THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Office of Human Subject Protection
7007 Bertner Avenue - Unit 1637
Houston, Texas 77030
Mainline: 713-792-6477 (2-6477)

APPROVAL

January 10, 2023

Steven Kornblau
Leukemia

On 1/10/2023, the IRB reviewed the following protocol:

IRB ID	LAB01-473_MOD010
Type of Review:	Modification / Update
Level of Review:	Expedited
Review Category:	(2)(b) Blood samples from others (5) Data, documents, records, or specimens
Title:	BLOOD, MARROW AND PHERESIS COLLECTION FROM PATIENTS WITH HEMATOLOGICAL MALIGNANCIES FOR THE STUDY OF CELL CYCLE, SIGNAL TRANSDUCTION AND APOPTOSIS RELATED PROTEINS IN HEMATOLOGICAL MALIGNANCIES: A TISSUE BANKING PROTOCOL.
Funding:	Name: Baylor; Name: Genentech; Name: Leukemia Spore, Funding Source ID: 5 P50 CA100632-09
IND, IDE or HDE:	None
Documents Reviewed:	None
Special Determinations and Waivers:	None

The IRB approved the modification on 1/10/2023. Investigators are required to submit a Continuing Review between 90 and 60 days prior to expiration. Investigators are required to conduct this Human Research in accordance with requirements in HRP-103 - INVESTIGATOR MANUAL.

As a reminder:

- Modifications to this study must be approved by the IRB in advance of implementing changes to the research
- New information related to this study must be reported to the IRB in accordance with institutional reporting requirements
- Close this study once all research activities are complete

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APPROVAL

April 25, 2022

Elisabet Manasanch
Lymphoma/Myeloma

On 4/25/2022, the IRB reviewed the following protocol:

IRB ID	PA15-0575_MOD011
Type of Review:	Modification / Update
Level of Review:	Expedited
Review Category:	(mm) Minor modification
Home IRB:	IRB 5
Title:	Prospective observational study of clinical and genomic predictors of progression to myeloma in asymptomatic monoclonal gammopathies
Funding:	Name: None (Not Unknown)
Grant Title:	
Grant ID:	None
IND, IDE or HDE:	None
Documents Reviewed:	None

You will conduct this Human Research in accordance with requirements in HRP-103 - INVESTIGATOR MANUAL.

Sincerely,

Michelle Linares
cc:

FWA #: 00000363
OHRP IRB Registration Number: IRB 5 IRB00006023

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APPROVAL

August 19, 2022

Elisabet Manasanch
Lymphoma/Myeloma

On 8/19/2022, the IRB reviewed the following protocol:

IRB ID	2015-0148_MOD020
Type of Review:	Modification / Update
Level of Review:	Expedited
Review Category:	None (mm) Minor modification
Home IRB:	IRB 2
Title:	Phase II Trial Of Isatuximab With or Without Lenalidomide In Patients With High Risk Smoldering Multiple Myeloma
Funding:	Name: MDACC; Name: Sanofi US Services Inc
Grant Title:	
Grant ID:	None
IND, IDE or HDE:	IND #132088
Documents Reviewed:	• 2015-0148 IND Summary of Changes 07.29.2022.docx, Category: Other; • 2015-0148 ISA-LEN CLEAN VERSION 10 7.29.2022.docx, Category: IRB Protocol; • 2015-0148 ISA-LEN TC VERSION 10 7.29.2022.docx, Category: Other; • ICD2015-0148_MOD008 TC 8.2.2022.pdf, Category: Approved Consent Form;

The IRB approved the modification on 8/19/2022. Reconsent active patients within 30 days or the first clinic visit.

You will conduct this Human Research in accordance with requirements in HRP-103 - INVESTIGATOR MANUAL.

Sincerely,

Aleen George
cc:

FWA #: 00000363
OHRP IRB Registration Number: IRB 2 IRB00002203

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APPROVAL

June 23, 2021

Paolo Strati
Lymphoma/Myeloma

On 6/16/2021, the IRB reviewed and approved the following protocol:

IRB ID	2005-0656_MOD009
Type of Review:	Modification / Update
Level of Review:	Expedited
Review Category:	None None
Home IRB:	IRB 2
Title:	A Collection of Blood and Tissue Samples from Patients with Lymphoma and/or Myeloma and Normal Donors
Funding:	Name: None (Not Unknown)
Grant Title:	
Grant ID:	None
IND, IDE or HDE:	None
Documents Reviewed:	• 2005-0656 Certificate of Translation dated April 23 2021.pdf, Category: Other; 2005-0656 Informed Consent dated April 23 2021_ar.pdf(0.01) 2005-0656 Informed Consent dated April 23 2021_chs.pdf(0.01) 2005-0656 Informed Consent dated April 23 2021_es.pdf(0.01) 2005-0656 Informed Consent dated April 23 2021_ja.pdf(0.01) 2005-0656 Informed Consent dated April 23 2021_ko.pdf(0.01) 2005-0656 Informed Consent dated April 23 2021_tr.pdf(0.01)

	ICD2005-0656_MOD005.docx(0.01) ePRTCL Smartform

You will conduct this Human Research in accordance with requirements in the Human Research Protection Program manual.

The IRB has made the determination that re-consenting is not required.

Sincerely,

Cimetra Cox
FWA #: 00000363
OHRP IRB Registration Number: IRB 2 IRB00002203
cc: