

Initial Case Quality Control Form

Acute Myeloid Leukemia (LAML)

Instructions: This form should be completed for all cases submitted for TCGA, prior to the shipment of samples to the BCR.

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.

Tissue Source Site (TSS): _____ TSS ID: _____ TSS Unique Patient ID: _____ Interviewer Name: _____ Interview Date ____/____/____

Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form? ☐ Yes ☐ No

Note: Provided time intervals must begin with the date of initial pathologic diagnosis.

Tumor Information: The following sections are to be provided by a Pathologist

#	Question	Entry Alternatives	Working Instructions
1	FAB Category	☐ Biophenotypic ☐ M0 Undifferentiated ☐ M1 ☐ M2 ☐ M3 ☐ M3v ☐ M4 ☐ M4eos ☐ M5 ☐ M6 ☐ M7 ☐ Not Classified ☐ WHO Only	Using the pathology/laboratory report, provide the patient's French American British (FAB) morphologic classification of leukemia. If the FAB classification is not available for this patient, provide the WHO classification below. 3124352
2	Tumor Type	☐ AML with t(8;21)(q22;q22), RUNX1 RUNX1T1 ☐ AML with inv(16)(p13q22) or t(16;16) (p13.1;q22), (CBFβ/MYH11) ☐ AML with t(9;11)(p22;q33);MLL3-MLL ☐ AML with t(6;9)(p23;q34);DEK-NUP214 ☐ AML with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2);RPN1-EV11 ☐ AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1 ☐ AML with mutated NPM1 ☐ AML with mutated CEBPA ☐ AML with minimal differentiation ☐ AML without maturation ☐ AML with maturation ☐ Acute myelomonocytic leukemia ☐ Acute monoblastic/monocytic leukemia ☐ Acute erythroid leukemia ☐ Erythroleukemia, erythroid/myeloid ☐ Acute megakaryoblastic leukemia ☐ Acute basophilic leukemia ☐ Acute panmyelosis with myelofibrosis ☐ AML with myelodysplasia-related changes ☐ FAB Only	Using the pathology/laboratory report, provide the patient's World Health Organization classification, when available. If the WHO classification is not available for this patient, provide the FAB classification above. 3257714
3	Diagnosis: Cytogenetic Analysis Abnormality Type (Check all that apply)	☐ Normal ☐ Not Tested ☐ Complex ☐ inv(3) or t(3;3) ☐ -5, del(5q), 5q- ☐ del(17p) ☐ -7, del(7q), or t(7q), 7q- ☐ +8 ☐ +9 ☐ Trisomy 4 ☐ inv(16) ☐ (q22;q22) ☐ t(6;9) ☐ t(8;21) ☐ t(9;11) ☐ t(4;11) ☐ t(9;22) ☐ t(21;21) ☐ t(15;17) ☐ del(20q) ☐ -13 del(13q) ☐ 3q ☐ Other, specify	Using the patient's laboratory report, provide any cytogenetic abnormalities found. 2760451
4	Diagnosis: Other	_____	If the cytogenetic abnormalities were found for this patient and they are not including in the provided list, specify the

#	Question	Entry Alternatives	Working Instructions
	Cytogenetic Analysis		abnormalities found. 2957553
5	Tumor Type	☐ De novo non-enriched AML specimen*	Indicate the type of tumor submitted for TCGA. 3288124 *NOTE: Ficoll'd samples are preferred.
6	Sample Type of Frozen Biospecimen Submitted	☐ Bone Marrow ☐ Peripheral blood	Provide the type of frozen biospecimen submitted to the BCR. 2735776
Date of Cancer Sample Procurement			
7	Month of Cancer Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197
8	Day of Cancer Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008195
9	Year of Cancer Sample Procurement		Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008199
10	Method of Cancer Sample Procurement	☐ Core Biopsy ☐ Blood Draw ☐ Bone Marrow Aspirate	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
11	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured. 3203072
12	Race	☐ American Indian or Alaska Native A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. ☐ Asian A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. ☐ White A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa. ☐ Black or African American A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." ☐ Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. ☐ Not Reported: Not provided or available. ☐ Unknown: Could not be determined or unsure.	Provide the patient's race using the defined categories. 2192199
13	Ethnicity	☐ Not Hispanic or Latino A person not meeting the definition of Hispanic or Latino. ☐ Hispanic or Latino A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. ☐ Not Evaluated Not provided or available. ☐ Unknown Could not be determined or unsure.	Provide the patient's ethnicity using the defined categories. 2192217

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#	Question	Entry Alternatives	Working Instructions
14	Total Cells Submitted	_____ (10 ⁷ required, 2x10 ⁷ preferred)	Provide the country where the tissue submitted for TCGA was procured. 3203072
15	Percent Myeloblasts for Submitted Specimen	_____%	Provide the total number of cells submitted for TCGA. 3297382
16	Vessel Used	☐ Cryovial ☐ Eppendorf Tube ☐ Other, specify _____	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 3081940
17	Other Vessel Used	_____	If the vessel used to ship the tissue to the BCR is not included in the provided list, specify the vessel used. 3288137
18	Was sample prescreened at site?	☐ Yes ☐ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
19	Will an aspirate slide be sent to the BCR?	☐ Yes ☐ No	Indicate whether a physical top slide for the sample submitted to the BCR will be shipped with the tissue sample. 3081944 <i>Please note: A slide image of a prescreened sample will be needed after the specimen passes all quality controls at the BCR.</i>
20	Will a cytospin slide be submitted to the BCR?	☐ Yes ☐ No	Indicate whether a cytospin slide for the sample submitted to the BCR will be shipped with the tissue sample. 3354862

Tumor Information If the TSS is submitting multiple pieces of the same primary tumor for this case; complete the following information for each piece of tumor sent to the

21	Tumor Identifier	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. 3288096
22	Number of Cells (for this sample)	_____	Provide the number of cells in this sample. 2955950
23	Percent Myeloblasts (for this sample)	_____ (%)	Provide the percent myeloblasts for this sample. 3297383
24	Aspirate Slide/ Digital Image ID #	_____	Provide the slide ID for the aspirate top slide OR the digital slide image being sent to the BCR. 3354867
25	Cytospin Slide ID #	_____	Provide the slide ID for the cytospin slide being sent to the BCR. 3354863

Normal Information A normal control must be present to qualify.

26	Type(s) of Normal Control Check all that apply	☐ Normal Tissue (procured at time of bone marrow aspirate) ☐ Extracted DNA*	Indicate the type of normal control submitted for this case. 3081936 <i>*See Extracted DNA section for special cases that require NCI approval.</i>
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Normal Control: Whole Blood

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#	Question	Entry Alternatives	Working Instructions
<u>27</u>	Method of Normal Sample Procurement	☐ Skin Punch ☐ Other, please specify	Indicate the procedure performed to obtain the tissue submitted for TCGA. 3288147
<u>28</u>	Other Method of Normal Sample Procurement	_____	If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure. 3288151
<u>29</u>	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
<u>30</u>	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
<u>31</u>	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
<u>32</u>	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
<u>33</u>	Anatomic Site of Non-Neoplastic Control Tissue	☐ Skin (6mm punch minimum)	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. 3081938
<u>34</u>	Normal Slide ID#	_____	If the normal control type is normal tissue, provide the slide ID for the physical top slide OR the digital slide image of the normal control being sent to the BCR. 3288217
Normal Control: Extracted DNA from Blood			
<u>35</u>	Source of Extracted DNA	☐ Extracted DNA from Normal Tissue ☐ Extracted DNA from Buccal Swab* ☐ Extracted DNA from Mouthwash*	Indicate the type of normal control submitted for TCGA. 3357428 <i>*Allowable only if approved by the NCI</i>
<u>36</u>	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
<u>37</u>	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
<u>38</u>	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
<u>39</u>	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
<u>40</u>	Extracted DNA Quantity	_____ (µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
<u>41</u>	Extracted DNA	_____	Provide the quantification method of the normal control sample

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#	Question	Entry Alternatives	Working Instructions
	Quantification Method		sent to the BCR for TCGA. 3288186
<u>42</u>	Extracted DNA Concentration	_____ (µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187
<u>43</u>	Extracted DNA Volume	_____ (µL)	Provide the volume (µL) of the normal control sample sent to the BCR for TCGA. 3288188

Verification: By providing the below information, the Principal Investigator acknowledges that the information provided by the institution is true and correct and has been quality controlled.

Pathology Review

Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.

44	Name of Pathologist	_____	Provide the name of the Pathologist that provided the information for all previous sections. 3288225
45	Date of Pathologist Review	_____	Provide the date of the pathology review performed by the TSS pathologist above. 3288224

Principal Investigator/Authorized Designee Confirmation

46	Myeloblasts percentage meets TCGA requirements?	☐ Yes ☐ No	Confirm that the myeloblast percentage, for all samples submitted, meet TCGA requirements. 3354858 Myeloblasts must be ≥ 30% to meet TCGA requirements.
47	De-Identified Pathology Report Submitted?	☐ Yes ☐ No	Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. 3288292
48	Flow Cytometry Report Submitted?	☐ Yes ☐ No	Confirm that a flow cytometry report will be sent to BCR prior to or with the shipment of the physical samples. 3297384
49	Cytogenetic Report Submitted?	☐ Yes ☐ No	Confirm that a cytogenetic report will be sent to BCR prior to or with the shipment of the physical samples. 3297385
50	Differential Report Submitted? (including peripheral blood and bone marrow)	☐ Yes ☐ No	Confirm that a differential report will be sent to BCR prior to or with the shipment of the physical samples. 3297386

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#	Question	Entry Alternatives	Working Instructions
51	Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the TCGA frozen section top slide) consistent with the histology listed in the final diagnosis on the pathology report?	☐ Yes ☐ No	Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted to TCGA is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. 3288300 If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: 1) Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. 2) Diagnosis on the CQCF includes at least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA. 3) Diagnosis on the CQCF is "histology, NOS" (i.e., Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histologic group 4) Diagnosis on the CQCF indicates "Mixed Subtype" and the pathology report lists two or more acceptable subtypes, provided that percent subtype(s) meet applicable TCGA disease-specific requirements.
52	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	☐ Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis (<i>see note at right</i>) ☐ Pathology analysis at TSS determined a specific histological subtype different from original pathology report (<i>see note at right</i>) ☐ Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (<i>see note at right</i>)	If the diagnosis provided on this form is not consistent with the diagnosis found on the pathology report provided, specify a reason for this inconsistency. 3288315 If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the original pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; or in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "TCGA Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.
53	History of Other Malignancy	☐ None ☐ History of Prior Malignancy ☐ History of Synchronous/ Bilateral Malignancy	Indicate whether the patient has a history of malignancies. If the patient has any history, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. 3382736 If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.

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#	Question	Entry Alternatives	Working Instructions
54	History of Neoadjuvant Treatment for Tumor Submitted for TCGA	☐ None ☐ Radiation prior to sample procurement* ☐ Pharmaceutical treatment prior to sample procurement* ☐ Both pharmaceutical treatment and radiation prior to sample procurement*	Indicate whether the patient received therapy for this cancer prior to the sample procurement of the tumor submitted for TCGA . If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. 3382737 <i>*Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the procurement of the sample submitted for TCGA are exclusionary. However, for the melanoma study, patients treated with interferon at least 90 days prior to procurement are accepted into TCGA.</i>
55	Consent Status	☐ Consented ☐ Exemption 4* ☐ Deceased ☐ Waiver*	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. 3288361 <i>*Exemptions and waivers for consent must be approved by NCI.</i>
Date of Consent			
56	Month of Consent	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient was formally consented, provide the month of consent. 3081955
57	Day of Consent	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient was formally consented, provide the day of consent. 3081957
58	Year of Consent	_____	If the patient was formally consented, provide the year of consent. 3081959
Date of Death <i>If the patient formally consented, only supply the date the patient consented.</i>			
59	Month of Death	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient consented by death, provide the month of death. 2897026
60	Day of Death	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient consented by death, provide the day of death. 2897028
61	Year of Death	_____	If the patient consented by death, provide the year of death. 2897030

Principal Investigator or Designee Signature

Print Name

____/____/_____
Date

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.

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Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.

#	Question	Entry Alternatives	Working Instructions
i	Number of Days from Date of Diagnosis to Date of Cancer Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA. 3288495
ii	Number of Days from Date of Diagnosis to Normal Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the normal control sample submitted for TCGA. 3288496
iii	Number of Days from Date of Diagnosis to Date of Pathological Review	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the pathological review performed as part of the submission process for TCGA. 3288497
iv	Number of Days from Date of Diagnosis to Date of Consent	_____ days	If the patient formally consented, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's formal consent. 3288498
v	Number of Days from Date of Diagnosis to Date of Death	_____ days	If the patient consented by death, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's death. 3288499 If the patient formally consented, only supply the date the patient consented.