PROTOCOL NUMBER/TITLE:

Name of Clinical Trials Disease Team Managing this Study:

**Disease Site** (Choose from list at end of this form):

**1)** Is there advocacy for this trial from the **Case Comprehensive Cancer Center**? YES  NO\*

\*The PRMC will not review a study without advocacy from the Case CCC

**2)**  Will this trial be conducted at **University Hospitals**? YES  NO\*\*  TBD

Satellites:

**3)**  Will this trial be conducted at **Cleveland Clinic**? YES  NO\*\*  TBD

Satellites:

**4)** Please state purpose for non-participation (**To be completed by institution NOT participating)**:

**5)** Please list all competing trials and prioritize below (more can be listed on a separate sheet):

Protocol #:        Highest (1st)  High (2nd)  Priority Other:

Protocol #:        Highest (1st)  High (2nd)  Priority Other:

**6)** Projected **annual** local accrual:       patients at CC       patients at UH

Projected **total** local accrual:       patients at CC       patients at UH

**7)** **SEE NEXT PAGE FOR FEASIBILITY + ACADEMIC MERIT SCORING**

CC PI:       UH PI:

**BOTH DISEASE TEAM CHAIR SIGNATURES MANDATORY FOR PRMC SUBMISSION:**

Print Name:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

UH Disease Team Chair (**email approval acceptable**)

Print Name:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

CC Disease Team Chair (**email approval acceptable**)

**NON-LEAD SITE: ADDITIONAL SIGNOFF FOR DISEASE SPECIFIC PHASE I STUDIES**

Print Name:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

UH Phase I Disease Team Chair (**email approval acceptable**)

Print Name:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

CC Phase I Disease Team Chair (**email approval acceptable**)

**\*\***The following signatures are required if the following 2 conditions are met (**email approval acceptable**):

1. Study is not being conducted jointly at UH and CC (per above signoff by disease team leader)
2. Study is a treatment investigator-initiated trial submitted by a Cancer Center member

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mitchell Machtay MD (or designate) │ Associate Director for Clinical Research, Case CCC

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mikkael Sekeres MD (or designate) │Deputy Associate Director for Clinical Research, Case CCC

**TREATMENT TRIALS ONLY**

**PROTOCOL NUMBER/TITLE:**

Person filling out this page:

Disease Team Leader

PI

Regulatory Staff

**Please score by checking the appropriate boxes under each section. For protocols being conducted at both institutions, scores should be agreed upon by both disease team leaders.**

**NOTE: PRMC does not base approval on priority scores.**

**I. Feasibility:**

Competing Trials

1. >2 competing current or in the pipeline over the next 6 months

2. 1 competing current or in the pipeline over the next 6 months

3. No competing trials current or in the pipeline.

Accrual expectations

1. Accrual expected to take more than 2 years with at least 4 patients from CCCC.

2. Accrual expected to take between 1-2 years with at least 4 patients from CCCC.

3. Accrual to be completed in less than a year with > four patients accrued from CCCC.

**II. Academic Merit:**

Innovation

1. Not innovative

2. Moderately innovative

3. Highly innovative

Academic credit

0. Multi-institutional trial with no chance of authorship or credit

1. Multi-institutional trial with no chance of authorship but with associated institutional credit (e.g. cooperative group trial)

2. Multi-institutional trial with likelihood of authorship (named investigator or high accrual expectations)

3. Case CCC investigator initiated trial, or PI/co-PI for multi-institutional trial

Clinical impact

1. Little or no clinical importance, registry or post-licensing marketing study

2. Phase I-III trial with possible practice changing potential

3. Phase II-III trial with likely practice changing implications

Return form (with complete PRMC submission application) to:

April Firstencel, Protocol Review and Monitoring Committee

Telephone: (216) 368-1819, Email: [April.Firstencel@case.edu](mailto:April.Firstencel@case.edu)

**Appendix of Disease Sites**

Not Applicable/Healthy Control

Lip, Oral Cavity and Pharynx

Esophagus

Stomach

Small Intestine

Colon

Rectum

Anus

Liver

Pancreas

Other Digestive Organ

Larynx

Lung

Other Respiratory and Intrathoracic Organs

Bones and Joints

Soft Tissue

Melanoma, skin

Kaposi's sarcoma

Mycosis Fungoides

Other Skin

Breast

Cervix Uteri

Corpus Uteri

Ovary

Other Female Genital

Prostate

Other Male Genital

Bladder

Kidney

Other Urinary

Eye and Orbit

Brain and Nervous System

Thyroid

Other Endocrine System

Non-Hodgkin Lymphoma

Hodgkin Lymphoma

Multiple Myeloma

Lymphoid Leukemia

Myeloid and Monocytic Leukemia

Leukemia, other

Other Hematopoietic

Unknown Sites

Ill-Defined Sites

Any Site