1. **Items to be provided to TGL along with this form:**

**a. IRB approval letter (please attach)**

**b. Protocol (please attach)**

1. **PROJECT DESCRIPTION – to be completed by Investigator**

|  |  |
| --- | --- |
| Study Name |  |
| Study Number (IRB #) |  |
| Principal Investigator |  |
| Contact Person |  |
| Contact Phone # |  |
| Contact Email Address |  |
| Submission Date |  |

|  |  |
| --- | --- |
| Gene(s) |  |
| Targete.g. whole gene, exon(s), or specific mutation(s) |  |
| Is mutation germ line or somatic? |  |
| Sample Type(s) e.g. blood, bone marrow, tissue, etc. |  |
| Desired Platform/Technology (if known) |  |
| Can you provide samples with known results for validation (controls)? (Validation samples should be the same sample type that will be submitted for the project.) |  |
|  If yes, how many control samples and of what genotype? |  |
| If no, are there commercial sources for control samples? |  |
| Is there a deadline for having CLIA testing available? |  |
|  If yes, please provide date |  |
| Turn-around time for testing |  |
| Number of samples to be tested in the project  |  |
| Will samples continue to come to the lab after the study is completed?  |  |
|  If yes, how many per year? |  |
| Other relevant information: |

1. **VALIDATION PROPOSAL – to be completed by TGL**

|  |  |
| --- | --- |
| Proposed Sensitivity | >90% in most cases |
| Proposed Specificity | >90% in most cases |
| Accuracy | >95% in most cases |
| Reproducibility | >95% in most cases |

1. **DIRECTOR REVIEW**

□ Evaluated for compliance with University/UMMC policy

|  |
| --- |
| Discussion:  |

Approval Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **COST ESTIMATE PER SAMPLE – to be completed by TGL**

|  |  |
| --- | --- |
| Consumables/Materials |  |
| Reagents |  |
| Labor |  |
| Regulatory Maintenance |  |
| Total |  |

1. **COST ESTIMATE FOR DEVELOPMENT AND VALIDATION – to be completed by TGL**

|  |  |
| --- | --- |
| Validation |  |
| Protocol development |  |
| Regulatory implementation |  |
| Total |  |

1. **PAYMENT INFORMATION – to be completed by Investigator or Authorized Person**

|  |  |
| --- | --- |
| Department and School |  |
| Fund |  |
| Program |  |
| PCBU & Project ID # |  |
| Account |  |

□ I agree to the proposed costing and wish TGL to proceed with validation.

Investigator Signature/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_