding patient sample tubes with a short-hand numerical identifier to keep samples separate through the process (usually 1, 2, 3, etc). 2. Before placing 10mL Streck tube into centrifuge, use scale to find the proper balance tube. (*usually a 15mL balancer*), then centrifuge the sample. a. 2000g (rcf) for 12 minutes at < 24□C - (“Program 2” or “Plasma”) 3. During centrifugation, prepare one 15mL tube per sample with short ID to receive plasma. 4. After centrifugation is complete, transfer the separated plasma into the new 15mL centrifuge tube from Step 3, taking care not to disturb the buffy coat on top of the RBCs. 5. Centrifuge the separated plasma layer. a. 2000g (rcf) for 12 minutes at < 24□C - (“Program 2” or “Plasma”) 6. While the plasma spins down a second time, use a 1000µL pipette tip and carefully extract the buffy coat (thin white layer sitting on top of the whole blood) and transfer to a 2mL cryovial.	*Optional: To avoid breaking the tube, using a 10mL pipet, transfer the blood from the Streck tube into a 15mL centrifuge tube.

		NOTE: Minimize the amount of unnecessary RBCs collected by taking off the buffy coat as you would PBMCs from a Ficoll gradient, sampling from above the boundary. Total buffy coat volume per Streck tube should be < 1mL. 7. When the plasma is finished spinning, transfer the plasma into 1.8mL matrix tubes. Make sure not to disturb the pellet at the bottom of the plasma tube. 8. Place matrix tubes for plasma and buffy coat next to all blood products from same patient in the matrix box in -80 freezer.	
5	Update Manifest Template	1. Download manifest from Synapse 2. Assure that you enter all information below per tube on line of manifest that matches tube placement in box a. Matrix ID i. Scan the barcode sticker on the bottom of each matrix tube.* b. LEO ID i. Enter LEO ID that was created for participant in RAVE c. Draw Date i. Enter Date of baseline draw d. Sample ID i. Site specific, max 10 characters e. Sample Type i. Select sample type from drop down 1. Buffy Coat 2. Serum 3. Plasma f. Do not split same patient samples into multiple boxes • Orientation of 48 Count Matrix Box: 	*Manifest Template sent to sites from Mayo Clinic *If there is a defect on the barcode sticker DO NOT use the tube, the matrix ID will not scan properly. Save and send all back to Mayo on a yearly basis and Mayo will replace.

6	Label box	1. Label outside of box with site name and box # a. Label boxes in sequential order for each shipment (Box 1 of xx, Box 2 of xx…) 2. At the end of the month, update box label with total boxes in shipment (portion in red) (ex: Box 1 **of 3**) a. If unable to write on box after being in the freezer, please write on a piece of paper and rubber band to the box.	
	Contact	1. If questions or issues with any step of this process please contact: a. LEOCohort@mayo.edu b. Borgschatz.Sara@mayo.edu c. Benson.Rachel@mayo.edu	

Package & Ship LEO Bloods to Mayo Clinic

Purpose: Describe frequency, process of packaging and shipping LEO Bloods to Mayo

Responsibility: LEO Coordinator at site

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Upload manifest to Synapse	1. On first Friday following the last day of the month, upload manifest to Synapse (Manifest should include all LEO blood samples collected since previous shipment) a. Log In to Synapse b. In search bar, type in site blood folder synapse ID i. University of Iowa: syn3725633 ii. Cornell: syn3728317 iii. Emory: syn3728378 iv. University of Miami: syn3728403 v. University of Rochester: syn3728446 vi. Wash U: syn3728465 vii. MD Anderson: syn3728428 c. Upload manifest to current month's folder (ex: Please upload [Month Year] to this folder)	*Sites will only have access to their sites blood folder
2	Ship Samples	1. Samples can be shipped the Wednesday following submission to Synapse.*	*Only ship bloods if you have submitted your center's LEO blood manifest to Synapse by the first Friday of the month. If the manifest was submitted after, please contact Sara Borgschatz (Borgschatz.Sara@mayo.edu) for shipping approval.
3	Prepare bloods for shipment	1. Place paper copy of manifest and labeled boxes in Styrofoam shipping container with 5-10 lbs of dry ice a. Update box label with total boxes in shipment (ex: Box 1 **of 3)** 2. **Place copy of RSTP approval in box.*** 3. **Select FedEx Priority Overnight (NOT first overnight)** 4. Place FedEx label on outside of shipping box a. Ship to: BAP Lab	*RSTP approvals are uploaded to Synapse. Please print and include with shipment. *Centers are responsible for printing their own FedEx labels.

		Attn: LEO Study 2915 Valleyhigh Drive NW Rochester, MN 55901 5. Arrange for FedEx pick-up	
4	Tracking Samples	1. Each shipping label will have a tracking number to track shipment/arrival. a. Enter shipping date and tracking number in Tracking Excel sheet located in sites Synapse Blood folder	
5	CONTACTS	1. If questions or issues with any step of this process please contact: a. LEOCohort@mayo.edu b. Borgschatz.sara@mayo.edu c. Benson.rachel@mayo.edu	

Serial Blood Screening

Purpose: Protocol for process of screening, ordering, and collection of LEO Serial MER blood samples.

Responsibility: Staff identifying samples for blood collection at LEO site

Guidelines	
Subject Eligibility Criteria	To be eligible for serial blood collections subject must meet all the following criteria: ✓ Currently enrolled in LEO ✓ Have a pre-treatment blood sample collected ✓ Be receiving systemic therapy

STEP	**SUBJECT**	**DETAILED DESCRIPTION**	**NOTES**
1	Collecting Research Blood Sample	1. Collect baseline research blood sample if: a. Prior to any lymphoma treatment b. Or if treatment history is unknown 2. Process per LEO blood processing protocol	
2	Document baseline blood collection in RAVE	1. Open subject in RAVE and navigate to the 'Research Blood Tab' 2. Enter Research Blood Collection Date 3. Select the appropriate Blood Collection Time Point a. Prior to any lymphoma treatment b. Lymphoma treatment initiated prior to baseline sample draw c. Timing of treatment unknown	If patient refuses blood draw check the 'Refused Research Blood Collection' box Research blood collection should be prior to any lymphoma treatment, but when patient records are unclear treatment may have already been started and blood collection time point should be updated to reflect accurate treatment records when able

3	Serial blood collection initiation	1. Document serial sample eligibility (Pre-tretment blood sample collected and receiving systemic treatment) a. Yes b. No c. Pending	If yes, additional fields will populate
4		1. Restage/Mid Treatment Draw/Collection Date a. Enter date blood collected 2. Restage/Mid Treatment Missed Appointment a. Check box if sample was not collected during time point requirements 3. End of Therapy Draw/Collection Date a. Enter date blood collected 4. End of Therapy Missed Appointment a. Check box if sample was not collected during time point requirements 5. Date of Relapse a. Enter date of relapse 6. Date of Relapse Draw/Collection Date a. Enter date blood collected 7. Relapse Missed Appointment a. Check box if sample was not collected during time point requirements 8. Date of Additional Relapse a. Enter date of relapse 9. Date of Additional Relapse Draw/Collection Date a. Enter date blood collected 10. Additional Relapse Missed Appointment a. Check box if sample was not collected during time point requirements 11. Date of 2nd Additional Relapse a. Enter date of relapse 12. Date of 2nd Additional Relapse Draw/Collection Date a. Enter date blood collected 13. Additional 2nd Relapse Missed Appointment a. Check box if sample was not collected during time point requirements 14. Comments a. Enter any applicable comments for serial blood collections that may be helpful for documentation	

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Identifying subjects for serial blood collection	1. Open EPIC 2. Run and save the **Blood Screening Clinic Schedule** report. It is helpful to name the document YYYYMMDD and use a consistent password for quick refence. *Contact the LEO Cohort or your site's EPIC support if you need assistance developing this report.*	

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2</td><td>Obtain list off subjects eligible for serial collections</td><td>1. Log into Synapse
2. Open the reports folder
3. Navigate to your site’s folder for blood screening
4. Open the report <<NAME>>
5. Save report</td><td></td></tr>
<tr><td>3</td><td>Merge EPIC report and synapse report</td><td>1. Open the report you downloaded and saved from EPIC
2. Select ‘Data’
3. Select ‘Get Data’
4. Select ‘Get Data From File’
5. Select ‘From Excel Workbook’
6. Navigate through your saved files and select the file that you saved from Synapse and select Open.
7. In the Navigator window that opens check the box that says ‘Select multiple items’ and then check the two worksheets that you will be working with
8. Select ‘Transform Data’ to open the Power Query Editor
9. Select Merge Queries and in the window that opens select the matching columns from each table.
10. Select ‘Inner (only matching rows)’ for the join kind and select ‘OK’
11. From the column that populates from your table select the items you want to add from your Synapse report into your EPIC report (Details needed to identify the blood sample needed when completing chart review)
12. Select Close and Load
13. Open the tab that has your filtered subject list to review in EPIC
a. This is the list of subjects who are eligible for a serial blood collection AND are coming to the clinic in the next week or designated time frame.</td><td></td></tr>
<tr><td>4</td><td>Chart review to determine subject blood collection eligibility</td><td>1. Review the subject’s medical record to determine if the subject meets the requirements for the specified time point as defined in the blood collection table below:
<table><tr><td>Time Point</td><td>Criteria</td></tr><tr><td>Mid Tx</td><td>After cycle 2 or 3</td></tr><tr><td>Post Tx</td><td>2-12 weeks following end of treatment or at FU PET/CT OR 5-6 months after treatment start date.</td></tr><tr><td>Progression</td><td>At time of progression, preferably prior to start of subsequent line therapy</td></tr></table>2. If patient does not meet criteria for specified time point review for progression</td><td>Verify that the patient has not had a progression prior to collecting Mid Tx or Post Tx</td></tr>
</table>

		3. If subject is eligible for blood collection follow institutional protocol for ordering and collecting blood sample.	

Saliva Collection Process

Purpose: collecting saliva samples for DNA extraction

Responsibility: LEO Coordinator at site

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Eligibility	1. Determine patient eligibility. 2. Consent patient to LEO consent. 3. Once patient signs the LEO consent give participant a saliva kit.	
2	Sample Collection Instructions	1. Patient should complete the saliva kit in the room. 2. Patient should not eat or drink 30 minutes prior to providing that sample. 3. Have patient spit until the amount of saliva **(not bubbles)** reaches the fill line. 4. Patient should close lid tightly by pushing down the hard on the funnel lid until you hear a loud click. 5. Unscrew the funnel from the tube. 6. Use the cap to close the tube tightly. 7. Shake the capped tube for 5 seconds. 8. Return kit to LEO coordinator.	**Coordinator should wear gloves while handling saliva kit** **Coordinator may help patient close lid in step 4.
3	Requisition Form	1. Complete each section of the requisition form. 2. Patient information a. Patient initials: F, M, L b. Patient ID or MC# number c. LEO ID d. DOB: Month-Date-Year* e. Gender f. Kit ID number 3. Study Number: 21-001804 4. Visit Description a. Check the box for Baseline or indicate if sample was collected at a different timepoint. 5. Specimen collection a. Date: Month-Day-Year b. Time c. Sample Type - **Saliva** d. Source - **Saliva** e. Container Type – **Saliva Kit** f. Sample Volume (mL) 6. Collection Site Contact a. Name b. Phone c. Email 7. Requisition form should be inserted into the biohazard bag for each kit.	**Kit ID number is a five-digit number located on the tube, highlighted in yellow below.  *Month should be listed as: Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec
4	Rave Entry	1. Research Saliva Tab 2. Enter date saliva kit was collected. 3. Enter date kit was sent/given to patient.	

		4. Enter date saliva kit was received (only enter this date if it is different than the collection date). 5. Next document the saliva kit ID. 6. Select timepoint of saliva kit was given to patient. a. Prior to any lymphoma treatment b. Lymphoma treatment initiated prior to baseline sample collection. c. Timing of treatment unknown 7. If the patient refuses to provide a saliva sample, then check the refused saliva kit box. 8. Lastly, click on save. 9. If additional saliva samples are collected the add a new log line by clicking on add new log line link below the Oragene Saliva Kit Collection Date.	**Kit ID number is a five-digit number located on the tube, highlighted in yellow below. 
5	CONTACTS	1. If questions or issues with any step of this process, please contact: a. LEOCohort@mayo.edu b. Borgschatz.sara@mayo.edu c. Benson.rachel@mayo.edu	

Package and Ship LEO Saliva to Mayo

Purpose: Describe frequency, process of packaging and shipping LEO Saliva to Mayo

Responsibility: LEO Coordinator at site

Instructions

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Upload manifest to Synapse	1. On first Friday following the last day of the previous month, upload manifest to Synapse (Manifest should include all LEO Saliva samples collected since previous shipment) a. Log In to Synapse b. In search bar, type in site saliva folder synapse ID i. University of Iowa: syn62013072 ii. Cornell: syn62013062 iii. Emory: syn62013065 iv. University of Miami: syn62013075 v. University of Rochester: syn62013078 vi. Wash U: syn62013081 vii. MD Anderson: syn62013070 c. Upload manifest to current month's folder (ex: Please upload [Month Year] saliva manifest to this folder) d. Manifest should include i. Sample type ii. Sample Source iii. Sample Collection Date iv. Container Type v. Sample volume (est) vi. Treatment Type vii. LEO Subject ID viii. Gender	*Sites will only have access to their sites saliva folder. *Manifest provided by Mayo and can be located in each centers saliva synapse folder.
2	Ship Samples	9. Samples can be shipped the Wednesday following submission to Synapse.*	*Only ship saliva if you have submitted your center's LEO saliva manifest to Synapse by the first Friday of the month. If the manifest was submitted after, please contact Sara Borgschatz (Borgschatz.sara@mayo.edu) for shipping approval.
3	Prepare saliva for shipment	1. Place paper copy of manifest in provided shipper container. a. Update box label with total boxes in shipment (ex: Box 1 **of 3**) 2. Complete the included **Biospecimens Accessioning & Processing Requisition Form** and confirm that the specimens are correctly labeled. Make a copy of the completed **Requisition Form** for your records.	*Shipper for saliva kits will be provided by Mayo.

		3. Package the specimen inside of the shipping box using te following instructions: a. Ambient specimens-place a layer of ambient cool-packs (4) in the bottom of the Styrofoam container. Place three to four paper towels (for insulation) over the cool-packs. Place the ambient specimen bag on top to the paper towels. Place a second layer ambient cool-packs (4) on top of the specimen bag. Seal the container with packaging tape. 4. **Place copy of RSTP approval in box.*** 5. **Select FedEx Priority Overnight <u>(NOT first overnight)</u>** 6. Place FedEx label on outside of shipping box a. Ship to: Mayo Clinic-BAP LAB Attn: LEO Study 150 Third Street SW Rochester, MN 55905 507-284-5777 7. Arrange for FedEx pick-up	*RSTP approvals are uploaded to Synapse. Please print and include with shipment. *Centers are responsible for printing their own FedEx labels.
4	Tracking Samples	1. Each shipping label will have a tracking number to track shipment/arrival. a. Enter shipping date and tracking number in Tracking Excel manifest located in sites Synapse Saliva folder	
5	Supplies	1. Saliva kits and the return shipper can be requested by emailing the contacts listed below.	
6	CONTACTS	2. If questions or issues with any step of this process, please contact: a. LEOCohort@mayo.edu b. Borgschatz.sara@mayo.edu c. Benson.rachel@mayo.edu	

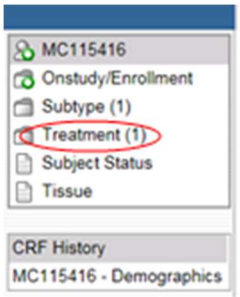
Data Quality

LEO Data Validation

Validation Points: (New Treatment, Progression, New Cancer, MD Review, Resolved Progression, Resolved Treatment, Disease Death No Progression, Improper Progression)

Purpose: To describe the process of data validation for patient reported new treatments, progressions, new cancer diagnosis, MD review, resolved progressions, resolved treatments, disease death no progression, and improper progressions

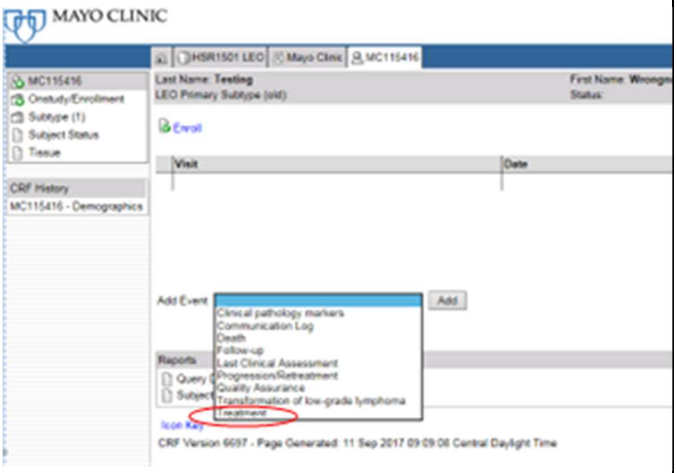
Responsibility: The individual responsible for this process as outlined at center.

STEP	SUBJECT	DETAILED DESCRIPTION	NOTES
1	Download Center's Follow-Up Report	1. www.synapse.org a. LEOàFilesàReportsàMissing Data ReportsàYour CenteràMonthlyàData_validation_report 2.  This report will have the lists for New Treatment, Progression, New Cancer, MD Review, Resolved Progression, Resolved Treatment, Disease Death No Progression, Improper progression as indicated by the tabs below:	
2	New Treatment	1. Review patient's treatment data previously entered into RAVE 2. Confirm if patient has received new treatment via the EMR if indicated treatment was received at LEO center 3. If the patient has received new treatment that is not entered into RAVE enter the new data into the patient's treatment form a. To access the treatment form, click on "Treatment" on the forms list on the left hand side of the screen.  b.	* If treatment is done at outside institution and only month and year are available, use the 15th of the month as the day.

c. Click “Add a new Log line”

#	Therapy 1	Therapy 2	Therapy 3	Therapy 4	If Other, specify
1	Observation (initial therapy only)	–	–	–	–
	Add a new Log line	Inactivate			

4. **If no treatment form exists in RAVE**, return to participants main page and in the “Add Event” drop down select “Treatment”



5. If treatment was received at an outside institution, request records and complete form when records have been received.
6. After form has been completed update the query status on follow-up form
    a. Go to the follow-up time point in RAVE as indicated on the Data Validation Report under column H: “timepoint”
    a. Click pencil icon at top of screen. This will open up all fields on the form for editing

    b. Make the appropriate selection from the “Treatment query resolved” dropdown*

c. Complete the form with information from the EMR

i. Complete treatment outcomes if sufficient time has passed and the patient has completed their post therapy assessment where the outcome was determined.

d. If treatment was received at an outside institution, request records and complete form when records have been received.

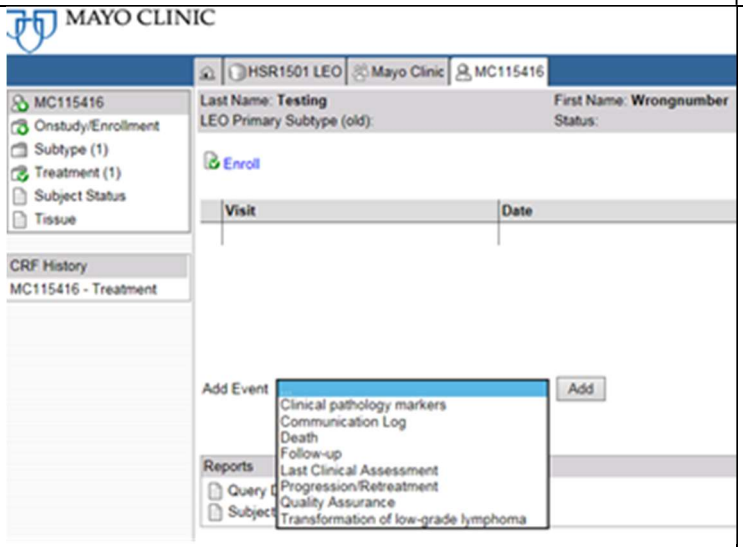
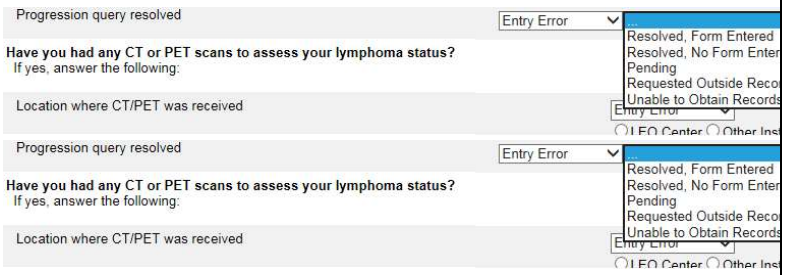
7. **If treatment form exists in RAVE**
   a. Open treatment form
   b. Click “Add a new Log line”

#	Therapy 1	Therapy 2	Therapy 3	Therapy 4	If Other, specify
1	Observation (initial therapy only)	–	–	–	–
Add a new Log line Inactivate					

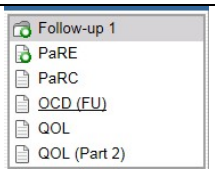
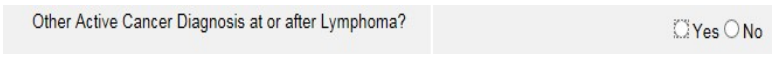
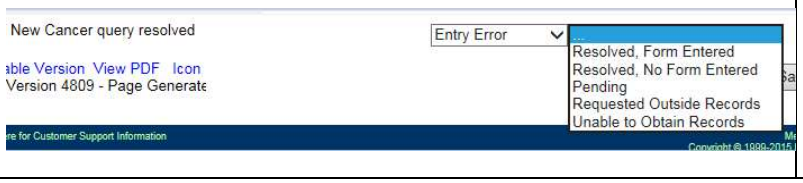
   c. Complete the form with information from the EMR
      i. Complete treatment outcomes if sufficient time has passed and the patient has completed their post therapy assessment where the outcome was determined.
   d. If treatment was received at an outside institution, request records and complete form when records have been received.
8. After form has been completed update the query status on follow-up form
   a. Click pencil icon at top of screen. This will open up all fields on the form for editing

   b. Make the appropriate selection from the “Treatment query resolved” dropdown*

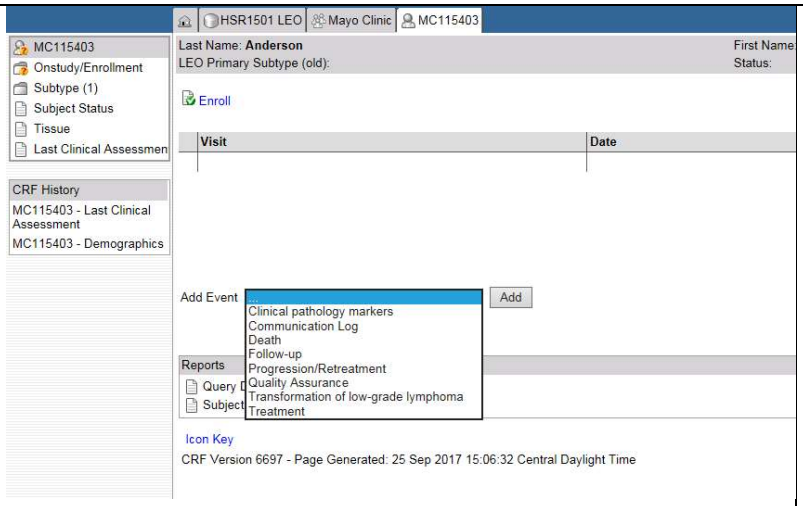
* If treatment is done at outside institution and only month and year are available, use the 15th of the month as the day.

3	Progression	1. Go to the follow-up time point indicated on the Data Validation Report 2. Confirm progression in EMR if diagnosed at LEO center. 3. On patients main page, chose “Progression/Retreatment” from the “Add Event” drop down.	
		 4. Complete Progression/Retreatment form a. This form only needs to be completed for the first progression and subsequent retreatment 5. If treatment was received at an outside institution, request records and complete form when records have been received. 6. After form has been completed or query otherwise resolved (no progression per EMR, etc.) update the query status on follow-up form  a. Click pencil icon at top of screen. This will open up all fields on the form for editing b. Make the appropriate selection from the “Treatment query resolved” dropdown* 	

4	New Cancers	1. Go to the follow-up time point indicated on the Data Validation Report 2. Confirm new treatment in EMR if new cancer was diagnosed at LEO center 3. Enter New Cancer form a. In the follow-up timepoint, select OCD on the forms list on the left side of the screen	

		 b. Answer question based on EMR information and click “Save”  i. If “No” you have completed the query 4. If “Yes” complete the rest of the form (This will populate after clicking “Save”) a. Enter date of diagnosis b. Site (ICD code) c. Histology (based on ICD-O book) 5. If diagnosed at an outside facility, request records and complete fields in OCD form.  6. After form has been completed update the query status on follow-up form  a. Click pencil icon at top of screen. This will open up all fields on the form for editing. b. Make the appropriate selection from the “Treatment query resolved” dropdown* 	*This field will not be visible unless you have opened all fields for editing

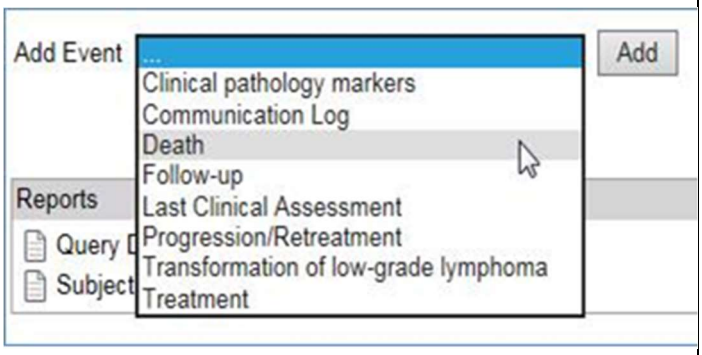
5	Progression/Retreatment Form	This form is used to indicate if a patient has started a second line therapy 1. If a patient has had a progression and/or started a new treatment a. On patient's main screen, use drop down to select "Progession/Retreatment" and click "Add"	



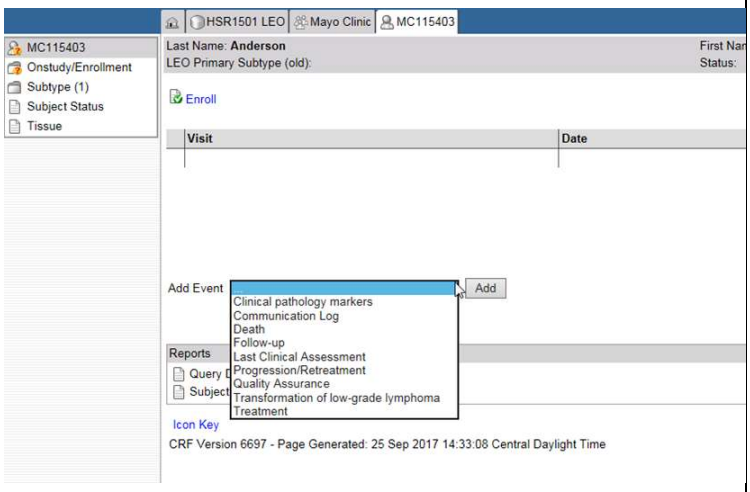
b. To access the treatment form, click on "Progression/Retreatment" on the forms list on the left hand side of the screen.

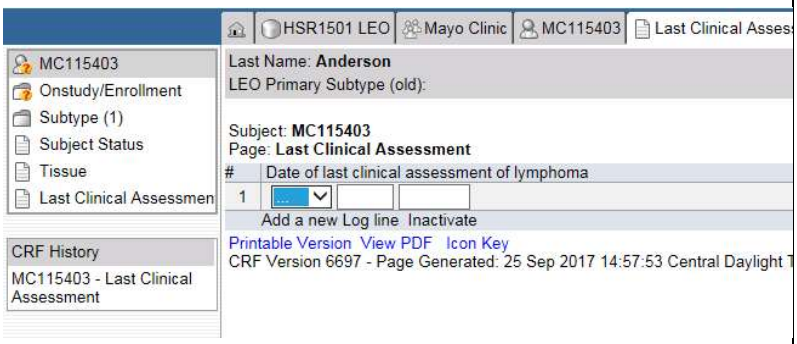
2. Complete form with information from the EMR

a. Firt-line therapy = initial treatment
b. Second line therapy = therapy given after progression or prior ineffective treatment
c. Physician Review = mark as "pending" until site PI has reviewed reports

		3. LEO Physician Review a. Must be done by a PI from your site b. Print PDF of the "Progression/Retreatment" form i. Bring printed CRF, path reports/clinical notes with to PI review c. Change "LEO Physician" from "Pending" to "Yes" after review occurs	
	LEO Cause of Death	**<u>COD Abstraction</u>** 1. Sign on to RAVE: https://login.imedidata.com/login 2. Select LEO database 3. Select HSR1501 LEO database a. If applicable, select role 4. Select Cause of Death form from Add Event drop down box  5. Click Add 6. Date of Death a. Enter date the patient died. **<u>Physician Review - COD</u>** 1. Print records pertaining to the patients passing. 2. If records aren't available, request using the ARMI/ NOK ARMI. a. Look at patients primary care facility in order to determine where records should be requested from b. Do not request records from Nursing Facilities/ Nursing Homes. 3. Once records have been gathered bring them to the monthly review scheduled with the LEO PI/ Reviewing Physician. a. The physician will indicate the primary COD using the numbers listed in section 8. 4. The physician will indicate the primary COD using the numbers listed below: 1. Due to this Disease(i.e. progressive lymphoma) 2. Due to Therapy-Infection 3. Due to Therapy-Cardiac 4. Due to Therapy-Other 5. Due to Secondary Malignancy	This can be obtained from the NOK, death certificate or medical record.

		6. Due to Other Causes- Enter other cause in text box. 7. Unable to obtain records. 5. Underlying COD (ICD-10) a. Enter ICD-10 code for underlying COD as listed on death certificate. 6. Primary COD (ICD-10) a. Enter ICD-10 code for underlying COD as listed on death certificate.	Underlying COD - Only answer per death certificate/note Primary COD - This information can be obtained from the physicians note

6	Last Clinical Assessment	Completed anytime you are in the patient's records. This form is important for STATs to determine Event Free Survival (EFS) 1. If the patient does not have a Last Clinical Assessment form already, create one using the Add Event dropdown on the patient's main page.  a. Select "Last Clinical Assessment" and click "Add" b. To access the treatment form, click on "Last Clinical Assessment" on the forms list on the left hand side of the screen.	Last Clinical Assessment

		2. Enter date of patient's last clinical assessment confirmed by EMR  3. Click "Add a new Log line" to enter new date whenever you are working in the patient's records.	

Quality Assurance Initiative

Purpose: To describe the process of completing the quarterly clinical quality assurance checks

Responsibility: Center coordinators and PIs

Instructions

STEP	TITLE	PURPOSE/ DESCRIPTION	GUIDELINES
1	Center receives list	2. List of patients to review is generated by LEO statistical core 3. List may be downloaded from center's QAI folder in Synapse.	
2	Center reviews cases	4. Coordinator gathers records and RAVE forms to review	
3	Center completes Form (coordinator)	5. Coordinator completes one form per patient **<u>FORM FIELDS – DEMOGRAPHICS/BASIC INFO</u>** 6. LOCAL ID b. Enter local patient ID (optional) 7. LEO ID c. Enter LEO ID 8. Date of Consent d. Enter Date of Consent as recorded in RAVE database demographics screen e. Compare against physical copy of consent form – check for accuracy 9. Patient DOB f. Enter Date of Birth as recorded in RAVE database demographics screen g. Compare against medical record – check for accuracy 10. Diagnostic Biopsy Date h. Enter the date of diagnosis as recorded in RAVE database Abstracted Subtype Form i. Compare against pathology report from medical record – check for accuracy **<u>FORM FIELDS – ABSTRACTED INFORMATION</u>** 11. Enter data for each of the key fields listed j. Column 1: lists the field or form in RAVE where the information is found k. Column 2: Enter the requested data as it appears in RAVE l. Column 3: Notes – Answer any questions, complete any information listed m. Column 4: Enter any changes that need to be made in RAVE. NOTE: If data is correct, select "Data is correct" checkbox or will be listed as "missing"	*see appendix 12 for QAI Form

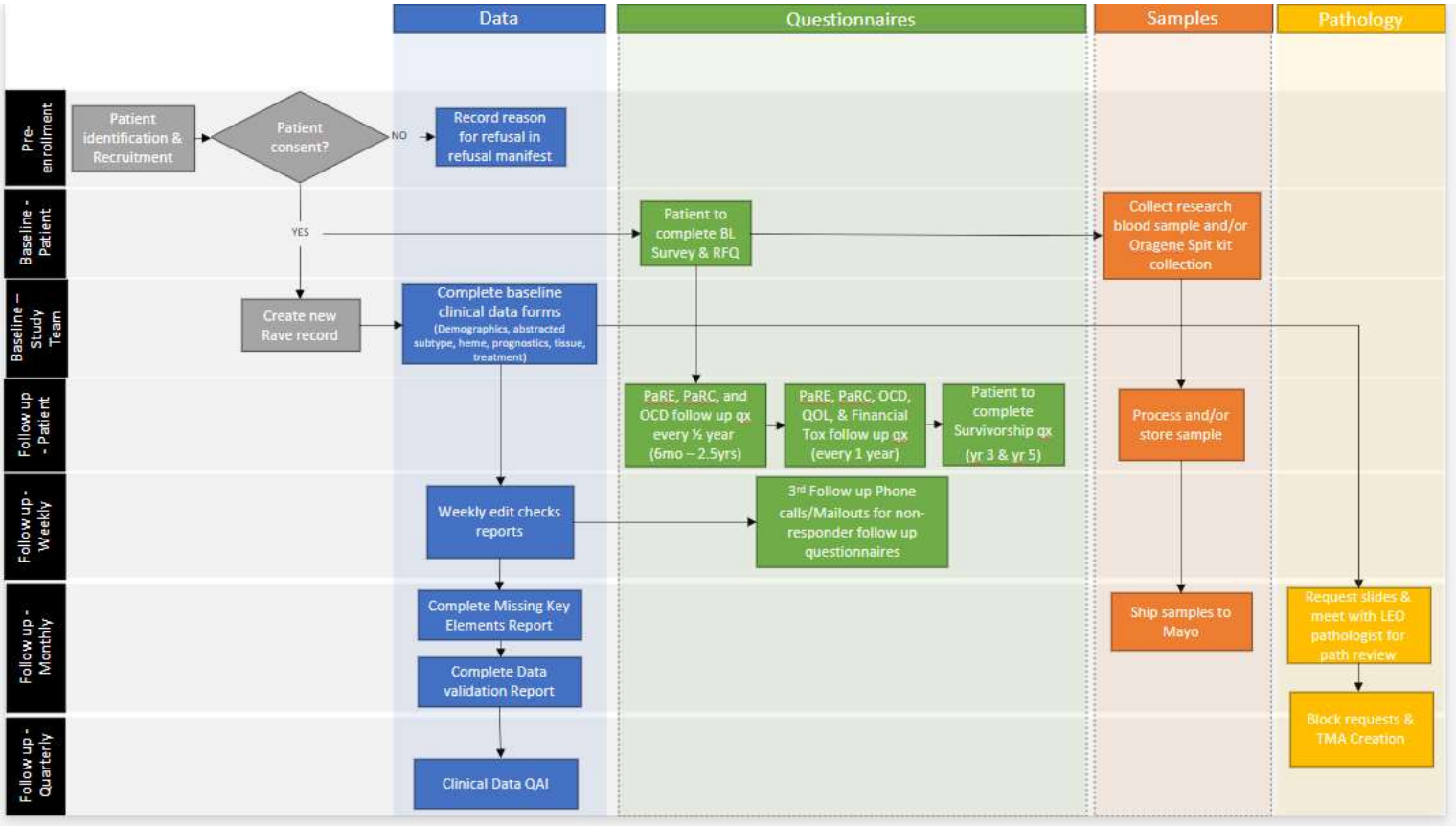
		n. Column 5: Any additional notes/comments can be listed here 12. Pathology o. Column 2: list the Primary Clinical and Primary Path subtype as recorded in the Abstracted Subtype form p. Column 3: enter the LEO Center Pathology Review Subtype as recorded in the LEO Center Pathology Review Form q. Column 4: i. Select concordant if subtype matches across all fields i. Select discordant if subtype does not match r. Column 5: Enter any notes 13. ECOG Performance Status s. Column 2: select the ECOG performance status as recorded in the RAVE Prognostic Factors form, if the field is blank in RAVE, select the “field not complete” checkbox t. Column 3: Select yes or no if the ECOG performance status was specifically listed in the clinical note u. Column 4: select appropriate checkbox based on if changes were need in RAVE or not v. Column 5: Enter any notes 14. Stage w. Column 2: Enter the stage as recorded in the RAVE Prognostic Factors Form, if the field is blank, select the “field not complete” checkbox x. Column 3: Select yes or no based on if the stage was specifically mentioned in the clinical note y. Column 4: select appropriate checkbox based on if changes were need in RAVE or not z. Column 5: Enter any notes 15. Bone Marrow Involvement aa. Column 2: Enter the bone marrow involvement as recorded in the RAVE Prognostic Factors Form, if the field is blank, select the “field not complete” checkbox bb. Column 3: Enter how bone marrow involvement was deter cc. Column 4: select appropriate checkbox based on data recorded in the RAVE Prognostic Factors form dd. Column 5: Enter any notes 16. Extranodal Sites of Disease	

		ee. Column 2: enter the Extranodal involvement as recorded in the RAVE Prognostic Factors Form ff. Column 3: List three extranodal sites as recorded in the RAVE Prognostic Factors Form gg. Column 4: select appropriate checkbox based on data recorded in the RAVE Prognostic Factors form hh. Column 5: Enter any notes 17. LDH & ULN ii. Column 2: Record the LDH Value as recorded in the RAVE Heme screen, if the field is blank, select the "field not complete" checkbox jj. Column 3: Select yes/no based on if the ULN (upper limit of normal) was recorded in the RAVE Heme Screen. If yes, enter the ULN value kk. Column 4: select appropriate checkbox based on data recorded in the RAVE Heme form ll. Column 5: Enter any notes 18. Treatment #1 (Baseline) mm. Column 2: Enter treatment regimen as listed in RAVE Treatment form, if field is blank, select "field not complete" checkbox nn. Column 3: Enter treatment start date as listed in RAVE Treatment form, if field is blank, select "field not complete" checkbox oo. Column 4: select appropriate checkbox based on data recorded in the RAVE Treatment form pp. Column 5: Enter any notes 19. Date of Progression/Relapse qq. Column 2: If patient has not progressed, select N/A. If patient has progressed or relapsed, select "Patient Progressed" and enter date of progression. Check yes or no regarding PI verification of progression on Progression/Retreatment form. rr. Column 3: N/A ss. Column 4: Select appropriate checkbox based on data recorded in the RAVE progression form. tt. Column 5: Enter any notes. 20. Date of Death uu. Column 2: If patient is alive, select N/A, if patient is deceased, select "patient deceased" and enter date of death as recorded in the RAVE Death Form ***NOTE: Assure patient status is also listed as deceased*** vv. Column 3: N/A	

		ww. Column 4: select appropriate checkbox based on data recorded in the RAVE Treatment form xx. Column 5: Enter any notes 21. COD (Cause of Death) yy. Column 2: If patient is alive, select "N/A Patient Alive" and skip to #18. If patient is deceased, enter information as recorded in the RAVE Death form zz. Column 3: Select checkbox as recorded in RAVE Death Form – Cause of Death aaa. Column 4: select appropriate checkbox based on data recorded in the RAVE Treatment form bbb. Column 5: Enter any notes 22. FU Status Recorded ccc. Column 2: Enter date of last clinical assessment as recorded in RAVE Last Clinical Assessment Form ***NOTE: If there is no Last Clinical Assessment Form, select "add form" and enter form*** ddd. Column 3: N/A eee. Column 4: select appropriate checkbox based on data recorded in the RAVE Treatment form fff. Column 5: Enter any notes	
4	Center completes PI Review of form	23. Coordinator and PI meet in person to review each field of the QAI form together for accuracy and completeness	
5	Center Signs form	24. PI and Coordinator both sign and date the form once complete	
6	Document QAI completion in RAVE	25. From the 'Add Event' drop down menu select 'Quality Assurance' 26. Open the 'Quality Assurance' form using the navigation panel on the left side of the screen. 27. Enter the date the QAI was completed. 28. Save form.	
7	Center uploads/sends completed forms	29. Once all reviews are complete for the quarter, scan in completed QAI forms to one .pdf and upload to center's QAI folder in synapse.	

Appendix

Appendix A: LEO Study Process Map



Appendix B: LEO Reminder Schedule

Weekly	Monday	Reports	Follow-Up Lists Uploaded to Synapse
		Reports	Weekly Edit Check Reports Uploaded to Synapse
Monthly	15th	RFQ Upload	Final Upload Date for Risk Factor Questionnaires
		Invoicing	Submit LEO Subaward Invoices to Mayo (for previous month)
Monthly	1st	Reports	Missing Data Reports Uploaded to Synapse
		Pathology	All Subtype Slide Manifest Uploaded to Synapse
Monthly	20th	Refusal/NR	Send Monthly Refusal/NonResponder Manifest to leocohort@mayo.edu
Monthly	First Monday	IRB	IRB Modifications Submitted
Monthly	First Friday	Blood	Submit LEO Blood Manifest to Synapse
Monthly	First Thursday	Blood	Reminder to Ship LEO Bloods in 2 days
Monthly	Second Monday	Blood	Ship LEO Bloods
Quarterly		Pathology	Last day to enter center pathology review forms into RAVE to be included on upcoming block manifest
Quarterly		Pathology	DLBCL, MCL, FL block manifest generated for previous quarter
Quarterly		Pathology	Earliest day to ship previous quarter's blocks to Mayo
Quarterly		Pathology	Last day to ship previous quarter's blocks to Mayo

GENERAL (reports, uploads, IRB) (ALL)

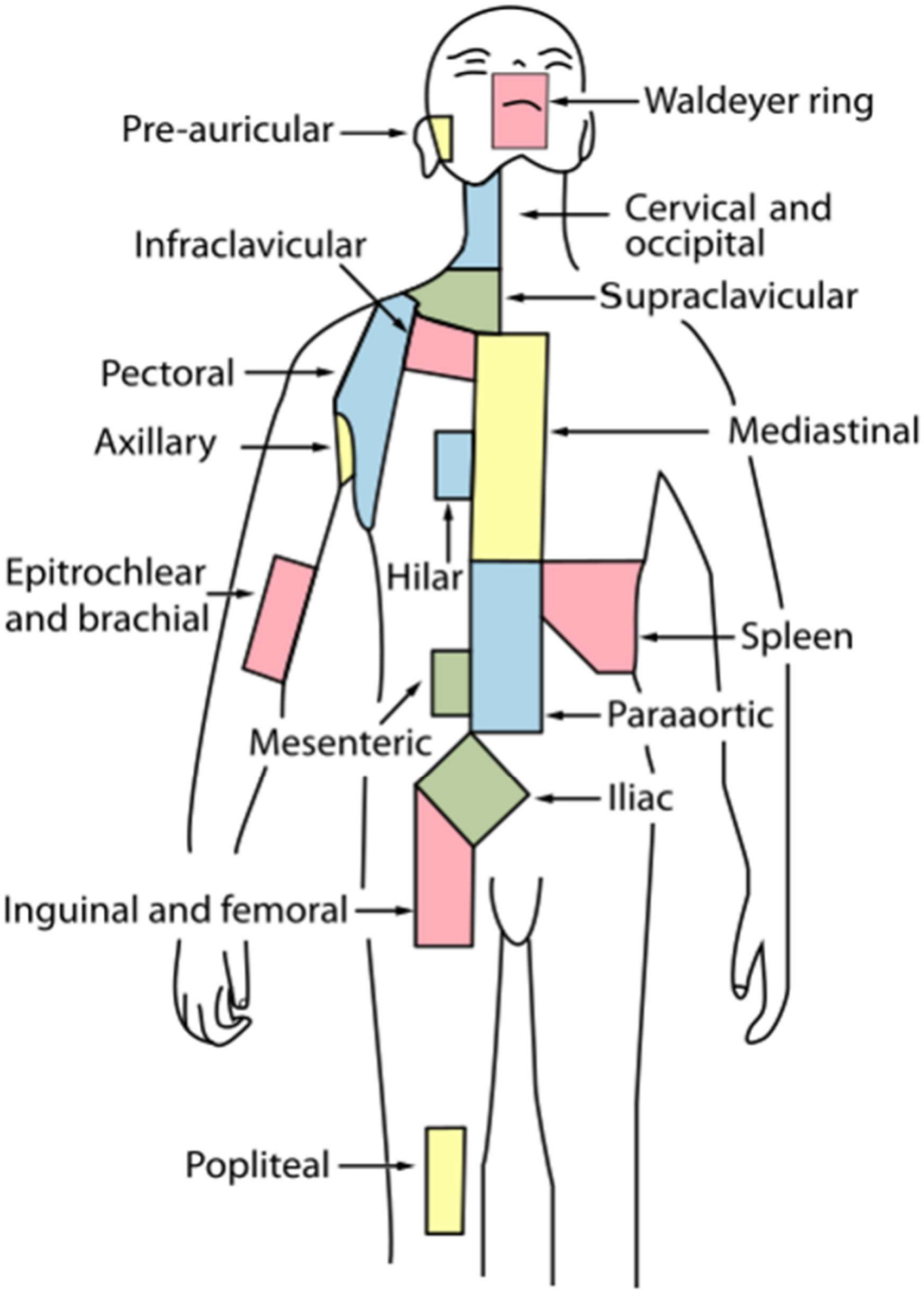
PATHOLOGY (Specific)

INVOICING (Specific)

BLOOD (Specific)

Appendix C: Nodal & Extranodal Reference Sheet

Nodal Sites	**Extranodal Sites**
axillary	Blood
celiac	Bone
cervical	Brain-parenchymal or cranial nerve
common illac	Breast
epitrochlear	CNS
external illac	Colon
femoral	Kidney/Adrenal Gland
hilar	Leptomeingeal or CSF
lower cervical	Liver
mediastinal	Lung
mesenteric	Mesentery
paraaortic	Nasal
paratracheal	Ocular/Eye
popliteral	Ovary
portal	Pancreas
posterior cervical	Parotid gland
pre-auricular	Pleura
retrocrural	Sinus
spleen	Skin (Cutaneous)
splenic hilar	Small bowel
supraclavicular	Soft tissue
tonsils	Spinal cord-parenchymal or spinal nerve
upper cervical	Stomach
Waldeyer's ring	Subcutaneous
	Submandibular gland
	Testes
	Thymus
	Thyroid
	Tongue
	Other, specify:


Waldeyer ring
Pre-auricular
Cervical and occipital
Infraclavicular
Supraclavicular
Pectoral
Mediastinal
Axillary
Epitrochlear and brachial
Hilar
Spleen
Paraaortic
Mesenteric
Iliac
Inguinal and femoral
Popliteal

Appendix D: Treatment List

Stats Code	Name in RAVE	Scientific Name	Abbreviation/Nicknames	Trade name	Combo Drugs
-1	Died prior to therapy initiation				
0	Observation (initial therapy only)				
1	cladribine (Leustatin)	cladribine	2CDA	Leustatin	
2	ABVD				dox, bleo, vinblastine, dacarbazine
3	alefecept (Amevive)	alefecept	LFA3TIP	Amevive	
4	alemtuzumab (Campath)	alemtuzumab	anti CD52	Campath	
5	Antibiotics				
6	BCNU	carmustine	BCNU	BiCNU, Becenum, Carmubris	
7	BEAM				BCNU, etoposide, ARA-C, melphalan
8	bendamustine (Treanda)	bendamustine	Benda	Treanda	
9	bleomycin (Blenoxane)	bleomycin sulfate	BLEO, BLM	Blenoxane	
10	bortezomib (Velcade)	bortezomib	PS-341	Velcade	
11	brentuximab (Adcetris)	brentuximab vedotin	SGN-35	Adcetris	
12	carboplatin (Paraplatin)	carboplatin	CBDCA	Paraplatin	
13	CEB				CTX, etoposide, BCNU
14	CEPP				CTX, etoposide, procarbazine, prednisone
15	chlorambucil (Leukeran)	chlorambucil		Leukeran	
16	CHOP				CTX, dox, VCR,

					prednisone
17	cisplatin (Platinol)	cisplatin	CDDP	Platinol	
18	CPG	agatolimod sodium	CPG, CPG 7909		
19	CVP				CTX, VCR, prednisone
20	cyclophosphamide (Cytoxan)	cyclophosphamide	CTX	Cytoxan, Neosar, Clafen	
21	cyclosporin (Noral)	cyclosporin	CsA, CYSP	Neoral, Sandimmun	
22	cytarabine (ARA-C)	cytarabine	ARA-C	Cytosar-U	
23	dacarbazine (DTIC)	dacarbazine	DTIC	DTIC-Dome	
24	daunorubicin (Cerubidine)	daunorubicin	rubiomycin, daunomycin,	Cerubidine	
25	dexamethasone (Decadron)	dexamethasone	DXM, dex	Decadron, Dexasone, Diodex	
26	DHAP				dex, cisplatin, ARA-C
27	doxorubicin, liposomal (Doxil)	doxorubicin liposomal	dox	Doxil	
28	doxorubicin (Adriamycin)	doxorubicin	dox, anthra	Adriamycin, Rubex	
29	EPOCH		DA-EPOCH		etoposide, CTX, dox, VCR, prednisone
30	REPOCH		DA-EPOCH-R		R + etoposide, CTX, dox, VCR, prednisone
32	ESHAP				etoposide, solu-medrol, ARA-C, cisplatin
33	etoposide (Toposar)	VP-16	VP-16	Toposar, VePesid, Etopophos	
34	everolimus (RAD001, Afinitor)	everolimus	RAD001	Afinitor	
35	FCR				fludarabine, CTX, R
36	fludarabine (Fludara)	fludarabine	2-F-ara-AMP	Fludara	

		phosphate			
37	gemcitabine (Gemzar)	gemcitabine hydrochloride	LY-188001, dFdC	Gemzar	
38	high dose methotrexate	methotrexate	MTX	Rheumatrex, Trexall	
39	Hyper-CVAD Reg A				CTX, dex, VCR, dox
40	Hyper-CVAD Reg B				MTX, ARA-C
41	ICE				ifosfamide, carboplatin, etoposide
42	ifosphamide (Ifex)	ifosfamide	IFF, IFO, IFX, IPP	Ifex, Cyfos, Ifosfamidum	
43	interferon (Infergen)	interferon alfacon-1	CIFN	Infergen	
44	intrathecal methotrexate	methotrexate	MTX	Rheumatrex, Trexall	
45	lenalidomide (Revlimid)	lenalidomide	Rev, Len	Revlimid	
46	leucovorin	leucovorin	LV		
47	light therapy				
48	MACOP-B				MTX, dox, LV, CTX, VCR, bleo, pred
49	mechlorethamine (Mustargen)	mechlorethamine hydrochloride	NM, HN2, chloramin, mustard	Mustargen	
50	melphalan (Alkeran)	melphalan	L-PAM, L-Sarcolysin	Alkeran	
51	methotrexate	methotrexate	MTX	Rheumatrex, Trexall	
52	mitoxantrone (Novatrone)	mitoxantrone hydrochloride	DHAD, DHAQ	Novatrone	
53	Modified Bonn (PELS)				MTX, VCR, IFO, dex, pred, ARA-C, CTX, vindesine
54	MOPP				mechlorethamine, VCR, procarbazine, pred

55	Other, specify				
56	oxaliplatin (Eloxatin)	oxaliplatin	1-OHP, L-OHP	Eloxatin	
57	panobinostat (Faridak)	panobinostat	LBH-589	Faridak	
58	PCR				pentostatin, CTX, R
59	pentostatin (Nipant)	pentostatin	DCF	Nipant	
60	photophoresis				
61	prednisone	prednisone	pred	Deltasone, Meticorten	
62	prevpac				
63	procarbazine (Matulane)	procarbazine		Matulane	
64	ProMACE-CytaBOM				pred, MTX, dox, CTX, etoposdie, ARA-C, bleo, VCR
65	PUVA				
66	R-HyperCVAD Reg A				R + CTX, dex, VCR, dox
67	R-HyperCVAD Reg B				R + MTX, ARA-C
68	rapamycin (Rapamune)	rapamycin	RAPA, SLM	Rapamune	
69	RCHOP				R + CTX, dox, VCR, pred
70	RCVP				R + CTX, VCR, pred
71	RESHAP				R + etoposide, solu-medrol, ARA-C, cisplatin
72	RICE				R + ifosfamide, carboplatin, etoposide
73	rituximab (Rituxan)	rituximab	R, IDC-C2B8	Rituxan, MabThera	
75	R-MACOP-B				
77	methylprednisolone (Medrol)	methylprednisolone	MePRDL	Solu-medrol, Medrol,Duralone, Medralone	
78	sorafenib (Nexavar)	sorafenib tosylate	SFN	Nexavar	
79	Stanford V				CTX, dox, vinblastine, VCR, bleo, etoposide, pred

80	bexaroten (Targretin)	bexarotene	LGD1069	Targretin	
81	temozolomide (Temodar)	temozolomide	TMZ	Temodar, Methazolastone	
82	temsirolimus (Torisel)	temsirolimus	CCI-779	Torisel	
83	tipifarnib (Zarnestra)	tipifarnib	R115777	Zarnestra	
84	topical steroids				
86	unknown				
87	Vanderbilt				CTX, etoposide, VCR, dox, bleo, MTX, pred
88	vinblastine (Velbane)	vinblastine	VLB	Alkaban-AQ, Velbane	
89	vincristine (Oncovin)	vincristine	VCR	Oncovin	
90	vinorelbine (Navelbine)	vinorelbine tartrate	NVB, VNB	Navelbine	
91	ibritumomab (Zevalin)	ibritumomab tiuxetan		Zevalin	
92	denileukin difitox (Ontak)	denileukin difitox		Ontak	
93	vcR-CVAD				bortezomib, R, CTX, dox, VCR, dex
94	bevacizumab (Avastin)	bevacizumab	rhuMAb-VEGF	Avastin	
95	BCVPP				BCNU, CTX, VLB, procarbazine, prednisone
96	dacetuzumab	dacetuzumab	SGN-40		
97	vorinostat (Zolzinza)	vorinostat	SAHA	Zolzinza	
98	fostamatinib	fostamatinib disodium	Syk Inhibitor, R788 sodium, R935788	Tavalisse	
99	ofatumumab (Arzerra)	ofatumumab		Arzerra	
100	iratumumab	iratumumab	MDX-060		
101	IVAC				ifosphamide,

					etoposide, ARA-C
102	CODOX-M				CTX, VCR, dox, MTX
103	pralatrexate (Folotyn)	pralatrexate	PDX	Folotyn	
104	ibrutinib (Imbruvica)	ibrutinib	CRA-032765, PCI-32765	Imbruvica	
105	idelalisib (Zydelig)	idelalisib	GS-1101, CAL-101	Zydelig	
106	MRT				R + MTX, TMZ
107	RGDP				R + gemcitabine, dex, cisplatin
108	belinostat (Belodaq)	belinostat	BXD101	Beleodaq	
109	romidepsin (Istodax)	romidepsin	FX228	Istodax	
110	obinutuzumab (Gazyva)	obinutuzumab	GA101	Gazyva	
111	RBendamustine		B-R, R-Benda		R + bendamustine
112	Autologous Stem Cell Treatment		auto		
113	Allogeneic Stem Cell Treatment		allo		
114	Other Stem Cell Treatment				
115	Radiation				
116	Proton beam				
117	Surgery				
118	CAR-T		CTL019, JCAR19, etc		
119	GDP				Gemcitabine, dex, cisplatin
120	BEACOPP				Bleo, etoposide, dox, CTX, vincristine, procarbazine, prednisone
121	CEOP				cyclophosphamide, epirubicin, vincristine, prednisone)
122	Thiotepa (Thioplex)	thiotepa		Thioplex	
123	Nivolumab (Opdivo)	nivolumab	BMS 936558	Opdivo	
124	Palliative therapy only				

125	Hospice care				
126	Pembrolizumab (Keytruda)	pembrolizumab	MK3475	Keytruda	
127	Venetoclax (VENCLEXTA)	venetoclax			
128	SMILE				dex, MTX, ifosfamide, l-asparaginase, etoposide
129	CHOEP				etoposide, CTX, dox, VCR, prednisone
130	axicabtagene ciloleucel (Yescarta)	Axicabtagene Ciloleucel	KTE-C19, KITE CAR-T, axi-cel	Yescarta	
131	acalabrutinib (Calquence)		ACP-196	Calquence	
132	copanlisib (Aliqopa)	copanlisib		Aliqopa	
133	tisagenlecleucel (Kymriah)	tisagenlecleucel	Novartis CAR-T	Kymriah	
134	subcutaneous rituximab (Rituxan Hycela)				
135	O-Bendamustine		O-R, O-Benda		obinutuzumab + bendamustine
136	R-GemOx				R + gemcitabine + oxaliplatin
137	Refused conventional therapy				
138	R-DHAP				R + dex, cisplatin, ARA-C
139	zanibrutinib (Brukinsa)	zanibrutinib		Brukinsa	
140	duvelisib (Copiktra)	duvelisib		Copiktra	
141	mogamulizumab (Poteligeo)	mogamulizumab		Poteligeo	
142	polatuzumab (Polivy)	polatuzumab Vedotin		Polivy	
143	selinexor (Xpovio)	selinexor		Xpovio	

144	tazemetostat (Tazverik)	tazemetostat hydrobromide		Tazverik	
145	Tafasitamab	tafasitamab	MOR208	Monjuvi	
146	Bi-specific antibody (trial)				
147	rituximab biosimilar			Truxima, ruxience	
148	R-DHAX				R + dex, oxaliplatin, ARA-C
149	Nordic				R-maxi-CHOP + HiDAC
150	R-maxiCHOP				R + dose intensified CHOP
151	R-HiDAC				rituximab + hi-dose ARA-C
152	VR-CAP				bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone
153	R-lenalidomide		R2		rituximab + lenalidomide
154	brexucabtagene autoleucel (Tecartus)	Brexucabtagene autoleucel		Tecartus	
155	lisocabtagene maraleucel (Breyanzi)	lisocabtagene maraleucel	liso-cel	Breyanzi	
156	R-BAC (rituximab, bendamustine, low dose cytarabine)				
157	loncastuximab tesirine (Zynlonta)	loncastuximab tesirine	lonca, ADCT402	Zynlonta	
158	CAR-T (other/local manufacture)				
159	mosunetuzumab	mosunetuzumab	RG7828		

160	odronextamab		REGN1979		
161	epcoritamab	epcoritamab	GEN3013		
162	glofitamab	glofitamab	RO7082859		
163	blinatumomab	blinatumomab			
164	plamotamab				
165	azacitidine (Vidaza)	azacitidine	CC-486	Vidaza	
166	BV-CHP				brentuximab + cyclophosphamide, doxorubicin, prednisone
167	BV-AVD				brentuximab + doxorubicin, vinblastine, dacarbazine
168	CHP				cyclophosphamide, doxorubicin, prednisone
169	placebo vs active (blinded)				
170	asparaganase (Elspar)		L-asparaginase, ASP-1, pegaspara ganase	Elspar, Oncaspar	
171	prephase steroids				
172	AVD				doxorubicin, vinblastine, dacarbazine
173	CALGB 10403		AYA Regimen		
174	busulfan				
175	pirtobrutinib	pirtobrutinib	LOXO-305		
176	R-BAC				
177	R-MVP		R-MPV		Rituximab + methotrexate, Procarbazine, Vincristine
178	umbralisib (Ukoniq)	umbrali		Ukoniq	

		sib			
179	parsaclisib				
180	MATRIX				methotrexate, cytarabine, thiotepa, rituximab
181	ipilimumab (Yervoy)	ibilimumab		Yervoy	
182	durvalumab (Imfinzi)	durvalumab		Infinzi	
183	crizotinib (Xalkori)	crizotinib		Xalkori	
184	Teddi-R				Temozolomide, Etoposide, Doxil, Dexamethasone, Ibrutinib, and Rituximab

Appendix E: QAI Form

LOCAL ID _____	LEO ID _____	Date of Consent _____
Patient DOB _____		Diagnostic Biopsy Date _____

Instructions:
Originally abstracted data in RAVE in column 2. Document any corrections in column 4.
Following this QAI review and approval from your center PI, please make all noted corrections in RAVE.

1. Field / Form in RAVE	2. Original Abstracted Data in RAVE	3. Notes	4. Coordinator / PI Changes to be made in RAVE	5. Notes / Center Specific Comments
Pathology Abstracted Subtype Forms (Subtype Folder)	Clinical Primary Subtype _____ Path Report Primary Subtype _____	LEO Center Pathology Review – Subtype _____	☐Concordant ☐Discordant	
ECOG Performance Status / Prognostic Factors Form (Onstudy/Enrollment Folder)	☐ 0 ☐ 1 ☐ 2 ☐3 ☐ 4 ☐ Field Not Complete	ECOG listed in the clinical note? ☐ Yes ☐ No	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
Stage / Prognostic Factors Form (Onstudy/Enrollment Folder)	☐ I ☐ II ☐ III ☐ IV ☐ Field Not Complete	Staging Listed in the clinical note? ☐ Yes ☐ No	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
Bone Marrow Involvement / Prognostic Factors Form (Onstudy/Enrollment Folder)	☐ Positive ☐ Negative ☐ Indeterminate ☐BM Biopsy Not Done ☐PET/CT Not Done ☐ Field Not Complete	Documentation: ☐Per Path Report ☐Per PET/CT ☐Both	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
Extranodal sites of disease / Prognostic Factors Form (Onstudy/Enrollment Folder)	☐Extranodal involvement ☐No EN involvement	List up to 3 EN sites: _____ _____ _____	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
LDH + Upper limit of normal for lab / Heme Form (Onstudy/Enrollment Folder)	LDH Value in RAVE: _____	ULN recorded? ☐ Yes ☐ No ULN Value:	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	

	☐Field Not Complete	_____		
Treatment #1 (Baseline) Regimen / Treatment Form	Regimen: _____ ☐Field Not Complete	Start Date: ____/____/____ ☐Field Not Complete	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
Date of Progression/Relapse (Progression/Retreatment form)	☐ N/A No Progression ☐Patient Progressed Date of Progression: ____/____/____ Has PI Verified relapse ? ☐Yes ☐ No		☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
Date of Death / Subject Status Form	☐ N/A Patient Alive ☐Patient Deceased Date of Death: ____/____/____		☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
COD	☐ N/A Patient Alive If Patient is Deceased: ☐COD Form Complete ☐COD Form Not Complete Has PI Verified COD ? ☐Yes ☐ No	☐Due to Disease ☐Lymphoma Trt Related ☐Infection ☐Cardiotoxicity ☐Secondary MDS/AML ☐Other malignancy ☐Other _____	☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	
FU Status Recorded / Last Clinical Assessment Form[1]	Date: ____/____/____		☐Data in RAVE is Correct ☐ Changes per PI / Coordinator Review:	

[1] If this form is not completed at the time of coordinator abstraction, please complete.

Printed Principal Investigator Name:
_____

Printed Research Coordinator Name:
_____

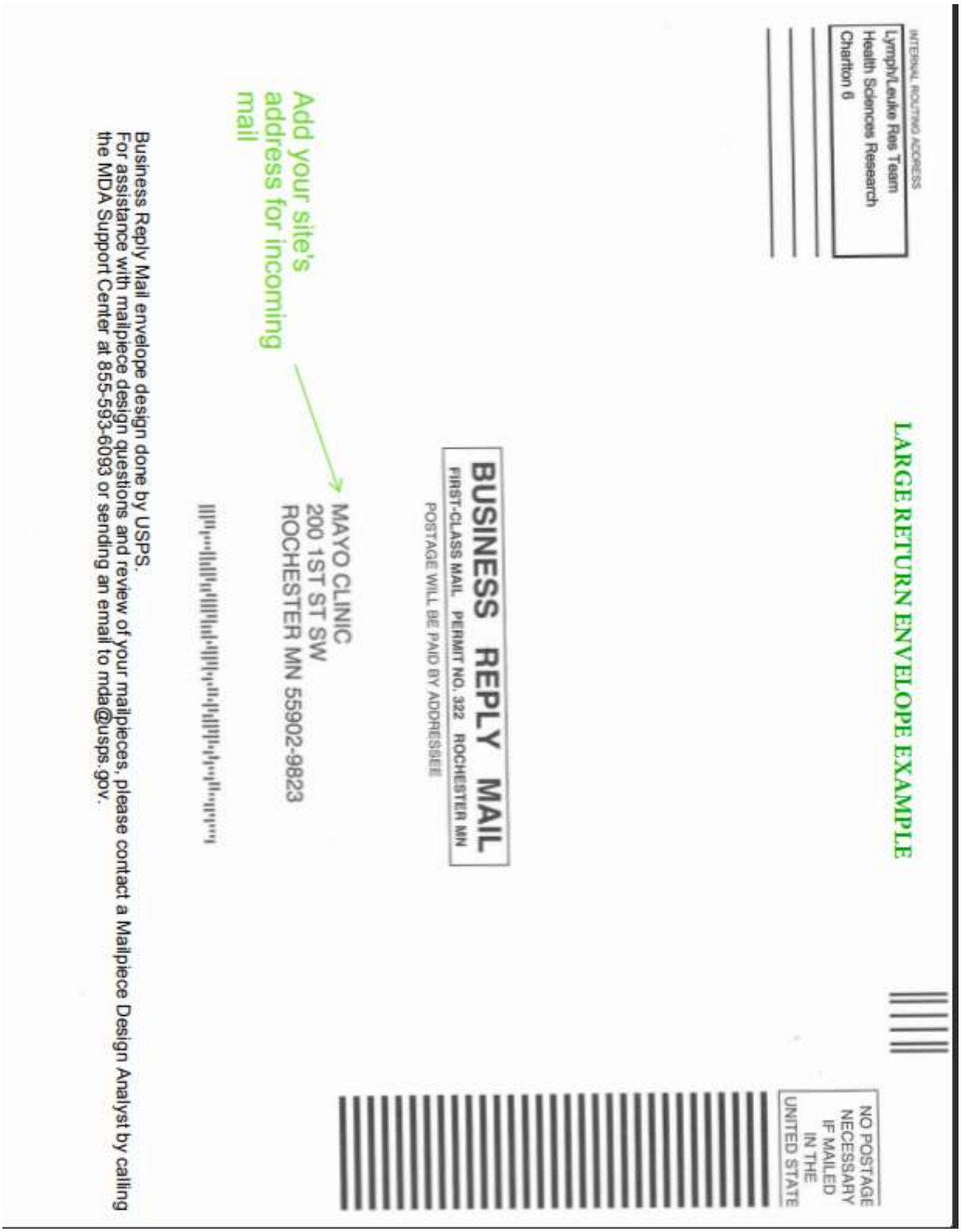
Principal Investigator Signature:
_____

Research Coordinator Signature:
_____

Date:
_____/_____/_____

Date:
_____/_____/_____

Appendix F: Return Envelope Example



Appendix G: LEO Central Pathology Review Process for TMA creation/ Cores for DNA and RNA Extraction (DLBCL, FL, MCL, TCL, MZL)

LEO Site CRA: Obtain H&Es (DLBCL, MCL, FL, TCL, MZL)

- Manifest of potential cases pulled from RAVE
  - separated by site & subtype
- Manifests uploaded into Synapse
- LEO site coodinators call all cases on the manifests
- LEO site coordinators record outcome of attempt to obtain H&E slides in RAVE and manifest

LEO Site CRA & Pathologist: Pathology Review

- Case slides, clinical subtype (LEO Enrollment Subtype form in RAVE) and pathology reports reviewed by site pathologist
  - subtype verification
  - block selection/ranking (1-4)
  - problem cases identified (Ex: mismatch with clinical dx)
    - will require clinical/path discussion
- LEO diagnosis (correlation between path & clincial) call
- Result of review recorded on manifest and in RAVE

LEO Site CRA: Obtain Blocks

- LEO site coordinators call selected blocks
- LEO site coordinators record outcome of request on manifest and RAVE
- LEO site coordinators send blocks to Mayo Clinic for central review and processing

LEO Path Core CRA & Pathologist: Block H&E, TMA creation/Coring, 45 days

- H&E cut from each block for central review
- Central review
  - circle block for coring, review subtype against LEO site call
- TMAs created by Pathology Research Core (PRC) mincore automated TMA machine
  - block will not be depleted
- 8 total cores
  - TMA (2x1mm cores in TMA + sister) max 30 cases/TMA
    - created by subtype, multiple LEO sites on same TMA
  - 4x1mm cores taken for up-front RNA and DNA extraction
- Blocks returned to LEO sites within 45 days of receipt

Appendix H: LEO Pathology Review Form

	Sample Date: **Internal Accession #:** **External Accession #:** **Location Institution:**	
	Baseline Clinical Primary Subtype (Coordinator Abstracted): **Clinical Subtype Subclassification:**	
	Baseline Clinical Secondary Subtype (Coordinator Abstracted): **Clinical Subtype Subclassification:**	
For Pathology Review Session Only	**Pathology Report Primary Subtype:** **Subclassification:**	
	Pathology Report Secondary Subtype: **Subclassification:**	
	Date of Pathologist Review: _____ ☐**Pathology Report Only Review**	
	Outcome of Review:	☐Too Small (not sufficient for coring) ☐Sufficient for coring (8x1mm cores) ☐Problem Case (needs further review) ☐ICC vs WHO Discrepancy
	Ranking:	Block 1: _____ Block 2: _____ Block 3: _____ Block 4: _____
	LEO Subtype: **(Use WHO5 Classification for diagnoses on or after 1/1/2025)**	Primary: _____ Primary Subclassification: _____ Secondary: _____ Secondary Subclassification: _____

*****Clinical Marker Review on Second Page- Complete for Large B-cell, T-cell, MCL, MZL, LPL**

Study ID/MRN: LEO ID: Sample # from Tissue Form: Accession Number:

Instructions: When working with a range, always use higher % when entering pathology markers

Key: IHC/Special Stain FISH Molecular □ Done, Not Reported = DNR

Large B cell lymphoma (IHC and FISH)					
CD10	□ < 30 % □ >= 30% _____ % positive □ Not Done		***MYC* (FISH) Translocation**	□ Yes □ No	□ DNR □ Not Done
BCL2	□ < 50 % □ >= 50% _____ % positive □ Not Done		***MYC* Extra Copies**	□ Yes □ No	□ DNR □ Not Done
MYC	□ < 40 % □ >= 40% _____ % positive □ Not Done		***BCL2* (FISH) Translocation**	□ Yes □ No	□ DNR □ Not Done
BCL6	□ < 30 % □ >= 30% _____ % positive □ Not Done		***BCL2* Extra Copies**	□ Yes □ No	□ DNR □ Not Done
IRF4/MUM1	□ < 30 % □ >= 30% _____ % positive □ Not Done		***BCL6* (FISH) Translocation**	□ Yes □ No	□ DNR □ Not Done
ALK	□ Positive □ Negative □ Not Done		***BCL6* Extra Copies**	□ Yes □ No	□ DNR □ Not Done
Ki67	_____ % positive □ Not Done		**Cell of Origin (Hans)**	□ GCB □ non-GCB	□ Unknown
EBV (EBER)	□ Positive □ Negative □ Not Done		**Cell of Origin (Nanostring):**	□ GCB □ ABC	□ Unclassified □ Not done
Mantle cell lymphoma (IHC and FISH)					
Cyclin D1/BCL1 IHC	□ Positive □ Negative □ Not Done		***CCND1* FISH**	□ Yes □ No	□ DNR □ Not Done
Ki67%	_____ % positive □ Not Done				
Marginal zone and Lymphoplasmacytic lymphomas (IHC and FISH)					
***MYD88* L265P**	□ Yes □ No	□ DNR □ Not Done	***H. pylori***	□ Positive □ Negative □ H&E □ Special stain	□ Not Done □ IHC
T cell lymphomas (IHC or Flow, ISH, Molecular)					
CD10	□ Positive □ Negative □ Not Done		**CXCR3**	□ Positive □ Negative	□ Not Done
BCL6	□ Positive □ Negative □ Not Done		**GATA3**	□ Positive □ Negative	□ Not Done
ALK	□ Positive □ Negative □ Not Done		**Granzyme B**	□ Positive □ Negative	□ Not Done
EBV (EBER)	□ Positive □ Negative □ Not Done		**ICOS**	□ Positive □ Negative	□ Not Done
CD2	□ Positive □ Negative □ Not Done		**PD1**	□ Positive □ Negative	□ Not Done
CD3	□ Positive □ Negative □ Not Done		**Perforin**	□ Positive □ Negative	□ Not Done
CD4	□ Positive □ Negative □ Not Done		**TBX21**	□ Positive □ Negative	□ Not Done
CD5	□ Positive □ Negative □ Not Done		**TCR BF1**	□ Positive □ Negative	□ Not Done
CD7	□ Positive □ Negative □ Not Done		**TCR GD**	□ Positive □ Negative	□ Not Done
CD8	□ Positive □ Negative □ Not Done		**TIA1**	□ Positive □ Negative	□ Not Done
CD15	□ Positive □ Negative □ Not Done		***IDH* R172**	□ Positive □ Negative	□ Not Done
CD30	□ Positive □ Negative □ Not Done		**pSTAT3-Y705**	□ < 30 % □ >= 30% _____ % positive □ Negative □ Not Done	
CCR4	□ Positive □ Negative □ Not Done		***DUSP22*-R (FISH)**	□ Positive □ Negative □ Not Done □ Equivocal	□ DNR

CXCL13	□ Positive □ Negative □ Not Done		*TP63*-R (FISH)	□ Positive □ Negative □ DNR □ Not Done □ Equivocal

Appendix I: LEO Subtype Codes

code	format	Subtype
1	1=Adult T-cell leukemia/lymphoma (MER1/WHO4R/WHO5/ICC)	TCL
2	2=Primary cutaneous anaplastic large cell lymphoma (WHO4R/WHO5/ICC)	TCL
4	4=Angioimmunoblastic T-cell lymphoma (MER1/WHO4R)	TCL
4	4=Nodal TFH cell lymphoma, angioimmunoblastic-type (WHO5)	TCL
4	4=TFH cell lymphoma, angioimmunoblastic type (ICC)	TCL
5	5=B cell unclassifiable with features indeterminate between DLBCL and Burkitt (MER1)	LBCL
6	6=B cell unclassifiable with features intermediate between DLBCL and Hodgkin (WHO4R)	LBCL
6	6=Mediastinal grey zone lymphoma (WHO5/ICC)	LBCL
8	8=Burkitt lymphoma (WHO4R/WHO5/ICC)	Other B
10	10=Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (MER1/WHO4R/WHO5/ICC)	CLL/SLL
12	12=Enteropathy-associated T-cell lymphoma (WHO4R/WHO5/ICC)	TCL
13	13=Extranodal marginal zone (MALT) (MER1/WHO4R)	MZL
13	13=Extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma) (WHO5/ICC)	MZL
14	14=Extranodal NK/T-cell lymphoma (WHO5)	TCL
14	14=Extranodal NK/T-cell lymphoma, nasal type (MER1/WHO4R/ICC)	TCL
18	18=Hepatosplenic T-cell lymphoma (MER1/WHO4R/WHO5/ICC)	TCL
20	20=Immunodeficiency-associated lymphoproliferative disorders (MER1/WHO4R/ICC)	Other NHL
21	21=T-cell large granular lymphocytic leukemia (WHO4R/WHO5/ICC)	TCL
22	22=Low-grade B-cell NOS (WHO4R/WHO5/ICC)	Other B
26	26=Lymphoplasmacytic lymphoma (MER1/WHO4R/WHO5/ICC)	Other B
27	27=Mantle cell lymphoma (MER1/WHO4R/WHO5/ICC)	MCL
29	29=Primary mediastinal (thymic) large B-cell lymphoma (WHO4R/WHO5/ICC)	LBCL
31	31=Mycosis fungoides (WHO4R/WHO5/ICC)	TCL
32	32=Nodal marginal zone B-cell lymphoma (MER1/WHO4R)	MZL
32	32=Nodal marginal zone lymphoma (WHO5/ICC)	MZL
33	33=Nodular lymphocyte predominant B cell lymphoma (ICC)	HL
33	33=Nodular lymphocyte predominant Hodgkin lymphoma (MER1/WHO4R/WHO5)	HL
35	35=Other B-lineage neoplasm (WHO4R/WHO5/ICC)	Other B
36	36=Other Hodgkin lymphoma (WHO4R)	HL
37	37=Other lymphoid neoplasm (WHO4R/WHO5/ICC)	Other NHL
38	38=Other T/NK-cell neoplasm (WHO4R/WHO5/ICC)	TCL
39	39=Peripheral T-cell lymphoma, not otherwise specified (WHO4R/WHO5/ICC)	TCL
42	42=Primary DLBCL of CNS (WHO4R/WHO5/ICC)	LBCL
44	44=Primary effusion lymphoma (MER1/WHO4R/WHO5/ICC)	Other NHL
45	45=Post-transplant lymphoproliferative disorder (PTLD) (WHO4R/WHO5/ICC)	Other NHL
46	46=Sezary syndrome (MER1/WHO4R/WHO5/ICC)	TCL
47	47=Splenic marginal zone lymphoma (MER1/WHO4R/WHO5/ICC)	MZL
48	48=Subcutaneous panniculitis-like T-cell lymphoma (MER1/WHO4R/WHO5/ICC)	TCL
61	61=B-cell prolymphocytic leukemia (WHO4R/ICC)	Other NHL
62	62=Hairy cell leukemia (WHO4R/WHO5/ICC)	Other NHL
63	63=Splenic B-cell lymphoma/leukemia, unclassifiable (WHO4R/ICC)	Other NHL

64	64=Splenic diffuse red pulp small B-cell lymphoma (WHO4R/WHO5/ICC)	Other NHL
65	65=Hairy cell leukemia - variant (WHO4R/ICC)	Other NHL
65	65=Splenic B-cell lymphoma/leukaemia with prominent nucleoli (SBLPN) (WHO5)	Other NHL
66	66=Follicular lymphoma (WHO4R/ICC)	FL
67	67=Primary cutaneous follicle center lymphoma (WHO4R/WHO5/ICC)	Other NHL
68	68=Diffuse large B-cell lymphoma (DLBCL), NOS (WHO4R/WHO5/ICC)	LBCL
69	69=T-cell/histiocyte rich large B-cell lymphoma (WHO4R/WHO5/ICC)	LBCL
70	70=Primary cutaneous DLBCL, leg type (WHO4R/WHO5/ICC)	LBCL
71	71=EBV positive DLBCL of the elderly (MER1)	LBCL
72	72=DLBCL associated with chronic inflammation (WHO4R/WHO5/ICC)	LBCL
73	73=Lymphomatoid granulomatosis (WHO4R/WHO5/ICC)	LBCL
74	74=Intravascular large B-cell lymphoma (WHO4R/WHO5/ICC)	LBCL
75	75=ALK positive large B-cell lymphoma (WHO4R/WHO5/ICC)	LBCL
76	76=Plasmablastic lymphoma (WHO4R/WHO5/ICC)	LBCL
77	77=Large B-cell lymphoma arising in HHV8-associated Castleman disease (MER1)	LBCL
78	78=T-cell prolymphocytic leukemia (WHO4R/WHO5/ICC)	TCL
79	79=Chronic lymphoproliferative disorder of NK cells (WHO4R/ICC)	TCL
79	79=NK-large granular lymphocytic leukaemia (WHO5)	TCL
80	80=Aggressive NK cell leukemia (WHO4R/WHO5/ICC)	TCL
81	81=EBV-positive T- and NK-cell lymphoid proliferations and lymphomas of childhood (WHO5)	TCL
81	81=Systemic EBV positive TCL of childhood (WHO4R/ICC)	TCL
82	82=Hydroa vacciniforme LPD (WHO5/ICC)	TCL
82	82=Hydroa vacciniforme-like LPD (WHO4R)	TCL
83	83=Lymphomatoid papulosis (WHO4R/WHO5/ICC)	TCL
84	84=Primary cutenaous gamma-delta TCL (WHO4R/WHO5/ICC)	TCL
85	85=Primary cutaneous CD4+ small/medium T-cell LPD (WHO4R/WHO5/ICC)	TCL
86	86=Anaplastic large cell lymphoma, ALK positive (WHO4R/WHO5/ICC)	TCL
87	87=Anaplastic large cell lymphoma, ALK negative (WHO4R/WHO5/ICC)	TCL
88	88=Classic Hodgkin lymphoma (WHO5/ICC)	HL
88	88=Classical Hodgkin lymphoma (WHO4R)	HL
89	89=Pediatric nodal marginal zone lymphoma (WHO4R/WHO5/ICC)	MZL
90	90=In situ follicular B-cell neoplasm (WHO5)	FL
90	90=In situ follicular neoplasia (WHO4R/ICC)	FL
91	91=Duodenal-type follicular lymphoma (WHO4R/WHO5/ICC)	FL
92	92=Pediatric-type follicular lymphoma (WHO4R/WHO5/ICC)	FL
93	93=In situ mantle cell neoplasia (WHO4R/ICC)	MCL
93	93=In situ mantle cell neoplasm (WHO5)	MCL
94	94=EBV positive DLBCL, NOS (WHO4R/ICC)	LBCL
94	94=EBV-positive DLBCL (WHO5)	LBCL
95	95=EBV+ mucocutaneous ulcer (WHO4R/WHO5/ICC)	Other NHL
96	96=Large B-cell lymphoma with IRF-4 rearrangement (WHO4R/WHO5/ICC)	LBCL
97	97=Burkitt-like lymphoma with 11q aberration (WHO4R)	LBCL
97	97=High-grade B-cell lymphoma with 11q aberrations (WHO5)	LBCL
97	97=Large B-cell lymphoma with 11q aberration (ICC)	LBCL
98	98=High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements (WHO4R)	LBCL
99	99=High grade B-cell lymphoma, NOS (WHO4R/WHO5/ICC)	LBCL
100	100=Large B-cell lymphoma, unable to distinguish between DLBCL and FL (WHO4R/WHO5/ICC)	LBCL

101	101=Monomorphic epitheliotropic intestinal T-cell lymphoma (WHO4R/WHO5/ICC)	TCL
102	102=Indolent clonal T-cell lymphoproliferative disorder of the GI tract (ICC)	TCL
102	102=Indolent T-cell lymphoma of the gastrointestinal tract (WHO5)	TCL
102	102=Indolent T-cell lymphoproliferative disorder of the GI tract (WHO4R)	TCL
103	103=Primary cutaneous acral CD8-positive LPD (WHO5/ICC)	TCL
103	103=Primary cutaneous acral CD8+ T-cell lymphoma (WHO4R)	TCL
104	104=Follicular T-cell lymphoma (WHO4R)	TCL
104	104=Nodal TFH cell lymphoma, follicular-type (WHO5)	TCL
104	104=TFH cell lymphoma, follicular-type (ICC)	TCL
105	105=Nodal peripheral T-cell lymphoma with TFH phenotyp (WHO4R)	TCL
105	105=Nodal TFH cell lymphoma, NOS (WHO5)	TCL
105	105=TFH cell lymphoma, NOS (ICC)	TCL
106	106=Breast implant-associated anaplastic large cell lymphoma (WHO4R/WHO5/ICC)	TCL
107	107=Florid follicular hyperplasia PTLD (WHO4R/ICC)	Other NHL
107	107=Hyperplasias arising in immune deficiency/dysregulation (WHO5)	Other NHL
108	108=Other (WHO4R)	Other NHL
109	109=ALK-positive histiocytosis (WHO5/ICC)	Other NHL
110	110=Classic FL, grading optional (WHO5)	FL
110	110=FL grades 1, 2 and 3A (ICC)	FL
111	111=DLBCL/High-grade B-cell lymphoma with MYC and BCL2 rearrangements (WHO5)	LBCL
111	111=High-grade B-cell lymphoma with MYC and BCL2 rearrangements (ICC)	LBCL
112	112=EBV+ nodal T- and NK-cell lymphoma (WHO5)	TCL
112	112=Primary nodal EBV-positive T-cell/NK-cell lymphoma (ICC)	TCL
113	113=FL with uncommon features (uFL) (WHO5)	FL
114	114=Fluid overload associated large B cell lymphoma (WHO5)	LBCL
114	114=HHV-8 and Epstein-Barr virus negative primary effusion-based lymphoma (ICC)	Other NHL
115	115=FL grade 3B (ICC)	FL
115	115=Follicular large B cell lymphoma (WHO5)	FL
116	116=Indolent NK-cell lymphoproliferative diorder of the gastrointestinal tract (WHO5/ICC)	TCL
117	117=HHV8-positive DLBCL, NOS (WHO4R/ICC)	Other NHL
117	117=KSHV/HHV8-positive DLBCL (WHO5)	Other NHL
118	118=HHV8-positive germinotropic lymphoproliferative disorder (WHO4R/ICC)	Other NHL
118	118=KSHV/HHV8-positive germinotropic lymphoproliferative disorder (WHO5)	Other NHL
119	119=High-grade B-cell lymphoma with MYC and BCL6 rearrangements (ICC)	LBCL
120	120=Type 2 refractory celiac disease (ICC)	Other NHL
121	121=Other immunodeficiency-related LPD (WHO5/ICC)	Other NHL
122	122=Primary cutaneous marginal zone LPD (ICC)	MZL
122	122=Primary cutaneous marginal zone lymphoma (WHO5)	MZL
123	123=Primary cutaneous peripheral T-cell lymphoma, NOS (WHO5)	TCL
124	124=Primary large B cell lymphoma of the testis (WHO5/ICC)	LBCL
125	125=Primary large B cell lymphoma of the vitreoretina (WHO5)	LBCL
126	126=Aggressive B cell lymphoma, NOS (WHO4R/WHO5/ICC)	LBCL