Fill in this information to identify the case:				
Debtor	Eiger BioPharmaceuticals, Inc			
United States Ba	nkruptcy Court for the: Northern	District of Texas(State)		
Case number	24-80040	_		

## Official Form 410

Proof of Claim 04/22

Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case. Do not use this form to make a request for payment of an administrative expense. Make such a request according to 11 U.S.C. § 503.

**Filers must leave out or redact** information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. **Do not send original documents**; they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Fill in all the information about the claim as of the date the case was filed. That date is on the notice of bankruptcy (Form 309) that you received.

P	Identify the Clair	m		
1.	Who is the current creditor?	University of Southern California  Name of the current creditor (the person or entity to be paid for this claim)  Other names the creditor used with the debtor		
2.	Has this claim been acquired from someone else?	✓ No  Yes. From whom?		
3.	Where should notices and	Where should notices to the creditor be sent?	Where should payments to the creditor be sent? (if different)	
	payments to the creditor be sent?	University of Southern California Melissa Archer		
	Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)	1975 Zonal Ave. KAM 400. Los Angeles, CA 90033, United States		
		Contact phone 3234969355	Contact phone	
		Contact email melissa.archer@med.usc.edu	Contact email	
		Uniform claim identifier for electronic payments in chapter 13 (if you use of	one):	
4. Does this claim amend one already				
	filed?	Yes. Claim number on court claims registry (if known)	Filed on	
5.	Do you know if anyone else has filed a proof of claim for this claim?	No Yes. Who made the earlier filing?		

Official Form 410 Proof of Claim

6.	Do you have any number	✓ No	
	you use to identify the debtor?	Yes. Last 4 digits of the deb	otor's account or any number you use to identify the de
7.	How much is the claim?	\$ <u>13,443.49</u>	Does this amount include interest or ot
			Yes. Attach statement itemizing inte charges required by Bankrupto
8.	What is the basis of the	Examples: Goods sold, money le	paned, lease, services performed, personal injury or w
	claim?	Attach redacted copies of any do	ocuments supporting the claim required by Bankruptcy
		Limit disclosing information that	is entitled to privacy, such as health care information.
		Services performed pur	suant to a clinical trial agreement

	debtor?	Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor:		
7.	How much is the claim?	\$ 13,443.49		
		charges required by Bankruptcy Rule 3001(c)(2)(A).		
8.	What is the basis of the claim?	Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.  Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).  Limit disclosing information that is entitled to privacy, such as health care information.		
		Services performed pursuant to a clinical trial agreement		
9.	Is all or part of the claim secured?	Yes. The claim is secured by a lien on property.  Nature or property:  Real estate: If the claim is secured by the debtor's principle residence, file a Mortgage Proof of Claim Attachment (Official Form 410-A) with this Proof of Claim.  Motor vehicle  Other. Describe:  Basis for perfection:  Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)		
ı		Value of property: \$		
		Amount of the claim that is secured:  Amount of the claim that is unsecured:  \$(The sum of the secured and unsecured amount should match the amount in line 7.)		
		Amount necessary to cure any default as of the date of the petition: \$		
		Annual Interest Rate (when case was filed)%  Fixed  Variable		
10	. Is this claim based on a lease?	✓ No  Yes. Amount necessary to cure any default as of the date of the petition.  \$		
11	. Is this claim subject to a right of setoff?	✓ No  ✓ Yes. Identify the property:		

Official Form 410 **Proof of Claim** 

12. Is all or part of the claim		No	
entitled to priority under 11 U.S.C. § 507(a)?		res. Check all that apply:	Amount entitled to priority
A claim may be partly priority and partly		Domestic support obligations (including alimony and child support) under 11 U.S.C. § 507(a)(1)(A) or (a)(1)(B).	\$
nonpriority. For example, in some categories, the law limits the amount		Up to \$3,350* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use. 11 U.S.C. § 507(a)(7).	\$
entitled to priority.		Wages, salaries, or commissions (up to \$15,150*) earned within 180 days before the bankruptcy petition is filed or the debtor's business ends, whichever is earlier. 11 U.S.C. § 507(a)(4).	\$
		Taxes or penalties owed to governmental units. 11 U.S.C. § 507(a)(8).	\$
		Contributions to an employee benefit plan. 11 U.S.C. § 507(a)(5).	\$
		Other. Specify subsection of 11 U.S.C. § 507(a)() that applies.	\$
		Amounts are subject to adjustment on 4/01/25 and every 3 years after that for cases begun	on or after the date of adjustment.
13. Is all or part of the claim entitled to administrative priority pursuant to 11 U.S.C. 503(b)(9)?	_	No Yes. Indicate the amount of your claim arising from the value of any goods receilays before the date of commencement of the above case, in which the goods he ordinary course of such Debtor's business. Attach documentation supportings	have been sold to the Debtor in
Part 3: Sign Below			
The person completing this proof of claim must sign and date it. FRBP 9011(b).  If you file this claim electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what a signature is.  A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both.  18 U.S.C. §§ 152, 157, and 3571.	☐ I a ☐ I a ☐ I a ☐ I a ☐ I have e ☐ I declar ☐ Execute	In the creditor.  In the creditor's attorney or authorized agent.  In the trustee, or the debtor, or their authorized agent. Bankruptcy Rule 3004.  In a guarantor, surety, endorser, or other codebtor. Bankruptcy Rule 3005.  It and that an authorized signature on this <i>Proof of Claim</i> serves as an acknowledge unt of the claim, the creditor gave the debtor credit for any payments received to examined the information in this <i>Proof of Claim</i> and have reasonable belief that the example under penalty of perjury that the foregoing is true and correct.  It is a Archer ature	vard the debt.
	Print th	e name of the person who is completing and signing this claim:	
	Name	Melissa Archer First name Middle name Last n	ame
	Title	Director, Clinical Trials Office	
	Compan		
	Address		
	Contact	hone Email	



Official Form 410 Proof of Claim

# Verita (KCC) ePOC Electronic Claim Filing Summary

For phone assistance: Domestic (888) 733-1544 | International (310) 751-2638

Debtor:					
24-80040 - Eiger BioPharmaceuticals, Inc					
District:					
Northern District of Texas, Dallas Division					
Creditor:	Has Supporting Doc	umentation:			
University of Southern California	Yes, please m	nail physical supporting documentation			
Melissa Archer	Related Document S	tatement:			
1975 Zonal Ave.					
KAM 400.		Has Related Claim:			
Los Angeles, CA, 90033	No Related Claim Filed I	<b>n</b>			
United States	Related Claim Filed I	зу:			
Phone:	Filing Party:				
3234969355	Creditor				
Phone 2:	Authorized age	ent			
Fax:					
Email:					
melissa.archer@med.usc.edu					
Other Names Used with Debtor:	Amends Claim:				
	No				
	Acquired Claim:				
	No				
Basis of Claim:	Last 4 Digits:	Uniform Claim Identifier:			
Services performed pursuant to a clinical trial agreement	No				
Total Amount of Claim:	Includes Interest or 0	Charges:			
13,443.49	No				
Has Priority Claim:	Priority Under:				
No					
Has Secured Claim:	Nature of Secured Amount:				
No	Value of Property:				
Amount of 503(b)(9):	Annual Interest Rate	c			
No Based on Lease:	Arrearage Amount:				
No	Basis for Perfection:				
Subject to Right of Setoff:					
No	Amount Unsecured:				
Submitted By:					
Melissa Archer on 21-Jun-2024 9:50:33 a.m. Eastern Time					
Title:					
Director, Clinical Trials Office					
Company:					

University of Southern California

# Additional Supporting Documents Received on 7/1/2024

\* RECEIVED

JUL 0 1 2024

KURTZMAN CARSON CONSULTANTS



Fill in this information to identify the case:				
Debtor	Eiger BioPharmaceuticals, Inc			
United States Ba	inkruptcy Court for the: Northern District of Texas (State)			
Case number	24-80040			

# Official Form 410 Proof of Claim

04/22

Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case. Do not use this form to make a request for payment of an administrative expense. Make such a request according to 11 U.S.C. § 503.

Filers must leave out or redact information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. Do not send original documents; they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Fill in all the information about the claim as of the date the case was filed. That date is on the notice of bankruptcy (Form 309) that you received.

1.	Who is the current creditor?	University of Southern California  Name of the current creditor (the person or entity to be pald for this claim)  Other names the creditor used with the debtor
2.	Has this claim been acquired from someone else?	✓ No  ☐ Yes. From whom?
3.	Where should notices and payments to the creditor be sent?  Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)	Where should notices to the creditor be sent?  University of Southern California Melissa Archer 1975 Zonal Ave.  KAM 400. Los Angeles, CA 90033, United States
R	ECEIVED	Contact phone 3234969355 Contact phone  Contact email melissa.archer@med.usc.edu Contact email
-	IL 0 1 2024 VCARSON CONSULTANTS	Uniform daim identifier for electronic payments in chapter 13 (if you use one):
-	Does this claim amend one already filed?	✓ No  Yes. Claim number on court claims registry (if known) Filed on
5.	Do you know if anyone else has filed a proof of claim for this claim?	No Yes. Who made the earlier filing?

<b>)</b> _	o you have any number	☑ No
	you use to identify the debtor?	Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor:
·.	How much is the claim?	\$ 13,443.49 Does this amount include interest or other charges?
		Yes. Attach statement itemizing interest, fees, expenses, or other charges required by Bankruptcy Rule 3001(c)(2)(A).
3.	What is the basis of the	Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.
	claim?	Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).
		Limit disclosing information that is entitled to privacy, such as health care information.
		Services performed pursuant to a clinical trial agreement
 9.	Is all or part of the claim	☑ No
	secured?	Yes. The claim is secured by a lien on property.
		Nature or property:
		Real estate: If the claim is secured by the debtor's principle residence, file a Mortgage Proof of Claim Attachment (Official Form 410-A) with this Proof of Claim.
		Motor vehicle
		Other. Describe:
		Basis for perfection:  Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)
		Value of property: \$
		Amount of the claim that is secured: \$
		Amount of the claim that is unsecured: \$(The sum of the secured and unsecured amount should match the amount in line 7
•	RECEIVED	Amount necessary to cure any default as of the date of the petition: \$
		Annual Interest Rate (when case was filed)%
	JUL 0 1 2024	Fixed
XU	RTZMAN CARSON CONSULTAS	Variable Variable
10	. Is this claim based on a	<b>№</b> No
	lease?	Yes. Amount necessary to cure any default as of the date of the petition.
Ì		
11	. Is this claim subject to a right of setoff?	₩ No

12. Is all or part of the claim	No No		
entitied to priority under 11 U.S.C. § 507(a)?	_	cell that apply:	Amount entitled to priority
A claim may be partly priority and partly	Domes	stic support obligations (including alimony and child support) u c.C. § 507(a)(1)(A) or (a)(1)(B).	inder \$
nonpriority. For example, in some categories, the law limits the amount	Up to \$ or serv	\$3,350° of deposits toward purchase, lease, or rental of proprices for personal, family, or household use. 11 U.S.C. § 507	perty
entitled to priority.	days b	s, salaries, or commissions (up to \$15,150*) earned within 1 efore the bankruptcy petition is filed or the debtor's businessever is earlier. 11 U.S.C. § 507(a)(4).	
	Taxes	or penalties owed to governmental units. 11 U.S.C. § 507(a)(	(8). \$
	Contrib	outions to an employee benefit plan. 11 U.S.C. § 507(a)(5).	\$
	Other.	Specify subsection of 11 U.S.C. § 507(a)() that applies.	\$
	* Amounts a	tre subject to adjustment on 4/01/25 and every 3 years after that for cas	es begun on or after the date of adjustment.
13. Is all or part of the claim entitled to administrative priority pursuant to 11 U.S.C. 503(b)(9)?	days before the ordinary	te the amount of your claim arising from the value of any go the date of commencement of the above case, in which the y course of such Debtor's business. Attach documentation s	e goods have been sold to the Debtor in
Part 3: Sign Below			
The person completing this proof of claim must sign and date it. FRBP 9011(b).  If you file this claim electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what a signature is.  A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both.  18 U.S.C. §§ 152, 157, and 3571.	I am the truste I am a guaran I understand that at the amount of the c		5. knowledgement that when calculating belived toward the debt.
	/s/Melissa Ar Signature Print the name of	the person who is completing and signing this claim:	
	Name	Melissa Archer First name Middle name	Last name
	Tide	Director, Clinical Trials Office	
RECEIVED	Company	University of Southern California Identify the corporate servicer as the company if the authorized agent is	a servicer.
JUI 0 1 2024	Address		
	70		
JURTZMAN CARSON CONSULTAN	S Contact phone	Email	

# Verita (KCC) ePOC Electronic Claim Filing Summary

For phone assistance: Domestic (888) 733-1544 | International (310) 751-2638

Debtor:		
24-80040 - Eiger BioPharmaceuticals, Inc		
District:		
Northern District of Texas, Dallas Division		
Creditor:	Has Supporting Doc	umentation:
University of Southern California	Yes, please m	all physical supporting documentation
Melissa Archer	Related Document S	tatement:
1975 Zonal Ave.		
KAM 400.	Has Related Claim:	
Los Angeles, CA, 90033	No	
United States	Related Claim Filed I	Ву:
Phone:	Filing Party:	
3234969355	Creditor	
Phone 2:	Authorized ag	ent
	עממוטוגיצפט פא	on.
Fax:		
Email:		
melissa.archer@med.usc.edu		
Other Names Used with Debtor:	Amends Claim:	
	No	
	Acquired Claim:	
	No	
Basis of Claim:	Last 4 Digits:	Uniform Claim Identifier:
Services performed pursuant to a clinical trial agreement	No	
Total Amount of Claim:	Includes Interest or	Charges:
13,443.49	No No	
Has Priority Claim:	Priority Under:	
No		
Has Secured Claim:	Nature of Secured A	mount:
No	Value of Property:	
Amount of 503(b)(9):	Annual Interest Rate	•
No		•
Based on Lease:	Arrearage Amount:	
No	Basis for Perfection:	1
Subject to Right of Setoff:	Amount Unsecured:	
No		
Submitted By:		
Melissa Archer on 21-Jun-2024 9:50:33 a.m. Eastern Tim	8	
Title:		
Director, Clinical Trials Office		
Company:		
University of Southern California		



JUL 0 1 2024

KURTZMAN CARSON CONSULTANTS

Invoice#	Amount	Description
CTO8948	773.09	Withholding Payment-Patient Visits
CTO9707	902.34	Withholding Payment-Patient Visits
CTO10952	1,721.11	Withholding Payment-Patient Visits
CTO13347	2,776.95	Patient Visits
11959	1,500.00	Office Monitor Visits for 2 days
12089	120.00	IND Safety Report
12165	500.00	Admin Maintenance Fee
12165	1,000.00	Annual Pharmacy
12538	800.00	Pharmacy Close out
12538	1,350.00	Record Storage
12538	2,000.00	Study Close out fee
Total	13,443.49	

# **INVOICE**

To:

**BIORASI, LLC** 

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

CTO8948

Invoice Date:

06/26/2023

**Payment Due:** 

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

Pl:

Terrault, Norah

Protocol

EIG-LMD-002

Subject ID	Milestone	Occurred Date	Amount Due	Comments
Oubject ID	Milestone	Occurred Date		
2021-2001	Screening Visit 1	12/15/2022	\$2,343.98	
2021-2001	Screening Visit 2	03/09/2023	\$3,042.90	
2021-2002	Screening Visit 1	01/30/2023	\$2,343.98	

Invoice Total: \$7,730.86

Total Withheld: \$773.09

Total Due After Withheld: \$6,957.77

Comments: The outstanding amount of this invoice is only the withholding payment of \$773.09

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

CTO9707

Invoice Date:

09/05/2023

**Payment Due:** 

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

Pi:

Terrault, Norah EIG-LMD-002

Protocol

Subject ID	Milestone	Occurred Date	Amount Due	Comments
2021-2001	ARM 1: D1	05/10/2023		updated to Amd1 rate
2021-2001	ARM 1: D8	05/16/2023		updated to Amd1 rat
2021-2001	ARM 1: D15	05/24/2023	\$1,483.65	updated to Amd1 rat
2021-2002	Screening Visit 2	06/26/2023	\$3.042.90	updated to Amd1 rat

Invoice Total:	\$9,023.40	
Total Withheld:	\$902.34	,
Total Due After Withheld:	\$8,121.06	paid

Comments: The outstanding amount of this invoice is only the withholding payment of \$902.34

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

CTO10952

Invoice Date:

12/15/2023

Payment Due:

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Protocol

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

PI:

Terrault, Norah EIG-LMD-002

Subject ID	Milestone	Occurred Date	Amount Due	Comments
2021-2001	ARM 1: D29	06/07/2023	\$1,675.35	
2021-2001	ARM 1: D43	07/05/2023	\$1,463.40	
2021-2001	ARM 1: D57	07/05/2023	\$1,679.40	
2021-2001	ARM 1: D85	08/02/2023	\$1,938.60	
2021-2001	ARM 1: D71	08/03/2023	\$1,503.90	
2021-2001	ARM 1: D113	09/07/2023	\$1,537.65	
2021-2002	ARM 2: D1	07/13/2023	\$1,800.90	
2021-2002	ARM 2: D15	07/28/2023	\$1,278.45	
2021-2002	ARM 2: D8	07/28/2023	\$1,444.50	
2021-2002	ARM 2: D29	08/10/2023	\$1,444.50	
2021-2002	ARM 2: D57	09/07/2023	\$1,444.50	

Invoice Total: \$17,211.15

Total Withheld: \$1,721.11

Total Due After Withheld: \$15,490.04

Comments: The outstanding amount of this invoice is only the withholding payment of \$1721.11

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

CTO13347

Invoice Date:

06/01/2024

Payment Due:

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

PI:

Terrault, Norah

**Protocol** 

EIG-LMD-002

Subject Mile	estone Items			
Subject ID	Milestone	Occurred Date	Amount Due	Comments
2021-2001	ARM 1: D337/EOT	10/13/2023	\$2,776.95	

Invoice Total:	\$2,776.95
Total Withheld:	\$0.00
Total Due After Withheld:	\$2,776.95

### Comments:

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

11959

Invoice Date:

03/06/2024

Payment Due:

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

PI:

Terrault, Norah

Protocol

EIG-LMD-002

Protocol Items			
Event	Occurred Date	Amount Due	Comments
Office Monitoring Visit	05/18/2023	\$750.00	
Office Monitoring Visit	05/19/2023	\$750.00	

Invoice Total:	\$1,500.00
Total Withheld:	\$0.00
Total Due After Withheld:	\$1,500.00

Comments:

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com

Invoice No:

12089

Invoice Date:

03/13/2024

**Payment Due:** 

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

PI:

Terrault, Norah

**Protocol** EIG-LMD-002

Protocol Items				
Event	Occurred Date	<b>Amount Due</b>	Comments	
IND Safety Reporting Fee	11/23/2022	\$40.00	EIG-LMD02- 22US0598 Initial	
IND Safety Reporting Fee	12/05/2022	\$40.00	EIG-LMD02-22TR0600	
IND Safety Reporting Fee	12/08/2022	\$40.00	EIG-LMD02- 22US0598 FU1	

Invoice Total:	\$120.00
Total Withheld:	\$0.00
Total Due After Withheld:	\$120.00

Comments:

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# **INVOICE**

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com

Invoice No:

12165

Invoice Date:

03/20/2024

**Payment Due:** 

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

PI:

Terrault, Norah

EIG-LMD-002 **Protocol** 

Protocol Items			
Event	Occurred Date	Amount Due	Comments
Administrative Maintenance Fee	03/17/2024	\$500.00	
Annual Pharmacy Maintenance & Storage Fee	03/17/2024	\$1,000.00	

Invoice Total: \$1,500.00

Total Withheld: \$0.00

**Total Due After Withheld:** \$1,500.00

Comments:

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

# INVOICE

To:

BIORASI, LLC

Harbour Centre at Aventura 18851 NE 29th Avenue, Suite 800

Aventura FL 33180 AP@biorasi.com Invoice No:

12538

**Invoice Date:** 

04/25/2024

**Payment Due:** 

**Upon Receipt** 

**USC Account:** 

GR1058930

Study:

Eiger-Hep D LIMT-2 Phase 3 Clinical Study

Pl:

Terrault, Norah

**Protocol** 

EIG-LMD-002

Protocol Items			
Event	Occurred Date	Amount Due	Comments
Pharm Close-Out Fee	04/25/2024	\$800.00	
Record Storage/Archiving Fee	04/25/2024	\$1,350.00	Document Archiving
Study Closeout Fee	04/25/2024	\$2,000.00	

Invoice Total: \$4,150.00

Total Withheld: \$0.00

Total Due After Withheld: \$4,150.00

Comments:

**Direct Inquiries** 

Lisa Manion +1 323-865-7755

lisa.manion@med.usc.edu

Federal ID 95-1642394

Make Checks Payable To:

University of Southern California

Attn: Keck School of Medicine of USC - Mylam Le

1975 Zonal Avenue, KAM 314

Los Angeles, CA 90033

### **Clinical Trial Agreement**

This Clinical Trial (CTA) Agreement ("Agreement") is made as of the date of its final execution (the "Effective Date") by and between the University of Southern California, a California non-profit public benefit corporation ("Institution") with an address located at 1640 Marengo St., 7th Floor, Los Angeles, CA 90033, and Eiger BioPharmaceuticals, Inc., a corporation having its principal place of business at 2155 Park Blvd., Palo Alto, CA 94306 ("Sponsor"). Sponsor and Institution are herein referred to collectively as "Parties." Individually, each of Sponsor and Institution is a "Party."

WHEREAS, the Institution and Sponsor have agreed to use this CTA, to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers;

WHEREAS, Sponsor is a for-profit organization that intends to conduct a sponsored multicenter clinical trial, described in 1.1 below, involving the use of certain diagnostic(s), drug(s) and/or biologic(s) provided by Sponsor;

WHEREAS, Biorasi, LLC (hereinafter "Biorasi" or "CRO") is providing clinical research organization services to Sponsor under a separate contract between Biorasi and Sponsor. Biorasi's services to sponsor include monitoring of the study, entering into this Agreement on behalf of Sponsor, and administering payment under this Agreement on behalf of Sponsor.

WHEREAS, the Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial; and

WHEREAS, the Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor, and will further the instructional and research objectives of Institution in a manner consistent with its status as a nonprofit educational, research and health care institution;

NOW, THEREFORE, in consideration for the mutual promises made in this Agreement and for valid consideration, the Parties agree as follows:

### 1. Scope of Agreement

- 1.1. Institution will undertake a sponsored multicenter clinical trial ("Study") described in Protocol Number: EIG-LMD-002 entitled, "A Phase 3, Randomized, Open-Label, Parallel Arm Study to Evaluate the Efficacy and Safety of 180 mcg Peginterferon Lambda-1a (Lambda) Subcutaneous Injection for 48 Weeks in Patients with Chronic Hepatitis Delta Virus (HDV) Infection (LIMT-2)" which is attached hereto and incorporated herein as <a href="Exhibit A">Exhibit A</a> ("Protocol"). Institution will only recruit subjects in accordance with the Protocol. The Study will be conducted by the Institution under the direction of **Dr. Norah Terrault, MD** an employee of Institution ("Principal Investigator").
- 1.2. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.
- 1.3. Unless otherwise agreed to by the Parties, Sponsor will provide to Institution on a timely basis, without charge, the required quantities of properly-labeled Sponsor drug(s) or biologic(s) ("Study Drug") and other materials (e.g., Investigator's Brochure, handling and storage instructions, and, if applicable, placebo) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until consumed via being administered or

dispensed to Study subjects during the course of the Study. Institution shall receive, store, and handle Study Drug in compliance with all applicable laws and regulations, the Protocol, and Sponsor instructions.

- 1.4. Sponsor and Institution shall comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations, including generally accepted standards of good clinical practice as adopted by current FDA regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions. Institution will only allow individuals who are appropriately trained and qualified to do so to assist in the conduct of the Study.
- 1.5. Institution shall obtain institutional review board ("IRB") approval for the Study prior to its initiation and written proof thereof shall be provided to Sponsor upon Sponsor's request. Initiation of the Protocol and Institution's obligation to conduct the Study shall not begin until IRB approval is obtained. Institution shall obtain from each subject, prior to the subject's participation in the Study, a signed informed consent and necessary authorization to disclose health information to Sponsor for any and all Sponsor uses in a form approved in writing by the IRB or a waiver of consent as directed by the IRB and further provided that the informed consent is consistent with Institution's policies.
- 1.6. Sponsor agrees to provide Institution with any data and safety monitoring reports related to the Study received by or in the possession of Sponsor, and Institution agrees they will be submitted to the IRB as required. During the Study and for at least two (2) years following the completion of the Study at all sites, Sponsor shall promptly provide Institution and Principal Investigator with the written report of any safety findings, including Study results and any routine monitoring findings in site monitoring reports, and data safety monitoring committee reports including, but not limited to, data and safety analyses, and any Study information that may (i) affect the safety and welfare of current or former Study subjects, or (ii) influence the conduct of the Study with respect to safety. Institution and/or Principal Investigator will communicate findings to the IRB and Study subjects, as appropriate.
- 1.7. Institution shall promptly, but not later than one (1) business day after becoming aware, inform Sponsor in writing of any (a) urgent safety measures as instructed in the Protocol, and (b) breaches of the Protocol of which Institution becomes aware.
- 1.8. Notwithstanding any provision in this Agreement to the contrary, Principal Investigator retains the right to deviate from the Protocol if, based upon his or her reasonable medical opinion, there is a need for such deviation to protect the health, safety or welfare of a Study subject. Such deviation shall not constitute a failure to comply with the Protocol or a breach of this Agreement or any clause hereof.

### 2. Payments

Sponsor agrees to pay Institution in accordance with the budget attached as **Exhibit B** ("**Budget**") on a prorated basis, according to the actual work completed, and any non-cancelable obligated expenses, for subjects who are enrolled into the Study. The Parties acknowledge that the Budget amounts represent an equitable exchange for the conduct of the Study in light of the professional time and expenses required for the performance of the Study.

In addition to other necessary routing information detailed in Exhibit B, each payment shall clearly reference the: Study Protocol Number and PI name.

For administrative convenience, various Study contact information may be attached hereto and incorporated by reference as **Exhibit C**, entitled, "Administrative & Study Points of Contact."

The Institution's tax identification number is: 95-1642394

The Parties agree that the compensation provided under the terms of this Agreement is consistent with fair market value; has been negotiated at arm's length; and has not been determined in any manner with regard to, or given in exchange for, any implicit or explicit agreement to procure Sponsor's products or to generate referrals or other business between the Parties outside the scope of this Agreement.

### 3. Confidentiality

3.1 It is anticipated that in the performance of this Agreement, Sponsor may need to disclose to Institution information which is considered confidential. The rights and obligations of the Parties with respect to such information are as follows:

"Confidential Information" refers to information of any kind which is disclosed to the Institution by Sponsor under and during the term of this Agreement for purposes of conducting the Study or Data (as defined below in Section 4).

Notwithstanding the foregoing, Institution's Data generated in the course of conducting the Study are not Sponsor's Confidential Information for publishing purposes in accordance with Section 9 of this Agreement.

Institution agrees, during the term of this Agreement and for a period of five (5) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received from Sponsor in accordance with this Section.

Institution agrees to use Sponsor's Confidential Information solely as allowed by this Agreement, and for the purposes of conducting the Study. Institution agrees to make Sponsor's Confidential Information available only to those of its or its affiliated hospitals' employees, personnel, IRB members, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study, and are subject to similar terms of confidentiality.

- 3.2 The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:
- a) is or becomes public knowledge through no breach of this Agreement by Institution;
- b) is disclosed to Institution by a third party entitled to disclose such information without known obligation of confidentiality; or
- c) is already known or is independently developed by Institution without use of Sponsor's Confidential Information as shown by Institution's contemporaneous written records.
- 3.3 Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, required to be disclosed to obtain IRB approval for the Study, required to support the medial care or a Study subject, or required by government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena, promptly notifies Sponsor. To the extent allowed under applicable law, Sponsor may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Institution will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by Institution's legal counsel.
- 3.4 No license or other right is created or granted hereby, except the specific right to conduct the Study as set forth by Protocol and under terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

- 3.5. Upon Sponsor's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor at Sponsor's expense pursuant to this Agreement except that Institution may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement. Notwithstanding anything in this Agreement to the contrary, in no event shall Institution be obligated to return or delete any Confidential Information integrated into its systems as part of its normal back-up and archival processes and Institution shall maintain the information as confidential in accordance this Agreement.
- 3.6 Institution may disclose the terms of this Agreement and any additional information to the extent necessary to ensure compliance with applicable Federal, State and Institutional policies, regulations, and laws.

### 4. Data Use/Ownership

"Data" shall mean all data and information generated by Institution as a result of conducting the Study in accordance with the IRB approved Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider. Sponsor shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, Institution shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

### 5. HIPAA/HIPAA Privacy

5.1 Institution shall comply with applicable laws and regulations, as amended from time to time, including without limitation, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA") with respect to the collection, use, storage, and disclosure of Protected Health Information ("PHI") as defined in HIPAA. Sponsor shall collect, use, store, access, and disclose PHI collected from Study subjects only as permitted by the IRB approved informed consent form or HIPAA authorization form obtained from a Study subject. Sponsor will collect, use, store, and disclose any Subject Material, defined in Section 15, it receives only in accordance with the informed consent form and, in any event, will not collect, use, store, or disclose any PHI attached to or contained within the Subject Material in any manner that would violate this Section of the Agreement. Institution shall only provide Data to Sponsor that has been de-identified in accordance with HIPAA and shall not provide Sponsor with PHI.

Institution acknowledges that, pursuant to Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA"), Sponsor has an obligation to submit certain reports to the Centers for Medicare & Medicaid Services with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which diagnosis or treatment costs are incurred. Sponsor recognizes that Institution and Sponsor are subject to laws and regulations protecting the confidentiality of research subject information. Accordingly: (1) Institution agrees upon prior written request to provide to Sponsor, or a third-party vendor as designated by Sponsor, certain identifiable patient information required by MMSEA for Study subjects who are Medicare beneficiaries and incur medical costs in association with a research injury and whose costs are reimbursed by Sponsor pursuant to this Agreement; and (2) Institution further agrees to otherwise cooperate with Sponsor (and any third-party vendors as designated by Sponsor) to the extent necessary for Sponsor to meet its MMSEA reporting obligations.

- 5.2 Sponsor's right to review the Study subjects' Study-related information contained in the Study subject's medical record shall be subject to reasonable safeguards for the protection of Study subject confidentiality and the Study subjects' informed consent form or HIPAA authorization form.
- 5.3 Sponsor shall not attempt to identify, or contact, any Study subject unless permitted by the informed

consent form.

### 6. Record Retention

As applicable by law, Institution shall retain and preserve a copy of the Study records for the longer of:

- a) two (2) years after a marketing authorization for Study Drug has been approved for the indication for which it was investigated or Sponsor has discontinued research on the Study Drug;
- b) such longer period as required by federal regulatory requirements; or
- c) as requested in writing by Sponsor at Sponsor's reasonable storage expense.

### 7. Monitoring and Auditing

- 7.1 Sponsor and Sponsor's designees shall have the right to perform visits of the site to ensure compliance with this Agreement and the Protocol. Site visits by Sponsor and/or its authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Sponsor's and/or authorized designee's access is subject to reasonable safeguards to ensure confidentiality of medical records and systems.
- 7.2 Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Institution agrees to provide Sponsor with prompt, but no later than one (1) business days', written notice of the auditor investigation. If legally permissible or allowable by the regulatory agency and permissible in accordance with the Institution's policy, Sponsor may be available or request to be present with approval from auditor during such audit, but Sponsor agrees not to alter or interfere with any documentation or practice of Institution. Institution shall be free to respond to any regulatory agency inquiries and will provide Sponsor with a copy of any formal response or documentation to the regulatory agency regarding the Study.

### 8. Inventions, Discoveries and Patents

- 8.1 It is recognized and understood that certain existing inventions, intellectual property rights and technologies owned or controlled by the Parties prior to or after the Effective Date, including with respect to the Sponsor the Study Drug, as applicable, and those arising outside of the research conducted under this Agreement, are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither Sponsor nor Institution shall have any claims to or rights in such separate inventions and technologies.
- 8.2 Any patentable inventions, developments, or discoveries conceived of, reduced to practice, invented and/or made during the term of this Agreement in the performance of the Protocol by Institution ("Inventions") shall be promptly disclosed to Sponsor in writing ("Invention Disclosure"). Title to Inventions that necessarily use or necessarily incorporate Sponsor's Study Drug shall be owned by Sponsor ("Sponsor Inventions"). Provided Sponsor has fully funded the Study and there are no government funds used, directly or indirectly, by Institution or Sponsor in the Study or Protocol, Institution agrees to assign to Sponsor, to the extent Institution has the legal right to do so, all of Institution's right, title and interest in, to and under all Sponsor Inventions to Sponsor in writing. Title to Inventions other than Sponsor Inventions ("Other Inventions") shall reside with Sponsor if Sponsor personnel are the sole inventors, with Institution personnel are the sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors, in each case as determined in accordance with U.S. patent law. Institution's obligations under Sections 8.2 and 8.3 hereunder shall be performed and administered by its appropriate office with technology transfer responsibilities, if required by and in accordance with Institution policies.
- 8.3 Provided that Sponsor has fully funded the Study to the extent that Institution owns sole or joint title in

any such Other Inventions, Sponsor is hereby granted, without option fee other than consideration of the Study sponsored herein, an option to acquire an exclusive, worldwide, royalty-bearing license to Institution's rights under any Other Invention, which option shall extend for no more than ninety (90) days after Sponsor's receipt of an Invention Disclosure from Institution ("Option Period"). The Parties shall use their reasonable efforts to negotiate, for a period not to exceed ninety (90) days after Sponsor's exercise of such option or such other time period as mutually agreed by the Parties, a license agreement satisfactory to both Parties ("Negotiation Period"). In the event Sponsor fails to exercise its option within the Option Period, or the Parties fail to reach agreement on the terms of such license within the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to the specific Other Invention.

- 8.5 Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either Party.
- 8.6 The Parties agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable federal laws, rules, and regulations, including without limitation the requirements of Rev. Proc. 2007-47; provided, however, if it is determined by the Internal Revenue Service or any other federal agency or instrumentality (the "Government") that the provisions of this Agreement are not in such compliance, then the Parties agree to modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal laws, rules, and regulations as determined by the Government.
- 8.7 Subject Sections 3(Confidentiality) and 9 (Publication), Institution shall retain a royalty-free, irrevocable license to use for its own internal noncommercial research, educational and patient care purposes, all Sponsor Inventions or Other Inventions licensed or assigned to Sponsor hereunder.

### 9. **Publication**

- 9.1 Subject to Section 9.2, Institution shall be free to publish, present, or use any of Institution's Data and results arising out of its performance of the Protocol (individually, a "Publication"). At least thirty (30) days prior to submission for Publication, Institution shall submit to Sponsor for review and comment any proposed oral or written Publication ("Review Period"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. The Review Period for abstracts or poster presentations shall be thirty (30) days. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires patent applications to be filed on any inventions disclosed or contained in the disclosures, Institution will defer Publication for a period not to exceed sixty (60) days, to permit Sponsor to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information as defined in Section 3 and Sponsor requests Institution in writing to delete such Sponsor's Confidential Information, the Institution agrees to delete such Sponsor's Confidential Information.
- 9.2 The Parties agree that this Study is a multi-center clinical trial. Therefore Institution agrees that the first publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Institution may publish the Data and Study results individually in accordance with this Section 9 upon first occurrence of one of the following: (i) multicenter publication is published; (ii) no multicenter publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center Publication.
- 9.3 If no multi-center Publication occurs within eighteen (18) months of the completion of the Study at all sites, upon request by Institution, Sponsor agrees to provide such Institution access to the aggregate Data from all Study sites.
- 9.4 If the Institution, through its Principal Investigator, is identified to participate in the multi-center

Publication: (i) Institution will have the opportunity to review the aggregate multi-center Data, upon request; and (ii) consistent with the International Committee of Medical Journal Editors (ICMJE) regulations, Institution will have adequate opportunity to review and provide input on any abstract or manuscript prior to its submission for Publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Publication.

### 10. Use of Name

- 10.1 Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the other Party whose name is being used. Such approval will not be unreasonably withheld.
- 10.2 Institution and Sponsor understand that the amount of any payment made hereunder may be disclosed and made public by the other Party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010, provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician.
- 10.3 Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Institution may publicly post information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's name, the Study title, and the Study period, and funding amount, on Institution publicly accessible lists of research conducted by the Institution.

### 11. Indemnification and Limitation of Liability

- 11.1 Sponsor agrees to defend, indemnify, and hold harmless the Institution and its medical affiliates and affiliated hospitals, and each of their trustees, officers, directors, governing bodies, subsidiaries, affiliates, investigators, employees, IRB members, agents, successors, heirs and assigns (collectively referred to as "Institution's Indemnitees"), from and against any third party claims, loss, damage, cost and expense of claims (including reasonable attorney's fees) and suits ("Claims"), alleged to be caused by or arising from the performance of the Study pursuant to the Protocol, or the correct and proper use of the Study Drug under the Protocol, or properly performed procedures required by the Protocol, or from the use of the Study results, or Sponsor's breach of this Agreement or violation of applicable law, or Sponsor's or CRO's negligence or willful misconduct, regardless of the legal theory asserted.
- 11.2 Sponsor shall have no obligation to provide such indemnification to the extent that such Claim is solely caused by Institution's Indemnitee(s)': (1) failure to adhere to and comply with all material and substantive specifications and directions set forth in the Protocol (except to the extent such deviation is reasonable to protect the rights, safety and welfare of the Study subjects); (2) material failure to comply with all applicable laws and regulations in the performance of the Study, or (3) if such claim is directly caused by the negligent acts or omissions of Institution's Indemnitees(s).
- 11.3 Subject to the limits and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law, regarding the status, powers and authority of the Institution or the Institution's principal(s)), Institution shall indemnify, hold harmless and defend Sponsor, its directors, officers, employees and agents, ("Sponsor's Indemnitees") from and against only those third party Claims to the extent directly attributable to Institution's negligence in its conduct of the Study or breach of this Agreement. Notwithstanding the above, Institution shall have no obligation to indemnify Sponsor for any other Claims (including, but not limited to, infringement or product liability Claims).

11.4 The indemnified Party shall give notice to the indemnifying Party promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise or settle such Claim in a manner that admits any liability on the party of the indemnified Party with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.

NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER PARTY, NOR ANY OF THEIR RESPECTIVE DIRECTORS, TRUSTEES, OFFICERS, EMPLOYEES, OR AGENTS, SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES, INCLUDING BUT NOT LIMITED TO THE LOSS OF OPPORTUNITY, OR LOSS OF REVENUE OR PROFIT, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

### 12. Subject Injury

If a Study subject suffers an adverse reaction, illness, or injury that was directly caused by or related to a Study Drug or any properly performed procedures required by the Protocol, then Sponsor shall pay for the reasonable and necessary costs incurred for the diagnosis and treatment of such Study subject injury, including hospitalization, but only to the extent such expenses are not caused by (i) Institution's negligence or willful misconduct or (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study.

### 13. Insurance

- 13.1 Institution shall, at its sole cost and expense maintain a policy or program of insurance or self-insurance at the level of at least \$1,000,000 per occurrence (or per claim) and \$3,000,000 annual aggregate to support its obligations assumed in this Agreement. However, if Institution is a public entity entitled to governmental immunity protections under applicable state law, then Institution may provide liability coverage in accordance with any limitations associated with the applicable law.
- 13.2 Sponsor shall, at its sole cost and expense, procure and maintain commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance, unless otherwise indicated in an attachment, in amounts not less than \$3,000,000 per occurrence and \$10,000,000 annual aggregate. Such commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance shall provide contractual liability coverage for Sponsor's indemnification obligations herein.
- 13.3 Upon written request, either Party will provide evidence of its insurance or self-insurance acceptable to the other Party. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement.

### 14. Term and Termination

14.1 This term of this Agreement shall commence upon the Effective Date and expire upon the completion of the Parties' Study-related activities under the Agreement, unless terminated early as further described in this Section.

- 14.2 Sponsor has the right to terminate the Study upon thirty (30) days prior written notice to the Institution. This Study may be terminated immediately at any time for any reason by the Institution or Sponsor when, in their judgment or that of the Principal Investigator, the Institution's IRB, Scientific Review Committee, if applicable, or the Food and Drug Administration, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify Sponsor. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated by either Party upon thirty (30) days written notice.
- 14.3 Notwithstanding the above, any Party may, in addition to any other available remedies:
- a) immediately terminate this Agreement upon the other Party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or
- b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default, breach, or failure to adhere to the Protocol within thirty (30) business days after written notice thereof.
- 14.4 In the event that this Agreement is terminated prior to completion of the Study, for any reason, Institution shall:
- a) notify the IRB that the Study has been terminated;
- b) cease enrolling subjects in the Study;
- c) cease treating Study subjects under the Protocol as directed by Sponsor to the extent medically permissible and appropriate;
- d) terminate, as soon as practicable, all other Study activities; and
- e) furnish to Sponsor any required final report for the Study in the form reasonably acceptable to Sponsor.

Promptly following any such termination, Institution will provide to Sponsor copies of Data collected pursuant to the Study Protocol. Upon Sponsor's written request, Institution shall provide to Sponsor, at Sponsor's expense, all Sponsor's Confidential Information provided under this Agreement provided, however, that Institution may retain such Confidential Information for record keeping purposes, monitoring its obligations, and exercising its rights hereunder, subject to Institution's ongoing compliance with the confidentiality and non-use obligations set forth in this Agreement.

- 14.5 If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred through that date. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Sponsor to provide for an orderly winddown of the Study.
- 14.6. Subsections 1.4, 1.6, and 14.6, and Sections 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 19 and 23, shall survive any termination or expiration of this Agreement, except that Section 3 shall survive for the period stated in Section 3.1. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

### 15. Subject Material

15.1 "Subject Material" means any biologic material of human origin that is obtained from a subject in the Study, including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids obtained or derived from the Study subjects in accordance with and pursuant to the Protocol ("Subject Material").

15.2 Institution agrees to provide the Subject Material to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party as permitted by the Study subject's informed consent form or pertinent institutional review board(s). Sponsor agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form, will require additional IRB review and approval.

### 16. Subcontract

Institution has the right to subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Agreement after obtaining the prior written approval of the Sponsor, which approval shall not be unreasonably withheld. If Institution subcontracts any Study related duties, Institution shall contract with such subcontractors incorporating terms substantially similar to the terms herein and shall be liable for the performance of such subcontractors as if performed by Institution. Such subcontracts shall be provided to the Sponsor upon written request. The Sponsor has the right to subcontract to a third-party CRO or Academic Research Organization (ARO) and assign Study-related duties and rights to any Sponsor affiliate. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights.

### 17. Notices

Any notice, authorization, approval, consent or other communication will be in writing and deemed given:

- a) Upon delivery in person;
- b) Upon delivery by courier;
- c) Upon delivery date by a nationally-recognized overnight delivery service such as FedEx.

d)

### If to Sponsor:

Eiger Biopharmaceuticals Inc.

Legal Department

Attn: Contracts2155 Park Boulevard, Palo Alto, CA 94306

Tel: 650-272-6138 Fax: 650-618-1621 legal@eigerbio.com

### If to Institution:

University of Southern California

Attn: General Counsel

3551 Trousdale Parkway, ADM 352

Los Angeles, California 90089-5013

Phone: (213) 740-7922

### With a copy to Principal Investigator:

University of Southern California Attn: Dr. Norah Terrault, MD Health Sciences Campus 2011 Zonal Ave. Building: HMR Los Angeles, California 90033

### 18. Independent Contractor

It is mutually understood and agreed that the relationship between Institution and Sponsor is that of independent contractors. No Party shall represent itself as the agent, employee, partner, joint venturer, or servant of the other. Except as specifically set forth herein, neither Party shall have nor exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint ventures, lease, or equity relationship, expressly or by implication, between the Parties.

### 19. Clinical Trial Registry

Prior to enrollment of the first subject in the Study, Sponsor agrees to ensure that the Study is fully registered on

www.clinicaltrials.gov in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85. Results of this Study will be reported in compliance with applicable laws.

### 20. Non-Referral/Anti-Corruption Language

- 20.1 The Institution and Sponsor agree that it is not their intent under this Agreement to induce or encourage the unlawful referral of subjects or business between the Parties, and there shall not be any requirement under this Agreement that either Party, its employees or affiliates, including its medical staff, engage in any unlawful referral of subjects to, or order or purchase products or services from, the other Party.
- 20.2 Institution and Sponsor agree that their employees, who are involved in the conduct of the Study, will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and shall not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of the other Party.

### 21. Force Majeure

If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party's direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the Party's control (a "Disability") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

### 22. Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

### 23. Debarment

The Institution certifies that to its knowledge neither it, nor any of its employees, agents or other persons performing the Study under its direction, is currently debarred, suspended, or excluded under the Federal Food, Drug and Cosmetic Act, as amended, or disqualified under the provisions of 21 CFR§312.70. In the event that the Principal Investigator or any Study personnel becomes debarred or disqualified during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event. Institution certifies that it is not excluded from a federal health care program, including Medicare and Medicaid. In the event an Institution becomes excluded during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event.

### 24. Choice of Law

This Agreement shall be governed by and construed in accordance with the State of California, without giving effect to the principles of conflicts of law thereof. Any legal suit, action, or proceeding relating to this Agreement shall be instituted in the courts of Los Angeles, California.

### 25. Entire Agreement

Section and clause headings are used herein solely for convenience of reference and are not intended as

substantive parts of the Parties' agreement. This CTA incorporates the Exhibits referenced herein. This written CTA constitutes the entire agreement between the Parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this CTA require the written approval of each Party's authorized representative.

The authorized representatives of the Parties have signed this CTA as set forth below.

### EIGER BIOPHARMACEUTICALS, INC.

Signer Name: Sergey Pavlenko, MD
Signing Reason: I approve this document
Signing Time: 11 March 2022 | 1:43:28 PM CST

18BB1EF28D0D45F2B72092F45DBEAC54
An authorized signatory of Biorasi, LLC under a
Power of Attorney authorizing the signatory to
execute in the name of and on behalf of Eiger
BioPharmaceuticals, Inc.

Name: Sergey Pavlenko, MD

Title: Director, Project Management

Date: 11 March 2022

# UNIVERSITY OF SOUTHERN CALIFORNIA

By: DocuSigned by:

E1FC2FDE26CD4E8...

Name: Jeri Muniz

Title: Executive Director

Date: 3/9/2022

Read & Acknowledged: PRINCIPAL INVESTIGATOR

DocuSigned by:

Date: 3/9/2022

### **EXHIBIT A PROTOCOL**

(Incorporated herein by reference.)

### **EXHIBIT B**

### **BUDGET & PAYMENT SCHEDULE**

### INVESTIGATOR INFORMATION

First Name	Norah
Middle Name	A
Last Name	Terrault
Medical Credentials	MD
NPI #	1225086283
License #	A60147
State	California
Country	US

### PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee"):

Payee Name	University of Southern California
Payee Street Address	3500 S. Figueroa Street, Suite 110
Payee City, State ZIP	Los Angeles, CA 90089
Payee Tax ID	95-1642394
Bank Name	Bank of America
Bank Address	333 S. Hope Street
	Los Angeles, CA 90071
Bank Routing	
Number	122000661
Payee Bank Account	1459406561
Payee Contact	Lisa Manion
information for	(323) 865-7896
recipient of payment	lisa.manion@med.usc.edu
notifications	

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

In case of changes in the Payee's address or bank account number, Institution is obliged to inform Biorasi in writing. The Parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax-exempt status, no further amendments are required.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by Biorasi to the Payee.

Investigator acknowledges that if Investigator is not the Payee, Biorasi will not pay Investigator evenif the

Payee fails to reimburse Investigator.

### PAYMENT TERMS

Sponsor has engaged Biorasi, LLC ("Biorasi") to administer payments for the Study. Biorasi will administer payment to the Payee monthly, on a completed visit per-subject basis in accordance with the attached Budget. Ninety percent (90%) of each payment due will be made based upon prior month enrollment data confirmed by subject CRFs received from the site supporting subject visits. No invoices will be required for Study Subject scheduled visit payments.

The balance of monies earned of the ten percent (10%), will be paid by Biorasi to the Payee upon, final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by this Agreement, the certified return or destruction of all unused supplies to Biorasi at Sponsor's sole cost, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Major, disqualifying Protocol violations may not be payable under this Agreement, provided that all procedures performed up to such Protocol violation, if any, shall be payable as otherwise required under this Agreement. Sponsor and Institution will engage in good faith discussions to address any such issues and payments thereof.

The Study initiation fees paid, including any IRB fees, are not refundable, and in the event of any termination of the Study, the Sponsor will be responsible for all actual costs including non-cancelable obligations of the Institution in accordance with the Budget. In the event of early termination, hereunder, the total sums payable by Sponsor shall be equitably pro-rated for actual work performed to the date of termination.

### PAYMENT DISPUTE

Site will use reasonable efforts to dispute any payment within ninety (90) business days from the receipt of payment during the course of the Study.

### DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination Study subjects will be prorated for actual work performed, based on the number of confirmed completed visits and/or procedures performed.

### **INVOICES**

Payments will be issued by Biorasi based on Budget, payment frequency and payment terms as described above. Payments will be made only upon receipt of corresponding invoices, including back-up documentation where available in the specified currency, as described below. Invoices will be payable within thirty (30) days from the date of receipt by Biorasi of the invoice, including any applicable back-up documentation where available.

Invoices for any additional payments to those noted above (i.e., additional reimbursements) must also be sent to Biorasi and approved by Sponsor or Biorasi. Other than for unscheduled visits, payments for visits do not require an invoice. All invoices shall be raised in the following manner:

Invoices to be **billed** to: Eiger BioPharmaceuticals, Inc. 2155 Park Blvd. Palo Alto, CA 9430

### Invoices to be sent to:

Biorasi, LLC 18851 NE 29th Ave #800 Aventura, FL 33180 AP@biorasi.com

The following information should be included on the invoice:

- Investigator Name
- Invoice Date
- Payee/Site Name (must match Payee indicated above)
- Sponsor Name
- Payment Amount
- Invoice Number
- Complete description of services rendered/details of expense(s)
- Study Number: EIG-LMD-002 /157-2

All invoice and payment related inquiries shall be addressed directly to Biorasi at <u>AP@biorasi.com</u>, telephone +1 785 388-0700

### Screening

Reimbursement for screen failures will be at the amount indicated up to the total of the screening visits within the Budget, staff time and overhead, per screen fail.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to Biorasi along with any additional information, which may be requested by Biorasi to appropriately document the subject screening procedures.

### UNSCHEDULED VISITS

Payment for unscheduled visits will be based on the procedures actually performed and invoiced at the amounts indicated in the Budget and institutional overhead. Unscheduled visits shall be reimbursed upon receipt of a valid invoice. Subject number and visit/dates must be included on the invoice for payment to be issued.

### STUDY SUBJECT STIPENDS

Study subjects may receive travel reimbursement to attend Study visits by Greenphire Clincard. Greenphire Clincard will generate payments directly to Study subjects as outlined in the informed consent form. Institution will not handle this reimbursement nor will incur any expenses.

### SITE FEES / CONDITIONAL FEES

### IRB Fees

Institution will be reimbursed on a pass-through basis upon receipt of invoice for local IRB/IEC costs in the amounts indicated on the attached Budget. Central IRB/IEC costs will be reimbursed directly to the Central IRB by Biorasi or Sponsor and these cost are not included in the attached Budget.

A non-refundable payment for the initial review and approval of the Protocol by Institution's IRB shall be paid by Sponsor to Institution based on an invoice submitted directly by Institution. For clarity, the Payee and remit-to address for all payments to Institution is the same for Institutional local IRB fees as for all other Study costs. Sponsor agrees to pay for the initial IRB review cost regardless of whether the Study Protocol is approved.

### Administrative Study Start-Up Fee

A one-time, non-refundable payment of \$18,180 USD which includes overhead, to cover Study start-up activities will be made upon execution of this Agreement and receipt of an invoice. This fee does not include the local IRB review fees as noted above and is not contingent on IRB approval.

### Pharmacy Set-Up Fee

A onetime, non-refundable Pharmacy Set-Up payment of \$1250 USD, will be made upon completion and receipt by Biorasi of all original contractual and regulatory documentation and receipt of an invoice.

### Record Storage Fee/Archiving Fee

A record storage payment of \$1350 USD inclusive of overhead, will be made upon receipt of invoice. In accordance with Sponsor's Protocol requirements, site shall maintain all site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

### Study Close-Out Fee

A one-time, non-refundable Study Close-Out payment of \$2000 USD inclusive of overhead will be made upon completion and approval by Biorasi of any outstanding data documentation (eCRFs and data clarifications issued) and regulatory documentation and upon receipt of invoice.

### Protocol Amendment Processing Fee

A Protocol Amendment Processing Fee of \$750 USD inclusive of overhead, will be made upon receipt of invoice in the event of a Sponsor-driven Protocol amendment.

### IND Safety Reporting Fee

IND Safety reporting will be reimbursed at a rate of \$40 USD inclusive of overhead, per report received by site. Date of report must be received with invoice.

### Sponsor Audits

A Sponsor Audit fee will be reimbursed upon receipt of invoice only in the event of such an audit which is conducted for any reason other than "for cause," at an amount not to exceed \$1000 USD per day inclusive of overhead, per audit.

### Inform Consent Form Re-Consent Processing Fee

An Inform Consent Form Revision Processing Fee of \$50 USD inclusive of overhead, will be made upon receipt of invoice in the event of a Sponsor-driven Protocol amendment, which requires resultant revisions to the inform consent form.

### **BUDGET TABLE**

	Sites Completed Cost for Sites Completed Cost for Patient Arm 1 Patient Arm 2:	
Site Total	\$ 45,759.60 \$ 55,036	.80

### Continues on next page

	Screening			herto s
Line No.	Study Period (		Study Visit 1 Screening for Run In	Study Visit 2 Screening for Eligibility
	Study Week			Carried March
	Study Day		-112	-28
	Study Procedure	Site Cost of Procedure		OPER PURPLE OF
1	Informed consent	\$ 150.00		
_2	Inclusion / Exclusion criteria	\$ 100.00	\$ 100.00	\$ 100.00
_3_	Medical History	\$ 80.00	\$ 80.00	\$ 80.00
4	Abdominal Imaging1	IN	/	INV:
5	Demographics	\$ 30.00	\$ 30.00	
6	Comprehensive Physical Exam	\$ 418.00		\$ 418.00
7	Vital Signs	\$ 225.00	\$ 225.00	Included w/ physical
8	Electrocardiogram	\$ 108.00	\$ 108.00	\$ 108.00
9	FibroTest and/or FibroScan (FibroScan only if equipment is available)	INV	1	INV
10	Ophthalmological Exam	\$ 333.0	Ö	\$ 333.00
11	Clinical Laboratory test (Local Lab) (Hematology, Chemistry, Urinalysis, Hepatitis B Core Antibody)	\$ 95.00	\$ 95.00	
12	Urine Drug Screen (Site will use Kit provided by Q2 to be done locally)	\$ 22.00	),	\$ 22.00
13	Blood Alcohol Test	\$ 30.00		\$ 30.00
14	Serum Pregnancy test (Local Lab)*3	INV	INV	
15	Pregnancy Test urine (Local)	INV	INV	
16	Central lab: collection, processing, shipping and handling. (Hematology, Chemistry, Urinalysis, HBV Genotyping, HBV DNA viral load, HBV Serology, HCV RNA viral load, HDV RNA viral load and HIV RNA Viral Load)	\$ 157.00		\$ 157.00
17	CTU services	\$ 246.00	Section 1	\$ 246.00
18	HCV RNA Viral load, HCV serology, HDV Serology, HDV RNA Viral Load, HIV RNA Viral Load, HIV Serology ( <u>Through</u> local laboratory only for SV1, if no historical data is available)*2	INV	INV	
19	Anti-HBV NUC therapy	\$ 30.00	\$ 30.00	\$ 30.00
20	Concomitant medications collection	\$ 45.00		
	Adverse events	\$. 45.00		\$ 45.00
22	Study Coordinator Fee	\$ 375.00	\$ 375.00	\$ 375.00
_	Investigator Fee	\$ 250.00		\$ 250.00
		Zavort z state April		
	Procedures Subtotal	***************************************	\$ 1,533.00	\$ 2,239.00
_	Overhead Fee	35%	\$ 536.55	\$ 783.65
2.7	Total Cost Per Subject	The state of the s	\$ 2,069.55	

\$ 5,092.20	TOTAL PER SUBJECT PAYMENT FOR SV 1 and SV 2

- 1. Abdominal imaging (eg, ultrasound, MRI, CT) performed if patient does not have abdominal imaging documentation  $\leq$  6 months before screening at Screening Visit 2.
- 2. If no Historical data within 6 months is available these are to be done through Local Laboratory
- 3. Screening Visit 1 urine pregnancy test will be done locally. Any positive tests must be confirmed by a serum pregnancy test performed locally. Screening Visit 2 serum pregnancy tests are to be performed at the study central lab.

### Payment Schedule:

- a. BIORASI will administer payments to site based on completed visits per subject after confirmation of EDC data completion.
- b. Reimbursement for screen failures will be in the amount indicated in the budget for work performed, staff time and overhead:
- Payment for unscheduled visits will be based on the procedures actually performed and invoiced at the amounts indicated within this Budget and overhead.

	Site Cost of
Additional Study Related Costs (Payable Upon Invoice) 35% OH included when applicable	Service/procedure
Study Start-Up Fee (includes Staff training, Document preparation and Protocol review)	\$ 6,325
CTO Startup Fee	\$ 5,000
CTU Startup fee	\$- 2,350
Medicine Research Unit (MRU) Fee	\$ 3,000
Radiology Set up fee	\$ 405
Pharmacy Fee Startup fee	\$ 1,250
Initial IRB Preparation Fee for Ceded review ( Central IRB)	\$. 1,100
IRB Initial Ceded Review Fee (Central IRB)	\$ 1,500
Protocol Amendment Processing Fee	\$ 750
Re-Consents per Occurrence (Invoiced)	\$ 50
Annual Administrative Maintenance Fee	\$ 500
Annual Pharmacy Maintenance & Storage Fee	\$ 1,000
IND Safety Reporting Fee (Per report, Invoiced)	\$ 40
Serious Adverse Event Reporting Fee (Per report)	\$ 250
Audit Fee (Per day)	\$ 1,000
Office Monitoring Visit* (Per day)	\$ 750
Remote Monitoring Visit (Per hour)	\$ 200
Pre- Screening (per patient)	\$ 135
The determing (per patient)	Per Third party invoice
i2b2 database use per hour	plus 35%
Informed Consent Form Translation Fee	Actual + 35% OH
Screen Failures 1	Actual cost + 35% OH
Screen Failures 2	Actual cost + 35% OH
Pharmacy Close-Out Fee	\$ 800
Document Archiving (Paid at Study Close Out) 10 years	\$ 1,350
Study Close Out	\$ 2,000
Ophthalmological exam (follow up) on EOS	\$ 2,000
Random Sparse PK Sampling (Central Lab Blood collection, processing and shipping)	\$ 180
Abbrv. Physical Exam (Invoiced) Fibrotest	\$ 498 \$ 97
FibroScan (If equipment is Available)	\$ 500
Clinical work-up test: anti-SLA liver kidney microsome type III antibody [anti-LKM3] and anti-p62 antibody - Local	
Laboratory if available	1NV
Urine Pregnancy test (Local Lab)	\$ 29
Serum Pregnancy test (Local Lab)	\$ 30
HCV RNA viral load (Local Lab)	\$ 70
HCV serology (Local Lab)	\$ 26
HDV serology (Local Lab)	\$ 28
HDV RNA viral load (Local Lab)	\$
HIV RNA viral load (Local Lab)	\$ 138
HIV serology (Local Lab)	\$ 40
CT Abdomen w/o & w/ Contrast	\$ 788
MRI Abdomen w/o & w/ Contrast	\$ 1,302
Ultrasound Abdominal (complete)	\$ 4326

Ultrasound Abdominal (complete)
\*The office monitoring fee does not include the changes from third parties to meet monitoring requirements.

	ARM 1		12000	And The	深端声,省	Tell 18-18-38	专为特别。	341 V	STATE OF THE PARTY	Trea	tment Phase A	rm 1		- PRESIDEN	经营等等	をあるまれる。	智能的學典的	电弧 使回报	999年的地方	
Line No.	Study Period		R/BL	ST 1	ST 2	. ភា3	, ST 4	ST 5	ST 6	ST 7	-518	ST 9	ST 10	ST.11	ST 12	\$7.13	ST 14	57 15	ST 16/ EOT	Complete Cost
	Study Week		Day 1	Week 1	Week 2	Week 4	₩eek 6	Week 8	Week 10	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	
	Study Day		22 W. 14768	8	15	29	43	57	<b>图4671</b> 为外	85	113	141	169	197	225	253	281	309	337	
	Study Procedure	Cost of Procedure		100	77450															
1	Comprehensive Physical Exam	\$ 418.00	\$ 418.00																\$ 418.00	\$ 836.00
2	Abbreviated Physical Exam*	\$ 369.00				INV		INV			tNV		INV		INV		INV			
3	Vital Signs	\$ 225.00								\$ 225.00			\$ 225,00			\$ 225.00			\$ 225.00	
4	Electrocardiogram	\$ 108.00	\$ 108.00								<u> </u>		\$ 108,00					<b></b>	\$ 108.00	\$ 324.00
	FibroTest and/or FibroScan (FibroScan only If equipment is available)	NV	1								ļ.,						L		INV	
	Central lab: collection, processing, shipping and handling. (Hematology, Chemistry, Urinalysis, HBV Genotyping, HBV DNA viral load, HBV Serology, HCV RNA viral load, HDV RNA viral load and HIV RNA Viral Load)	\$ 157.00	s 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 2,669,00
	CTU Facility and Services	Varies	5 279.00										\$ 219.00		\$ 162.00	\$ 159.00	\$ 147.00	\$ 87.00	\$ 264.00	\$ 2,529.00
	Pregnancy test Serum	2.4 INV	INV	1 222,03	1	*					-					-				\$ -
	Pregnancy Test urine	TO LINV	INV	_				INV			INV		INV		INV		INV		INV	\$ -
	Serum sample for PK and ADA	\$ 60.00	5 60.00	\$ 60.00	\$ 60.00	\$ 60.00	\$ 60.00	\$ 60.00	\$ 60.00	\$ 60.00			\$ 60.00			\$ 60.00			\$ 60.00	
	Concomitant medications	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 765.00
	Clinical work-up <sup>1</sup> (Additional Central Labs)	5 233.00	5	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV		\$ -
	Adverse events	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00			
	Study Drug Dispensation	\$ 55.00	\$ 55.00			\$ 55.00		\$ 55.00		\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00		\$ 660.00
20	Study Drug Administration	\$ 108.00	\$ 108.00								l									\$ 108.00
	Study Drug Accountability (Pharmacy log and IRT)	\$ 40.00		\$ 40.00	\$ 40.00		\$ 40.00	\$ 40.00	\$ 40.00			\$ 40.00		\$ 40.00	\$ 40.00	\$ 40.00	\$ 40.00	\$ 40.00		
22	PRO - mTSQM and treatment experience	\$ 30.00				\$ 30.00				\$ 30.00			\$ 30,00						\$ 30.00	
23	Patient Diary	\$ 40.00		7	7		\$ 40.00					\$ 40.00								
24	Study Coordinator Fee	\$ 75.00					\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 375.00	\$ 6,375.00
25	Investigator Fee	\$ 250.00		\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250,00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 250.00	\$ 4,250.00
400	THE STATE OF THE PROPERTY OF THE STATE OF TH	Links of Property	7 28 1 34 1 34	Control of	<b>売りまする (学者</b>	<b>国家国家</b> 英语	18.8 287	ARTON COM	THE PERSON	<b>新疆公司</b>	10 10 10 10 10 10 10 10 10 10 10 10 10 1	100 300 142	事務業等为	大湖 人物	Ser Serve	30000000000000000000000000000000000000	250	Section 1	<b>国本工程工程</b>	
	Procedures Subtotal		\$ 1,980.00	\$ 1,174.00			\$ 1,114.00		\$ 1,129.00	\$ 1,481.00	\$ 1,094.00	\$ 1,094.00		\$ 1,094.00	\$ 1,169.00	\$ 1,451.00		\$ 1,094.00		\$ 22,321.00
	Overhead Fee	35%	\$ 693.00				\$ 389.90		\$ 395.15			\$ 382.90	\$ 577.15	\$ 382.90	\$ 409.15	\$ 507.85	\$ 403.90	\$ 382.90		\$ 7,812.35
29	Notal Cost Per Sublect		S 2,673.00	LS_1.584.90	L5_1,524:15	L\$_1,638,901	S 1.503,90	LS 1,679,40	\$_1,524,15	5. 1,999,35	\$_1,476,90	LS_1:476.90	\$_2,226.15	\$ 1,476.90	\$ 1,578,15	1,958,85	1,557,90	\$ 1,475.90	[.\$_2,776.95	\$30,133.35

TOTAL PER SUBJECT PAYMENT FOR ARM 1 \$, 30,133.35

<sup>1</sup> All patients who develop hepatobiliary abnormalities suggestive of a potential DILI (Table 8) should have a clinical work-up as described in Section 5.1.9.1. (INV)

DocuSian Enve	elone ID: 822A3	9DB-13D5-457	5-8178-B308FC3B1F0A

	Contract programmer was ARM 2 for white or a factor of the section	1	Part of the Part	1271-169-1128	ning fig. Ann Sections	NUC IN	atment Phase	Arm 2	Wall Carelly	THE WAR	19 (20%) B	Dage 6764	ST AND WAR	MARKET BURNES	では、実施を表し	Miles " thinks	27.27 A 25.67	Study Treatm	ent Phase Arm	2. 计如连续分别从	THE WEST	大大学の	LANGE MAL	元本等 化增加	185 JON 185 ALVO	をおいて、網路の大幅	
ine	Study Period		R	NT1	NT2	NT 3	NT4	NT S	HT 6	81	511	512	573	ST 4	57.5	ST 6	ST 7	ST 8	ST 9	ST 10	57 11	S7 12	57 19	ST 14 🐇	5T 15	ST 16/ EDT	
101	Study Week	1	Day 1	Week 1	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 23	Week 14 *	Week 16	Week 18	Week 20	Week 22	Week 24	Week 28	Week 32	Week 35	Week 40	Week 44	Week 48	Week 52	Week 56	Week 60	
	Study Day		表 4 1 3 5 7	S 8 . 12	15 de 15 de 15	-i/a-29	% 43€	276 8 57 70 W	77.0171.42	85	92	99	113	127	海洋 141%	155	169	197	225	253	% 281 ·	309	337	CF 365	393	421	
	Study Procedure	Site Cost of Procedure	章·蒙	2012		1			POR A	6 m												4.1					Complete Co
1	Comprehensive Physical Exam	\$ 418,00								\$ 418.00													_			\$ 418.00	\$ 836.00
2	Abbreviated physical Exam*	\$ 369.00	INV			INV		INV					INV		INV		_	INV		INV		INV		INV			5 .
	Vitat Signs	\$ 225.00	\$ 225.00							Included w/ physical							\$ 225.00			\$ 225.00		<u> </u>	\$ 225.00			included w/ physical	5 900.0
4	Electrocardiogram	\$ # 103.00								\$ 108.00										\$ 108.00				1		\$ 108.00	\$ 324.0
	FibroTest and/or FibroScan (FibroScan only if equipment is available)	INV																						<u> </u>		INV	
	Central lab: collection, processing, shipping and handling, (Hematology, Chemistry, Urinarysis, HBV Genotyping, HBV UNA viral load, HBV Scrology, HCV RNA viral load, HDV RNA viral load and HIV RNA Viral Load)	\$ 157.00	\$ 157.00	\$ 157.0	0 \$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157,00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.0	0 \$ 157.00	5 157.00	5 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 157.00	\$ _157,00	\$ 157.00	\$ 157.00	\$ 157.00	\$ 3,768.0
7	CTU Facility and Services	orthoriti Varies	\$ 237.00	\$ 135.0	0 \$ 75.00	\$ 135.00	\$ 60,00	\$ 135.00	\$ 60.00	\$ 252.00	\$ 165.00	\$ 105.00	\$ 165.00	\$ 90.00	\$ 165.0	0 \$ 105.00	\$ 147.00	\$ 135.00	\$ 75.00	\$ 207.00	\$ 75.00	\$ 150.00	\$ 147.00	\$ 135.00	\$ 75.00	\$ 257.00	\$ 3,297.0
8	Pregnancy test Serum	"中央原"及SNV(海洋平安	JNV							INV	1									L .							5
	Presmancy Test urine	INV.	INV				-			INV					INV		-	INV		1NV_		INV	Ļ	INV		iNV	\$
14	Serum sample for PK and ADA	\$ 60.00								\$ 60.00				\$ 60.00						\$ 60.00			\$ 60.00			\$ 60.00	
16	Concomitant medications	\$ 45.00	\$ 45.00	\$ 45.0	0 \$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.0				\$ 45.00		\$ 45.00			\$ 45,00		\$ 45.00	\$ 1,080.0
17	Clinical work-up <sup>1</sup> (Additional Central Labs)	\$ 233.00			1 .						. INV	INV	UNV	INV	INV	_ INV	INV	INV	INV	INV	INV	INV	INV	INV	INV		5
18	Adverse events	\$ 45.00	\$ 45.00	\$ 45.0	0 \$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00	\$ 45.00		\$ 45.00	\$ 45.00					\$ 45.00	\$ 45,00				\$ 45.00				\$ 45.00	\$ 1,080.0
19	Study Drug Dispensation	\$ 55.00								\$ 55.00			\$ 55.00		\$ 55.0	00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00	\$ 55.00		\$ 660.0
	Study Orug Administration	\$ 103.00			1					\$ 108.00					ļ <u> </u>		<del> </del>			<del>                                     </del>							\$ 108.0
	Study Drug Accountability	\$ 40.00								\$ 40.00	\$ 40.00					00 \$ 40.00											
	Patient Diary	\$ 40.00		ļ	+	<u> </u>				\$ 40.00	\$ 40.00	\$ 40.00			\$ 40.0	0 \$ 40.00		\$ 40.00	\$ 40,00		\$ 40.00	\$ 40.00	\$ 48.00	\$ 40.00	\$ 40.00	\$ 40,00	
23	PRO - mTSQM and treatment experience	\$ 6 20 15 15 130.00			-					ļ <u> </u>		l	\$ 30.00			1	\$ 30.00			\$ 30.00							
	Study Coordinator Fee	\$ 375.00			\$ 375.00		\$ 375.00		\$ 375.00			\$ 375.00				6 \$ 375.00			\$ 375.00		\$ 375.00				\$ 375.00		\$ 9,000,00
25	Investigator Fee	\$ 250.00			\$ 250.00				\$ 250.00			\$ 250.00	\$ 250.00			0 \$ 250.00	5 250.00	\$ 250.00			\$ 250.00	\$ 250.00	5 250.00	\$ 250.00	\$ 250.00	5 250.00	\$ 6,000.00
		· [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [	读与检验的	Mary a decision	<b>新り、他の他の事業を持ち</b>		April Merc				A-6-25	T N 26 1	The state of the s		· 一大大		CHARLES AS	W. 230 W.	· · · · · · · · · · · · · · · · · · ·		10 mg 10 mg 2	retain the Titl	· 通知 · · · · · · · · · · · · · · · · · ·	12 7 Page 120		A IS ONLY THE WAY	39675 35 800 50
	Procedures Subtotal	1													5 1,232.00	5 1,117,00	5 1,469.00	\$ 1,142.00	\$ 1,082.00		\$ 1,082.00	5 1,157.00	\$ 1,439.00	5_1,142.00	5 1,082.00		\$ 29,193.00
	Overhead Fee	7-4-10-0-35% TO 00	\$ 466.90	\$ 352.45	\$ 331.45	\$ 352.45	\$ 326.20	\$ 352.45		\$ 683.55				\$ 385.70				\$ 399.70						\$ 399.70			\$ 10,217.55
29	Motal Cost Per Subject		5, 1,800,90	5. 1359 4	51.54.1.228.45	1859218	S 2258 201	\$ 1,359.65	1.5 1,258:20	6 2,636.55	15. 1.588.95	1.507.95	\$ 4,703.70	L\$ 1.482.70	1,5 x 1,663.2	01 \$_1.507.95	E- 5	51) 51.541(20)	I'S 1,460,70	(S 2209,95)	IS 1,460,70	1.551.95	15. 1.942.65	11.5 1.5 11.20	15, 1,460,701	5 2.477,25	.5 39,410.5

Template total per subject payment for Arm 2 TOTAL PER SUBJECT PAYMENT FOR ARM 2	<b>从本部的</b>
TOTAL PER SUBJECT PAYMENT FOR ARM 1	\$ 39,410.55
	A STATE OF THE STA

<sup>1</sup> All patients who develop hepatobiliary abnormalities suggestive of a potential DIU (Table 8) should have a clinical work-up as described in Section 5.1.9.1. (INV)

	ARM,18,2					. 1	Post Treatme	nt Follow-Up			710		]	
Line No.	Study Period		PT-1		PT-2		PT-3	PT-4		PT-5		PT-6		
	Study Week (Arm 1)		52	1	. 56		60	64		68		72		
	Study Day (±4 days) (Arm 1)		365	*	393		421	449	が	477		505		
	Study Week (Arm 2)		64		68		72	76	2 2 2 2	80		84		
	Study Day (+4 days) (Arm 2)		449		477	22	505	533		561		589		
	Study Procedure	Cost of Procedure											Com	plete Cost
1	Abbreviated physical Exam	\$ 369.00	INV				INV				\$	369.00	\$	369.00
2	Vital Signs	\$ 225.00	\$ 225.00	\$	225.00	\$	225.00	\$ 225.0	0 \$	225.00		uded w/ nysical	\$	1,125.00
3	Electrocardiogram	\$ 108.00	\$ 108.00	)		\$	108.00				\$	108.00	\$	324.00
4	Fibroscan and FibroTest	INV										INV	-	
5	Central lab: collection, processing, shipping and handling. (Hematology, Chemistry, Urinalysis, HBV Genotyping, HBV DNA viral load, HBV Serology, HCV RNA viral load, HDV RNA viral load and HIV RNA Viral Load)	\$ 157.00	\$ 157.00	\$	157.00	\$	157.00	\$ 157.0	0 \$	157.00	\$	157.00	\$	942.00
6	CTU Facility and Services	Varies	\$ 183.00	\$	183.00	\$	198.00	,	0 \$		\$	213.00		
_7_	Pregnancy Test urine	INV	INV		INV	_	INV	INV	1	INV		INV	\$	
10	Serum sample for PK and ADA	\$ 60.00	\$ 60.00	\$	60.00	\$	60.00	\$ 60.0	0 \$	60.00	\$	60.00	\$	360.00
d	Concomitant medications	\$ 45.00	\$ 45.00	\$	45.00	\$	45.00	\$ 45.0	0 \$	45.00	\$	45.00	\$	270.00
13	Adverse events	\$ 45.00	\$ 45.00	) \$	45.00	\$	45.00	\$ 45.0	0 \$	45.00	\$	45.00	\$	270.00
14	Ophthalmological Exam (Only to be conducted for patients observed with clinically meaningful ocular findings during the Treatment period)	INÝ										INV		
15	Study Coordinator Fee	\$ 350,00	\$ 350.0	<u> </u>	350.00	÷	350.00				<u> </u>	350.00	\$	2,100.00
16	Investigator Fee	\$ 150.00	\$ 150.0	) \$	150.00	\$	150.00	\$ 150.0	0 \$	150.00	\$	150.00	\$	900.00
17_		25 Miles 200						hy define						
18	Procedures Subtotal	4000000 9400000	\$ 1,323.00		1,215.00	\$	1,338.00	\$ 1,215.0				,497.00	\$_	7,803.00
19	Overhead Fee	35%	\$ 463.05	-	425.25	\$		\$ 425.2	$\rightarrow$		\$	523.95	\$	2,731.05
20	Total Cost Per Subject		\$ 1,786.0	\$	1,640.25	\$	1,806.30	\$ 1,640.2	5 \$	1,640.25	\$	2,020:95	\$	10,534.05

		Section
100	TOTAL PER SUBJECT PAYMENT FOR PT Follow up Arm	l & 2

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED provided that unanticipated costs will be submitted by Institution to Sponsor for its approval.

These amounts include all applicable taxes.

All payments for this Study in accordance with this Exhibit B and Budget will be administered and paid by Biorasi electronically.

Protocol # EIG-LMD-002

# **EXHIBIT C**

Administrative & Study Points of Contact

**Certificate Of Completion** 

Envelope Id: F1AC351DF0E34B9281B11007F7980329

Subject: Please DocuSign: Site 2021 Terrault / EIG-LMD-002 Site CTA / #3571

Sponsor Project Code: 157-2 **Quality Document Type:** Source Envelope:

Document Pages: 24 Certificate Pages: 5

AutoNav: Enabled

**Envelopeld Stamping: Disabled** 

Time Zone: (UTC-06:00) Central Time (US & Canada)

Envelope Originator:

Status: Completed

Cara Jacobs

18851 NE 29th Ave #800 Aventura, FL 33180 cjacobs@biorasi.com IP Address: 136.35.127.99

Sent: 3/11/2022 1:13:10 PM

Viewed: 3/11/2022 1:43:03 PM

Signed: 3/11/2022 1:43:36 PM

Viewed: 3/11/2022 1:14:07 PM

**Record Tracking** 

Status: Original

3/11/2022 1:10:54 PM

Holder: Cara Jacobs

cjacobs@biorasi.com

Location: DocuSign

Timestamp

Signer Events

Sergey Pavlenko, MD spavlenko@biorasi.com Director, Project Management

**Biorasi** 

Security Level: Email, Account Authentication

(Required)

Signature

Signatures: 1

Initials: 0

Sergey Parlenko, MD

Signature Adoption: Pre-selected Style

Signature ID:

18BB1EF2-8D0D-45F2-B720-92F45DBEAC54

Using IP Address: 134.56.192.8

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

COPIED

**Electronic Record and Signature Disclosure:** 

Accepted: 6/23/2020 6:45:34 PM

ID: f35aea54-68c8-4277-beef-87a199a92bce

		بالمعي فينا والمستوارين والمستوارين والمستوارين والمستوارين والمستوارين والمستوارين والمستوارين والمستوارين	Control of the second s
Carbon Copy Events	Status	Timestamp	
Certified Delivery Events	Status	:Timestamp	
Intermediary Delivery Events	Status	Timestamp	
Agent Delivery Events	Status	Timestamp	
Editor Delivery Events	Status	Timestamp:	
In Person Signer Events	Signaturė	Timestamp	

kvasquez@biorasi.com

Security Level: Email, Account Authentication

(Required)

**Electronic Record and Signature Disclosure:** 

Not Offered via DocuSign

Witness Events Signature Timestamp
Notary Events Signature Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/11/2022 1:13:11 PM
Certified Delivered	Security Checked	3/11/2022 1:43:03 PM
Signing Complete	Security Checked	3/11/2022 1:43:36 PM
Completed	Security Checked	3/11/2022 1:43:36 PM
Payment Events	Status	Timestamps
Electronic Record and Signature D	lisclosure	

#### ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Biorasi, LLC (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

## Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

### Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

#### Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

#### How to contact Biorasi, LLC:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: mrudolph@biorasi.com

#### To advise Biorasi, LLC of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at mrudolph@biorasi.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

### To request paper copies from Biorasi, LLC

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to mrudolph@biorasi.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

# To withdraw your consent with Biorasi, LLC

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to mrudolph@biorasi.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

#### Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <a href="https://support.docusign.com/guides/signer-guide-signing-system-requirements">https://support.docusign.com/guides/signer-guide-signing-system-requirements</a>.

#### Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Biorasi, LLC as described above, you consent to receive
  exclusively through electronic means all notices, disclosures, authorizations,
  acknowledgements, and other documents that are required to be provided or made
  available to you by Biorasi, LLC during the course of your relationship with Biorasi,
  LLC.

Site 2021

# First Amendment To Clinical Trial Agreement

This First Amendment ("First Amendment") to the March 11, 2022 Clinical Trial Agreement ("Agreement") between Eiger BioPharmaceuticals, Inc., a corporation having its principal place of business at 2155 Park Blvd., Palo Alto, CA 94306 ("Sponsor") and the University of Southern California, a California non-profit public benefit corporation with an address located at 1640 Marengo St., 7th Floor, Los Angeles, CA 90033 ("Institution") is made as of November 14, 2022 ("First Amendment Effective Date"). Sponsor and Institution are herein referred to collectively as "Parties." Individually, each is a "Party."

#### Background:

The Parties wish to amend the Agreement to update the budget as set forth below based on Protocol Amendment 2, V 3.0 dated 15April2022.

NOW, THEREFORE, in consideration for the mutual promises made in this First Amendment and for valid consideration, the Parties agree as follows:

- 1. The Budget Table in Exhibit B (Budget & Payment Schedule) is hereby deleted in its entirety and replaced with the revised Budget Table attached hereto as Attachment 1.
- 2. Except as specifically amended by this First Amendment, all other provisions of the Agreement remain in full force and effect. This First Amendment shall not constitute or operate as a waiver of, or estoppel with respect to, any provisions of the Agreement by any party hereto.

The authorized representatives of the Parties have signed this First Amendment to the Agreement as set forth below.

Eiger BioPharmaceuticals, Inc.

University of Southern California

DocuSigned by:

DocuSigned by: Nancy Newark

By: Name: Title:

Date:

Signer Name: Nancy Newark Nan Signing Reason: I approve this document Sining Lime: 05 May 2023 | 11:42:36 AM PDT /ice President, Project Mgmt. D9FAC241E8AA4256BC00A9169041C586

An authorized signatory of Biorasi, LLC under a Power of Attorney authorizing the signatory to execute in the name of and on behalf of Eiger BioPharmaceuticals, Inc.

Teresa Trejo By:

Name: Teresa Trejo

Title: Clinical Trials Budgeting Manager, CTO Date:

5/1/2023

Read & Acknowledged: Principal Investigator

DocuSigned by:

Signed:

Norale Terrault, M.D.

Name: Title:

Norah Terrault, MD Principal Investigator

Date:

4/26/2023

PI Name: Terrault, Norah / Site 2021

Project Code 157-2 Biorasi Contract ID 5775 First Amendment To Clinical Trial Agreement EIG-LMD-002 Site 2021

Attachment 1 - Revised Budget Table

PI Name: Terrault, Norah / Site 2021

Project Code 157-2 Biorasi Contract ID 5775

1	Screening	a company of the contraction	Carlor Commence	4.00
Line No.	Study Period		Study Visit 1 Screening for Run In	Study Visit 2 Screening for Eligibility
	Study Week			a water and the second of the second
	Study Day		-112	-28
	Study Procedure	Cost of Procedure	CONTRACTOR VI	A PARTY TOTAL
1	Informed consent	\$150.00	\$150.00	
2	Inclusion / Exclusion criteria	\$100.00	\$100.00	\$100.00
3	Medical History	\$80.00	\$80.00	\$80.00
4	Abdominal Imaging *1	INV		INV
5	Demographics	\$30.00	\$30.00	
6	Comprehensive Physical Exam	\$418.00	Volice	\$418.00
Ë		\$225.00	\$225.00	Included w/
	Vital Signs		\$108.00	physical
	Electrocardiogram	\$108.00	\$108.00	\$108.00
9	FibroTest*6 and/or FibroScan (FibroScan only if equipment is available)	tNV		INV
10	Ophthalmological Exam	\$333.00		\$333.00
11	Local Labs: Clinical Laboratory test (Hematology, Chemistry, Urinalysis, Amylase, cholesterol, creatine kinase, GGT, LDH, Magnesium, Phosphorus, T3, TSH, Triglycerides Uric Acid, Coagulation parameters, CKD-EPI, thyroid panel and AFP) *4	\$202.28	\$202.28	
12	Urine Drug Screen (Site will use Kit provided by Q2 to be done locally)	\$22.00		\$22.00
13	Blood Alcohol Test	\$30.00		\$30.00
14	Serum Pregnancy test (Local Lab)*3	INV	INV	
15	Pregnancy Test urine (Local lab)*3	INV	INV	
	Central Lab: collection, processing, shipping and handling. (Routine Hematology, chemistries, coagulation parameters, and urinalysis; CKD-EPI, thyroid panel, and AFP, HBV DNA viral load, HBV Serology, HCV RNA viral load, HDV RNA viral load and HIV RNA Viral Load (Gentral Lob)	\$157.00		\$157.00
	HCV RNA Viral load, HCV serology, HDV Serology (*4&5), HDV RNA Viral Load (*4&5), HIV RNA Viral Load, HIV Serology (Through local laboratory only for SV1, if no historical data is available) *2	INV	INV	
18	CTU Services	Varies	\$66.00	\$261,00
	Anti-HBV NUC therapy	\$30.00	\$30.00	\$30.00
	Concomitant medications collection	\$45.00	\$45.00	\$45.00
21	Adverse events	\$45.00	\$45.00	\$45.00
	PHO9	\$30.00	\$30.00	Ç-13.00
	Study Coordinator Fee	\$375.00	\$375.00	\$375.00
24		\$375.00	\$250.00	\$250.00
	Investigator Fee		\$250.00	The second secon
25			5 (7. 1. 25/20 pp. 1. bet 7. 1. 70/20)	63.354.00
26	Procedures Subtotal	200/	\$1,736.28	\$2,254.00
	Overhead Fee	35%	\$607.70	\$788.90
28	iot (costic as the cost	L	\$2,043.50	\$3,042,90

TOTAL PER SUBJECT PAYMENT FOR SV.1 and SV.2 \$ 5,386.88

- 1. Abdominal imaging (eg, ultrasound, MRI, CT) performed if patient does not have abdominal imaging documentation < 6 months before screening at Screening Visit 2.
- 2. If no Historical data within 6 months is available these are to be done through Local Laboratory
- 3. Screening Visit 1 urine pregnancy test will be done locally. Any positive tests must be confirmed by a serum pregnancy test performed locally. Screening Visit 2 serum pregnancy tests are to be performed at the study central lab.
- 4. Please note different inclusion criteria for Screening Visit 1 and Screening Visit 2. Screening Visit 1 eligibility criteria defines initial eligibility criteria for the run-in phase and Screening Visit 2 eligibility criteria defines eligibility criteria for the randomization phase. If no historical lab data is available, Screening Visit 1 labs can be performed locally (with exception of the HBV DNA viral load which will be analyzed centrally). All labs collected at Screening Visit 2 will be analyzed at the central lab.
- 5. At Screening Visit 1, there is no blood draw for a HDV RNA or HDV serology testing required. To document evidence of chronic HDV infection, patients must have documented evidence of chronic HDV infection for a minimum of 3 months with either a positive HDV serology test or a HDV RNA detectable test (HDV RNA ≥ 5 IU/mL). At Screening Visit 2, patients must have documented evidence of chronic HDV infection with a quantifiable HDV RNA (≥40 IU/mL) by RT-PCR test.
- 6. If FibroScan cannot be conducted at the site due to equipment !Imitations, only a FibroTest will be conducted. Sample tube will be collected and sent to study central lab. Reimbursement for sample collection and handling is included as part of the proposed costs in Row 11
- 7. NUC Therapy can be provided either centrally by sponsor or locally by site, and reimbursed by sponsor. Please include a price related to the NUC therapy supply, in case your site procures it locally.

#### Payment Schedule:

- a. Biorasi will invoice site each month on a per visit and per procedure basis in accordance with the Budget (Exhibit B) for procedures completed during the prior month.
- b. Subjects that screen fail during the Screening Visit will be paid according to procedures completed for a total of 5 screen fail uring the Screen fail payments will occur monthly.
- c. Unscheduled visits will be paid according to procedures completed and with prior approval from Biorasi/Sponsor.

#### DocuSign Envelope ID: A8F895FB-7E73-4F3D-AD2A-596F730A4D2C

Study Start-Up Fee (includes Staff training, Document preparation and Protocol review)	\$ 6,32
CTO Startup Fee	\$ 5,000
CTU Startup fee	\$ 2,350
Medicine Research Unit (MRU) Fee	\$ 3,000
Radiology Set up fee	\$405
Pharmacy Fee Startup fee	\$ 1,250
nitial IRB Preparation Fee for Ceded review ( Central IRB)	\$ 1,100
RB Initial Ceded Review Fee (Central IRB)	\$
Protocol Amendment Processing Fee	\$ 750
Re-Consents per Occurrence (Invoiced)	\$ 50
Annual Administrative Maintenance Fee	\$ 500
Annual Pharmacy Maintenance & Storage Fee	\$ 1,000
ND Safety Reporting Fee (Per report, Invoiced)	\$ 40
Serious Adverse Event Reporting Fee (Per report)	\$ 250
Audit Fee (Per day)	\$ 1,000
Office Monitoring Visit* (Per day)	\$ 750
Remote Monitoring Visit (Per hour)	\$ 200
Pre-Screening (per patient)	-\$ 135
to entering the bearing	Per Third party Involc
i2b2 database use per hour	plus 355
Informed Consent Form Translation Fee	Actual + 35% OH
Screen Failures 1	Actual cost + 35% OH
Screen Failures 2	Actual cost + 35% OH
Pharmacy Close-Out Fee	\$ 800
Document Archiving (Paid at Study Close Out) 10 years	\$ 1,350
Study Close Out	\$ 2,000
Ophthalmological exam (follow up) on EOT in Arm1 and Arm2	\$ 416.00
Random Sparse PK Sampling (Central Lab Blood collection, processing and shipping)	\$ 180
Abbry, Physical Exam (Involced)	\$ 498
Fibrotest *6	\$ 98
FibroScan (If equipment is Available) *6	\$ 500
	V 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Clinical work-up test: anti-SLA liver kidney microsome type III antibody [anti-LKM3] and anti-p62 antibody - Local Laboratory if available	\$ 25
Urine Pregnancy test (Local Lab) *3	\$ 29
Orine Pregnancy test (Local Lab) *3 Serum Pregnancy test (Local Lab)	\$ 30
HCV RNA viral load (Local Lab)	\$ 70
HCV serology (Local Lab)	\$ 26
HDV serology (Local Lab)	\$ 28
HDV RNA viral load (Local Lab)	\$ 57
HIV RNA viral load (Local Lab)	\$ 138
HIV serology (Local Lab)	And the second of the second o
CT Abdomen w/o & w/ Contrast	\$ 788
MRI Abdomen w/o & w/ Contrast	\$
Ultrasound Abdominal (complete) Study Drug Administration (if performed by study staff)	\$ 326

	Completed Cost for Patient Arm 1 Completed Cost for Patient Arm 2	
Total	\$ 46,050.23 \$ 60,703.13	

2 Abbit 3 Vital 4 Elect Fibro 5 Clini	Study Period  Study Week Study Day  Study Procedure (Blood samples taken will be analysed in central labs)  mprehensive Physical Exam breviated physical Exam* al Signs ctrocardiogram	Cost of Procedure \$418.00 \$369.00 \$225.00	R/BL Day 1(1)	ST 1  Week 1  8	ST-2 Week 2	ST 3 Week 4	ST 4 Week 6 43	ST 5 Week 8	ST 6 Week 10	ST 7	Treatment Ph	ST 9	ST 10	ST 11	ST 12	ST 13	ST 14	ST 15
1 Com 2 Abbi 3 Vital 4 Elect Fibre 5 Clini	Study Week Study Day  Study Procedure (Blood samples taken will be analysed in central labs)  mprehensive Physical Exam breviated physical Exam* al Signs ctrocardiogram	\$418.00 \$369.00	Day 1	Week 1	Week 2	Week 4	Week 6	Week 8				ST 9	ST 10	ST 11	ST 12		ST.14	ST 15
1 Com 2 Abbi 3 Vital 4 Elect Fibro	Study Week Study Day  Study Procedure (Blood samples taken will be analysed in central labs)  mprehensive Physical Exam  breviated physical Exam* al Signs ctrocardiogram	\$418.00 \$369.00	1						Week 10	99, 7,599 (871 ) 465 (	ACM BOWN TO THE	是"15世界,我有效是16 mg	Alice . B . A . T. 65 .	大水二部 TE TE TO A SE	用工。大學的社會學	12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2. 不可以 是这种的种种	
2 Abbit 3 Vital 4 Elect Fibro 5 Clini	Study Procedure (Blood samples taken will be analysed in central labs)  mprehensive Physical Exam  breviated physical Exam*  al Signs  ctrocardiogram	\$418.00 \$369.00		8	15	29	43	10 x 2 x 2 x 2 x 2 x 2 x 2 x 2 x 2 x 2 x		Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44
2 Abbit 3 Vital 4 Elect Fibro 5 Clini	mprohensive Physical Exam brevlated physical Exam* al Signs ctrocardiogram	\$418.00 \$369.00	\$418.00			<b>经</b> "加州和连续		57	73	85	113	141	169	197	- 225	253	281	309
2 Abbi 3 Vital 4 Elect Fibro 5	breviated physical Exam* al Signs etrocardiogram	\$369.00	\$418.00															
3 Vital 4 Elect Fibro 5 Clini	al Signs ctrocardiogram																	
4 Elect	ctrocerdlogram	\$225.00				INV		INV			INV		INV		INV		INV	
Fibro			\$225.00							\$225.00			\$225.00			\$225.00		
5 Clini		\$108.00	\$108.00										\$108.00					
	roTest and/or FibroScan (FibroScan only if equipment is available)	INV																
Sero	nical Laboratory test (Hematology, Chemistry and Urinalysis, Cogaulation ameters and TFTs= thyroid function tests), HBV DNA viral load and HBV rology, HDV RNA Viral Load, HDV RNA sequencing, HDV Genotyping, HIV A and HCV RNA	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00
7 CTU	J Facility and Services	Varles	\$ 231.00	\$ 162.00	\$ 87.00	\$ 144.00	\$ 72.00	\$ 177,00	\$ 102.00	\$ 114.00	\$ 132.00	\$ 72.00	\$ 201.00	\$ 72.00	\$ 189.00	\$ 114.00	\$ 159.00	\$ 72.00
	gnancy test Serum	iNV	INV															
_	gnancy Test urine	NV NV	INV			INV		INV		INV	INV	INV	INV	INV	INV	INV	INV	INV
$\overline{}$	um sample for PK and ADA	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00			\$60.00	ļ —	<b></b> _	\$60.00		
	ti-HBV NUC therapy	INV	INV	INV	INV	INV	INV	INV	INV	inv	INV	INV	INV	INV	INV	INV	INV	INV
	ncomitant medications	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00
	nical work-up <sup>1</sup>	\$133.00 \$45.00	*4F.00	iNV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV
	verse events	\$45.00	\$45.00 \$55.00	\$45.00	\$45.00	\$45.00 \$55.00	\$45.00	\$45.00 \$55.00	\$45.00	\$45.00 \$55.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00 \$55.00	\$45.00	\$45.00
	dy Drug Dispensation  dy Drug Administration	\$108.00	\$108.00			\$55.00		\$00.00	-	\$00,00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$00.00	\$55.00	\$55.00
	dy Drug Accountability (Pharmacy log and IRT)	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40,00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00
	hthalmology Exam	DNV	7.0.00	7.0.00	7.0.00	7.0.00	Ţ.0/00	¥ 10.00	410.00	<b>\$10.00</b>	¥10.00	V-10.00	V-10.00	410.00	410.00	¥10.00	V10.00	410.00
-	O questionnaires	\$30.00	<del>                                     </del>	<del> </del>		600.00				P20.00			\$20.00				<del>  </del>	
	ent Diary	\$40.00	\$40.00	\$40.00	\$40.00	\$30.00 \$40.00	\$40.00	\$40.00	\$40.00	\$30.00 \$40.00	\$40.00	\$40.00	\$30.00 \$40.00	\$40.00	\$40.00	840.00	\$40.00	\$40.00
	dy Coordinator Fee	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$40.00	\$375.00	\$40.00	\$40.00	\$375.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00 \$375.00	\$40.00	\$40.00
22 Inve	estigator Fee	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00
						14								2 3				
23 Proc	ocedures Subtotal		\$2,157.00	\$1,174.00	\$1,099.00	\$1,241.00	\$1,084.00	\$1,244.00	\$1,114.00	\$1,436.00	\$1,139.00	\$1,079.00	\$1,631.00	\$1,079.00	\$1,196.00	\$1,406.00	\$1,166.00	\$1,079.00
24 Ove	erhead Fea	35%	\$754.95	\$410.90	\$384.65	\$434.35	\$379.40	\$435.40	\$389.90	\$502.60	\$398.65	\$377.65	\$570.85	\$377.65	\$418.60	\$492.10	\$408.10	\$377.65
es lies			92000E3	1	30/29963													

TOTAL PER SUBJECT PAYMENT FOR ARM 1 \$30,129.30

<sup>1</sup> All patients who develop hepatobiliary abnormalities suggestive of a potential DILI (Table 8) should have a clinical work-up as described in Section 5.1.9.1. (INV)

	ARM 2					NUC Trea	unent Phase	Arm 2		P							S	tudy Treatme	nt Phase Arm	n 2	
Line No.	Study Period		R	NT 1	NT2	NT3	NT 4	NT 5	NT 6	BL.	ST 1	ST 2	ST 3	ST 4	ST 5	ST 6	ST 7	ST 8	ST 9	ST 10	ST 11
	Study Week	Constitution of the second	Day 1	Week 1	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 13	Week 14	Week 16	Week 18	Week 20	Week 22 7	-Week 24	Week 28	Week 32	Week 36	Week 40
	Study Day		漫图4.100	8	15,	29	43	57	A. 71	85	92	99	113	127	141	155	169	. 197	225	253	281
	Study Procedure (Blood samples taken will be analysed in central labs)	Cost of Procedure						蒙海													
1	Comprehensive Physical Exam	\$418.00								\$418.00										<u> </u>	
2	Abbreviated physical Exam*	\$369.00	INV	<u> </u>		INV		INV				<u></u>	INV	<u> </u>	INV			INV	<b>└</b>	INV	
3	Vital Signs	\$225.00	\$225.00				<u> </u>			\$225.00							\$225.00			\$225.00	
4	Electrocardiogram	\$108.00								\$108.00								L		\$108.00	
5	FibroTest and/or FibroScan (FibroScan only if equipment is available)	INV																			
	Clinical Laboratory test (Hematology, Chemistry and Urinalysis, Cogaulation parameters and TFTs= thyroid function tests), Anti-HBV NUC therapy, HBV DNA viral toad and HBV Serology, HDV RNA Viral Load, HDV RNA sequencing, HDV Genotyping, HIV RNA and HCV RNA	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157,00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00
7	CTU Facility and Services	Varies	\$ 237.00	\$ 198.00	\$ 75.00	\$ 198.00	\$ 60.00	\$ 198.00	\$ 60.00	\$ 341.00	\$ 269.00	\$ 167.00	\$ 269.00	\$ 152.00	\$ 269.00	\$ 182.00	\$ 194.00	\$ 269.00	\$ 152.00	\$ 296.00	\$ 152.00
8	Pregnancy test Serum	INV	INV	1			,			INV											
9	Pregnancy Test urine	INV	INV							INV		,	INV	-	INV		INV	ŧNV	INV	INV	INV
10	Serum sample for PK and ADA	\$60.00								\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00			\$60.00	
11	Anti-HBV NUC therapy	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	İNV	INV	INV	INV	INV
12	Concomitant medications	\$45,00	\$45.00	\$45.00	\$45.00	\$45.00	\$45,00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00
13	Clinical work-up <sup>1</sup>	\$133.00	7.0.00	1	V	V	1			7	INV	INV	INV	INV	INV	INV	INV	iNV	INV	INV	INV
14	Adverse events	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00
15	Study Drug Dispensation	\$55.00		1	T					\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00	\$55.00
16	Study Drug Administration	\$108.00		1						\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00	\$108.00
_	Study Drug Accountability (Pharmacy log and IRT)	\$40.00								\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00
18	Ophthalmology Exam	INV		1					Ĺ												
19	PRO questionnaires	\$30.00											\$30.00				\$30.00			\$30.00	
20	Patient Diary	\$40.00						1		\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00
21	Study Coordinator Fee	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00
22	Investigator Fee	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00
				3.23565	TAME OF	THE THE	140	\$1683v	A PART OF A	1,100,100	<b>与16</b> 00人		**************************************		最大社会	K 5-0-72	74-73.	Section 1	DOM: 18	1.25	
200	THE REPORT OF THE PARTY OF THE																				
23	Procedures Subtotal	C my party place and the	\$1,334.00	\$1,070.00	\$947.00	\$1,070.00	\$932.00	\$1,070.00	\$932.00	\$2,267.00	\$1,444.00	\$1,342.00	\$1,474.00	\$1,327.00	\$1,444.00	\$1,357.00	\$1,624.00	\$1,384.00	\$1,267.00	\$1,834.00	\$1,267.00
23 24	Control of the second s	35.00%	\$1,334.00 \$466.90	\$1,070.00 \$374.50	\$947.00 \$331.45	\$1,070.00 \$374.50	\$932.00 \$326.20	\$1,070.00 \$374.50	\$932.00 \$326.20	\$2,267.00 \$793.45	\$1,444.00 \$505.40	\$1,342.00 \$469.70	\$1,474.00 \$515.90	\$1,327.00 \$464.45	\$1,444.00 \$505.40	\$1,357.00 \$474.95	\$1,624.00 \$568.40	\$1,384.00 \$484.40	\$1,267.00 \$443.45	\$1,834.00 \$641.90	\$1,267.00 \$443.45

TOTAL FER BUBLECT PAYMENT FOR ARE 2

\$44,782.20

i All patients who develop hepatobiliary abnormalities suggestive of a potential DIU (Table 8) should have a clinical work-up as described in Section 5.1.9.1. (INV)

	ARM:1 & 2				Post Treatme	ent Follow-Up			
Line No.	Study Period		PT-1	PT-2	PT-3	PT4	PT-5	PT-6	
	Study Week (Arm 1)		52	56	60	64	68	. 72	
	Study Day (+4 days) (Arm 1)	221.170	365	393	421	449	477	505	
	Study Week (Arm 2)		64	68	72	- 76	80	84	
	Study Day (+ 4 days) (Arm 2)		449	477	505	533	561	589	
	Study Procedure	Cost of Procedure							Complete Cost
1	Abbreviated physical Exam	\$369.00	INV		INV			\$369.00	\$369.00
2	Vital Signs	\$225.00	\$225.00	\$225.00	\$225.00	\$225.00	\$225.00	Included with physical	\$1,125.00
3	Electrocardiogram	\$108.00	\$108.00		\$108.00			\$108.00	\$324.00
4	Fibroscan and FibroTest	INV						INV	
	Clinical Laboratory test (Hematology, Chemistry, Urinalysis, Coagulation and serum), HBV DNA viral load and HBV Serology, HDV RNA Viral Load, Serum sample for PK and ADA	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$157.00	\$942.00
6	CTU Facility and Services	Varies	\$ 183.00				\$ 183.00	\$ 213.00	
7	Pregnancy Test urine	INV	INV	INV	INV	INV	INV	INV	\$0.00
8	Serum Sample for PK and ADA	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$60.00	\$360.00
9	Anti-HBV NUC therapy	INV	INV	INV	INV	INV	INV	INV	\$0.00
	Concomitant medications	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$270.00
11	Adverse events	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$45.00	\$270.00
12	Study Coordinator Fee	\$350.00	\$350.00	\$350.00	\$350.00	\$350.00	\$350.00	\$350.00	\$2,100.00
13	Investigator Fee	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$900.00
			64.000.00	\$4.045.00	64 000 00	64 045 00	64.045.00	64 407 00	<b>67</b> 000 00
14	Procedures Subtotal	0.504	\$1,323.00	\$1,215.00	\$1,338.00	\$1,215.00	\$1,215.00	\$1,497.00	\$7,803.00
15	Overhead Fee	35%	\$463.05 \$1,786.05	\$425.25 \$1,640.25	\$468.30 \$1,806.30	\$425.25 \$1,640.25	\$425.25 \$1,640.25	\$523.95 \$2,020.95	\$2,731.05 \$10,534.05

TOTAL PER SUBJECT PAYMENT FOR PT Follow up Arm 1 & 2

\$10,534.05

Certificate Of Completion

Envelope Id: A8F895FB7E734F3DAD2A596F730A4D2C

Subject: Complete with DocuSign: EIG-LMD-002 2021 Terrault CTA Amendment 4.17.2023 Final.pdf

Source Envelope:

**Document Pages: 7** 

Certificate Pages: 5

AutoNav: Enabled

Envelopeld Stamping: Enabled

Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Status: Completed

Envelope Originator:

Erica Oliva

2011 N. Soto Street, 2nd Floor Los Angeles, CA 90032 erica.oliva@med.usc.edu IP Address: 68.181.17.91

Record Tracking

Status: Original

4/18/2023 10:44:35 AM

Holder: Erica Oliva

erica.oliva@med.usc.edu

Location: DocuSign

Signer Events

Norah Terrault, M.D.

norah.terrault@med.usc.edu

Security Level: Email, Account Authentication

(None)

Signature

Signatures: 2

Initials: 0

Norale Terrault, M.D.

Signature Adoption: Pre-selected Style Using IP Address: 194.206.55.238

Timestamp:

Sent: 4/18/2023 11:27:31 AM Resent: 4/26/2023 12:11:18 PM Viewed: 4/26/2023 3:13:05 PM Signed: 4/26/2023 3:13:47 PM

**Electronic Record and Signature Disclosure:** 

Accepted: 4/26/2023 3:13:05 PM

ID: 0fdeda5a-be62-4ca9-a394-ddfeb2c93ddd

Teresa Trejo

Teresa.Trejo@med.usc.edu Clinical Trials Budgeting Manager **USC Clinical Trials Administrations** 

Security Level: Email, Account Authentication

(None)

Teresa Trejo

Signature Adoption: Pre-selected Style Using IP Address: 68.181.17.39

Sent: 4/26/2023 3:13:48 PM Viewed: 5/1/2023 3:43:01 PM Signed: 5/1/2023 3:47:08 PM

**Electronic Record and Signature Disclosure:** 

Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent Certified Delivered	Hashed/Encrypted	4/18/2023 11:27:31 AM 5/1/2023 3:43:01 PM
Signing Complete	Security Checked Security Checked	5/1/2023 3:47:08 PM

Envelope Summary Events	Status	Timestamps
Completed	Security Checked	5/1/2023 3:47:08 PM
Payment Events  Electronic Record and Signature Disc	Status osure	Timestamps

#### ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, USC Clinical Trials Administrations (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

#### Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

#### Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

#### Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

#### All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

#### **How to contact USC Clinical Trials Administrations:**

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: dshelp-l@usc.edu

#### To advise USC Clinical Trials Administrations of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at dshelp-l@usc.edu and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

#### To request paper copies from USC Clinical Trials Administrations

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to dshelp-l@usc.edu and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

#### To withdraw your consent with USC Clinical Trials Administrations

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to dshelp-l@usc.edu and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

#### Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <a href="https://support.docusign.com/guides/signer-guide-gigning-system-requirements">https://support.docusign.com/guides/signer-guide-gigning-system-requirements</a>.

#### Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify USC Clinical Trials Administrations as described above, you
  consent to receive exclusively through electronic means all notices, disclosures,
  authorizations, acknowledgements, and other documents that are required to be provided
  or made available to you by USC Clinical Trials Administrations during the course of
  your relationship with USC Clinical Trials Administrations.

# DocuSign

Certificate Of Completion

Envelope Id: 9A6FEE654744459B82C26B3AB638748F

Subject: Complete with DocuSign: EIG-LMD-002\_2021\_Terrault\_CTA Amendment 1\_01May2023.pdf

Sponsor Project Code: 157-2 Quality Document Type: Form

Source Envelope:

Document Pages: 12 Certificate Pages: 1 AutoNav: Enabled

Envelopeld Stamping: Disabled

Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Signatures: 1

Initials: 0

atures: 1 Envelope Originator:
s: 0 Vanessa Tortolero
18851 NE 29th Ave #800
Aventura, FL 33180

vtortolero@biorasi.com
IP Address: 174.68.94.215

Sent: 5/4/2023 1:18:19 PM

Viewed: 5/5/2023 11:42:15 AM

Signed: 5/5/2023 11:42:38 AM

**Record Tracking** 

Status: Original

5/4/2023 1:15:23 PM

Holder: Vanessa Tortolero vtortolero@biorasi.com Location: DocuSign

Timestamp

Status: Completed

Signer Events

Nancy Newark nnewark@biorasi.com VP Project Management

Security Level: Email, Account Authentication

(Required), Logged in

Signature

Nancy Newark

Signature Adoption: Pre-selected Style Signature ID:

D9FAC241-E8AA-4256-BC00-A9169041C586

Using IP Address: 69.218.221.196

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

**Electronic Record and Signature Disclosure:** 

Not Offered via DocuSign

Completed	Security Checked	5/5/2023 11:42:38 AM
Signing Complete	Security Checked	5/5/2023 11:42:38 AM
Certified Delivered	Security Checked	5/5/2023 11:42:15 AM
Envelope Sent	Hashed/Encrypted	5/4/2023 1:18:19 PM
Envelope Summary Events	Status	Timestamps
Notary Events	Signature	Timestamp
		mesamp
Witness Events	Signature	Timestamp
Carbon Copy Events	Status	Timestamp
Certified Delivery Events	Status **	Timestamp
ntermediary Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Editor Delivery Events	Status	Timestamp