#### DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Form Approved: OMB No. 0910-0396 Report Date: 11/29/2021

sBLA

### **CERTIFICATION: FINANCIAL INTERESTS AND** ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box. **(**1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f). Clinical investigators (See attached)  $\square$  (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2 (a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)). Clinical investigators (See attached) (3)As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant. I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

Clinical investigators (See attached)

NAME (b) (6)		TITLE (b) (6)	
FIRM/ORGANI Pfizer Inc.	ZATION		
SIGNATURE	(b) (6)	DATE 11/29/2021	

This section applies only to the requirements of the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of the PRA Staff email address below. information unless it displays a currently valid OMB control number. Public reporting burden for this Department of Health and Human Services collection of information is estimated to average 1 hour per response, including time for reviewing Food and Drug Administration instructions, searching existing data sources, gathering and maintaining the necessary data, and Office of Operations completing and reviewing the collection of information. Send comments regarding this burden PRAStaff@fda.hhs.gov estimate or any other aspect of this collection of information to the address to the right:

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Product's Established Name:	bnt162
Protocol Number:	C4591001
Study Name:	A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS
Disclosure Start Date:	04/29/2020
Disclosure Cut-off Date:	11/03/2021

Institution Name: Rochester Clinical Research, Inc.

Protocol Number: C4591001

Center Number: 1005

**List of Investigator Names** 

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Chelsea Bork

Mrs. Michelle Lyn Burgett

Julie M. Callahan

Cristina Cramer-Mills

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Protocol Number: C4591001				
Center Number: 1006	Institution Name: J. Lewis Research, Inc. / Foothill Family Clinic			
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Dr. Alexander Paul Clark				
Dr. Shana Kinsey Eborn				
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Center Number: 1007	Institution Name: Cincinnati Children's Hospital Medical Center			
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Dr. Paul W. Spearman				
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### sBLA BNT162b2 Section 1.3.4 Financial Disclosure THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT **Protocol Number: C4591001** Center Number: 1008 **Institution Name: Clinical Research Professionals List of Investigator Names** Dr. Timothy W. Jennings (b) (6) Tonya Clausen Dr. Siddharth Kaul Dr. Anthony J. Margherita Stacey Miner Mrs. Brittany Nguyen Mrs. Ann M Patek Dr. Fredric Prater Dawn M Ringling Richard A. Summa Dr. Terry Joe Weis Ms. Alaina Yarber Center Number: 1009 Institution Name: J. Lewis Research, Inc. / Foothill Family Clinic South **List of Investigator Names** Dr. Shane Glade Christensen Dr. Holly Marie Anderson Ms. Emily Kathleen Bloomquist Dr. Ross Anthony Brunetti Dr. Thomas Kane Conner Dr. Gina Marie Cox Dr. Diana G. Grazulis Dr. Wesley James Lewis

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**Protocol Number: C4591001** 

Center Number: 1013 Institution Name: Clinical Neuroscience Solutions, Inc. Dba Cns Healthcare

**List of Investigator Names** 

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Joan Elizabeth Cutillo

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**Protocol Number: C4591001** 

Center Number: 1016

Institution Name: Kentucky Pediatric/ Adult Research

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Center Number: 1039

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Center Number: 1044

List of Investigator Names

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### THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Center Number: 1066 **Institution Name: Solaris Clinical Research List of Investigator Names** Dr. David J. Butuk Janelle T Barney Janaie Emily Bounsana Erin Brennan Melissa Conrad Scott T Frisby Meredith K. Mangum Paige Paige McKenzie Kaylee Christine Ruckrigl Center Number: 1077 Institution Name: Meridian Clinical Research LLC **List of Investigator Names** Dr. Suchet R. Patel Caitlyn Burford Dr. Kimberly Desantis Michael Federico Dr. Demetrios Gasparis Dr. Lazarus Brent Christian Gehring Dr. James C Holler Eric Joseph Lorraine Miss Katherine Macarak Dr. Rekha S. Patel John Simon Perry

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### THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT **Protocol Number: C4591001** Center Number: 1084 Institution Name: Clinical Trials Of Texas, Inc. **List of Investigator Names** Dr. Douglas Scott Denham Darlington Akahara Muhammad Omair Ahsan Ata Dr. Ayoade O Avworo Stephen E Brick Cathleen Chen Maristelle Co Graham Ellis Kimberly R. Evans Zachariah E Francois Dr. Parke Hedges Matthew K Korte Anshumaan Maharaj

**Protocol Number: C4591001** 

Center Number: 1091

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Center Number: 1124

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## THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Center Number: 1126 Institution Name: Kaiser Permanente Santa Clara **List of Investigator Names** Rebecca Alexander Janelle Baires Mrs. Jessica M Barraza Latisha Burun Christine Cash Gail L. Cook Dr. David Michael Cooper JOLYNNE GERARDO ENCARNACION Douglas Ernst Lauren Blair Fontenot La Vonne Freed Jeremy Giese Julia R. Glanternik Sarah Kang Lisa Kennedy Rebekah Danell Kotyk Roma Kaur Kullar Ludy Pasaoa Lemus Mrs. Eva S Lowe Lorrie Aileen Lowe Nicole Makram Ms. Shannon Mullen

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Center Number: 1131

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Center Number: 1139

Institution Name: Accessioning Unit And Repository

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Center Number: 1140

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Protocol Number: C4591001	
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Protocol Number: C4591001

Center Number: 1152

Institution Name: California Research Foundation

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