Cancer Moonshot Biobank: Eligibility

General Criteria

- 13 or older
- Any sex or gender
- ECOG PS of 0,1,2
- Signed informed consent

Patient has clinical presentation consistent with OR has been diagnosed with a listed cancer:

- Colorectal cancer: Stage IV
- Non-small cell or small cell lung cancer: Stage III/IV
- Prostate cancer: metastatic castration-resistant prostate cancer
- Gastroesophageal cancer: Stage IV
- Melanoma: Clinical Stage IV with Pathologic Stage III OR Clinical Stage IV
- Acute myeloid leukemia
- Multiple myeloma

Biospecimens Required at Enrollment

	Clinical enrollment scenarios	Fresh Tissue and Procedure Type	Archival Biospecimen	Blood
a	Undergoing diagnostic workup & treatment will likely include a new regimen from Appendix A	REQUIRED Must be before starting a regimen from Appendix A. Must be a standard of care procedure.	IF AVAILABLE†	REQUIRED
b	Scheduled to begin treatment with a new regimen from Appendix A	REQUIRED* Must be before starting a regimen from Appendix A. May be a standard of care procedure -OR- a "research-only biopsy"	IF AVAILABLE†	REQUIRED
c	Currently progressing on a regimen from Appendix A	REQUIRED* Must be before starting a regimen from Appendix A. May be a standard of care procedure -OR- a "research-only biopsy"	REQUIRED†	REQUIRED
d	Currently being treated with a regimen from Appendix A without evidence of progression		REQUIRED†	REQUIRED

***FOR RESEARCH- ONLY BIOPSIES OR ASPIRATES**

- Procedure must not be associated with significant risk
- Tumor must amenable to image guided or direction vision biopsy.
- Procedure cannot be mediastinal, laparoscopic, open or endoscopic, and not a brain biopsy.
- Patient must be over the age of majority

†ARCHIVAL TISSUE SUBMISSION

A. Contains the cancer type for which the participant is enrolled, AND
B. Was collected no more than 5 years prior to initiation of a therapy listed in Appendix A, AND
C. No more than 1 line of standard of care systemic therapy was administered from the date of archival material collection to the date of initiation of Appendix A therapy, AND
D. Contains at least a surface area of $5mm^2$ and optimum surface area of $25mm^2$ OR 3-5mL cryopreserved bone marrow aspirate to yield 200 million bone marrow mononuclear cells

4. PATIENT SELECTION

4.1 Eligibility Criteria

4.1.1 Patient diagnosed with Stage IV colorectal cancer, Stage III/IV non-small cell or small cell lung cancer, metastatic castration-resistant prostate cancer, Stage IV gastroesophageal cancer, Stage III/IV melanoma, or treatment refractory multiple myeloma, is undergoing first or subsequent lines of standard of care therapy per NCCN guidelines (https://www.nccn.org/professionals/physician_gls/default.aspx) and has consented to provide longitudinal biospecimens.

4.1.2 Patients with ECOG Performance Status (PS) 0 or 1 may be enrolled retrospectively (i.e. at time of progression) if archival material is submitted that contains the cancer type for which the participant is enrolled and that was collected up to 5 years prior to initiation of a therapy listed in Table 1, assuming that no more than 1 line of intervening standard of care systemic therapy was administered from the date of archival material collection to the date of initiation of Table 1 therapy (Archival Material Collection; Section 7.2.1). Table 1 therapies maybe as a singular/monotherapy or in combination with any FDA-approved chemotherapies. Patients with a PS of 2 may be enrolled only at the discretion of the treating physician and radiologist.

4.1.3 Age 13 or older, any sex and any gender may be enrolled, but participants under the age of majority will only contribute biospecimens from procedures that are scheduled due to medical necessity and not for the sole purpose of collecting samples for this study.

4.1.4 Patients must have tumor amenable to image guided or direct vision biopsy and be willing and able to undergo a tumor biopsy for molecular profiling (https://www.ncbi.nlm.nih.gov/pubmed/?term=30285529). The biopsy must not be associated with a significant risk of severe or major complications or death. In particular, endoscopic, open or laparoscopic surgical procedures are not to be performed to provide research biospecimens. However, research biospecimens may be provided if the patient needs to undergo such procedures for clinical reasons. Severe or major complications are considered to be those:

- Requiring therapy, minor hospitalization (more than overnight but <48 h).
- Requiring major therapy; unplanned increase in level of care, prolonged hospitalization >48 h.
- Resulting in permanent adverse sequelae.
- Resulting in death.

The following tumors may be collected only when patients will be undergoing a procedure due to medical necessity during which the tissue may be collected and not for the sole purpose of the clinical study:

- Brain biopsies: ONLY if the patient has medical necessity for craniotomy for clinical care.
- Mediastinal, laparoscopic, gastrointestinal, or bronchial endoscopic biopsies: ONLY to be obtained incidentally to a clinically necessary procedure.

4.1.5 Study participants with LCA, CRC, PCA, GEC, MEL and MML may contribute samples

for PDM development if they meet specific PDMR eligibility criteria (Appendix E).

4.1.6 To ensure that individuals who experience diminished decision making capacity during the course of their cancer treatment are eligible, consent may be provided by a Legally Authorized Representative (LAR) in accordance with 45 CFR 46.102(i). This protocol is minimal risk.

4.2 Exclusion Criteria

4.2.1 Patients who are currently or have previously enrolled in an oncology interventional clinical trial.

4.2.2 Uncontrolled intercurrent illness that in the physician's assessment would pose undue risk for biopsy.

4.2.3 If the patient is on chronic anticoagulation treatment, they must be able and willing to have this treatment discontinued for the biopsy. Discontinuation procedures will be those of the treating site.

4.2.4 Patients with CRC, LCA, PCA, GEC and MEL who are being evaluated at NCORP sites that are currently participating in the NCORP Tissue Procurement Protocol #10231.