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

Form Approved: OMB No. 0910-0396 Report Date: 03/31/2021

BLA

## DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning (see <u>Summary Table</u>), who participated as clinical investigators in the submitted study (see <u>Summary Table</u>), is submitted in accordance with 21 CFR part 54. The named individuals have participated in one or more of the following financial arrangements or hold financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.
 any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
 ✓ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
 ☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;
 ✓ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.
 Details of the individuals' disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

(b) (6)	TITLE (b) (6)	
FIRM/ORGANIZATION Pfizer Inc.		
SIGNATURE (b) (6)	DATE 03/31/2021	

## This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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FORM FDA 3455

PSC Publishing Services (301) 443-8740 EF

SUMMARY TABLE		
SIGNIFICANT PAYMENTS OF OTHER SORTS		
List of investigators	List of Protocol Numbers	
Dr. Nicola Penny Klein	C4591001	
Dr. Stephen Ira Pelton	C4591001	
Margaret Tiktin	C4591001	

ANY SIGNIFICANT EQUITY INTEREST		
List of investigators	List of Protocol Numbers	
Dr. Diego Wappner	C4591001	
Dr. Jill A. Sangree	C4591001	
Dr. Robert Joel Heller	C4591001	
Dr. Susan Edwards	C4591001	

DISCLOSURE DETAILS: FINANCIAL INTERESTS AN	ND ARRANGEMENTS OF CLINICAL INVESTIGATORS
Product's Established Name:	BNT162b2

Name of Clinical Investigator or Related Entity:	Dr. Diego Wappner
Clinical Investigator ID:	1466818
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1231
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

DISCLOSURE TYPE: EQUITY SNAPSHOT SUMMARY *					
Investigator Na	Investigator Name: Dr. Diego Wappner				
Protocol Number: C4591001					
Study Number	Disclosure Date	Publicly Held Company	Number of Shares	Value at Disclosure Date	Value Disclosed
[USD]					
C4591001	07/28/2020	BioNTechech	(b) (6)	(b) (6)	(b) (6)

<sup>\*</sup> The Equity Snapshot Summary contains equity details disclosed by an investigator through one or more Financial Disclosure Forms completed from the start of the study through one year after the completion of the study. Please note the value disclosed is the value determined at the provided Disclosure Date and should not be accumulated with any other listed value.

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Name of Clinical Investigator or Related Entity:	Dr. Jill A. Sangree
Clinical Investigator ID:	281831
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1150
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

DISCLOSURE TYPE: EQUITY SNAPSHOT SUMMARY *					
Investigator Na	Investigator Name: Dr. Jill A. Sangree				
Protocol Number: C4591001					
					Value Disclosed [USD]
C4591001	08/03/2020	Pfizer Inc.	(b) (6)	[USD] (b) (6)	(b) (6)

<sup>\*</sup> The Equity Snapshot Summary contains equity details disclosed by an investigator through one or more Financial Disclosure Forms completed from the start of the study through one year after the completion of the study. Please note the value disclosed is the value determined at the provided Disclosure Date and should not be accumulated with any other listed value.

Name of Clinical Investigator or Related Entity:	Dr. Nicola Penny Klein
Clinical Investigator ID:	280164
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1126
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

Investigator Name: Dr. Nicola Penny Klein				
Protocol Number: C4591001				
Clinical Investigator or Related Entity	Check Number	Purpose	Payment Date	Amount [USD]
KAISER RESEARCH FOUNDATION	0140480897	CLINICAL AND RESEARCH COLLABORATIONS	06/15/2020	(b) (6)
KAISER RESEARCH FOUNDATION	PAID	CLINICAL AND RESEARCH COLLABORATIONS	01/18/2021	(b) (6)
Payment exceeds threshold amoun	t of \$24,999.00		Total:	(b) (6)

Name of Clinical Investigator or Related Entity:	Dr. Robert Joel Heller
Clinical Investigator ID:	44801
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1254
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

Investigator Name: Dr. Robert Joel Heller				
Protocol Number: C4591001				
Study Number Disclosure Date Publicly Held Company Number of Shares Value at Disclosure Date Value Disclosed				
C4591001 07/24/2020 Pfizer Inc. (b	[USD] (b) (6)	(b) (6)		

<sup>\*</sup> The Equity Snapshot Summary contains equity details disclosed by an investigator through one or more Financial Disclosure Forms completed from the start of the study through one year after the completion of the study. Please note the value disclosed is the value determined at the provided Disclosure Date and should not be accumulated with any other listed value.

Name of Clinical Investigator or Related Entity:	Dr. Stephen Ira Pelton
Clinical Investigator ID:	4633
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1015
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

nvestigator Name: Dr. Stephen Ira Pelt	ton			
Protocol Number: C4591001				
Clinical Investigator or Related Entity	Check Number	Purpose	Payment Date	Amount [USD]
STEPHEN I PELTON	PAID	PROFESSIONAL SERVICES- ADMIN/ COMMERICAL (915)	07/20/2020	(b) (6)
STEPHEN I PELTON	PAID	PROFESSIONAL SERVICES- ADMIN/ COMMERICAL (915)	07/24/2020	
STEPHEN I PELTON	PAID	HCP AUTHORSHIP (902)	09/28/2020	
STEPHEN I PELTON	PAID	OUTCOMES RESEARCH- CLINICAL TRIALS	12/01/2020	
STEPHEN I PELTON	PAID	PROF & CONSULTING-MEDICAL EXPENSES (915)	12/14/2020	
STEPHEN I PELTON	PAID	HCP AUTHORSHIP (902)	12/14/2020	
STEPHEN I PELTON	PAID	OUTCOMES RESEARCH- CLINICAL TRIALS	12/28/2020	
STEPHEN PELTON MD	PAID	HCP CONSULTING	01/27/2021	

Name of Clinical Investigator or Related Entity:	Dr. Susan Edwards
Clinical Investigator ID:	51458
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1006
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

DISCLOSURE TYPE: EQUITY SNAPSHOT SUMMARY *					
Investigator Name: Dr. Susan Edwards					
Protocol Number: C4591001					
Study Number	Disclosure Date	Publicly Held Company	Number of Shares	Value at Disclosure Date	
				[USD]	[USD]
C4591001	04/30/2020	Pfizer Inc.	(b) (6)	(b) (6)	(b) (6)

<sup>\*</sup> The Equity Snapshot Summary contains equity details disclosed by an investigator through one or more Financial Disclosure Forms completed from the start of the study through one year after the completion of the study. Please note the value disclosed is the value determined at the provided Disclosure Date and should not be accumulated with any other listed value.

Name of Clinical Investigator or Related Entity:	Margaret Tiktin
Clinical Investigator ID:	404556
Product's Established Name:	BNT162b2
Study Name(s):	C4591001: 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
Protocol Number(s):	C4591001
Center Number(s):	C4591001:1122
Disclosure Start Date(s):	C4591001:4/29/2020
Disclosure Cut-off Date(s):	C4591001:3/25/2021

DISCLOSURE TYPE: SIGNIFICANT PAYMENTS OF OTHER SORTS					
Investigator Name: Margaret Tiktin					
Protocol Number: C4591001					
Clinical Investigator or Related Entity	Check Number	Purpose	Payment Date	Amount [USD]	
MARGARET TIKTIN	PAID	HCP CONSULTANT	10/26/2020	(b) (6)	
Payment Payment exceeds threshold	old amount of \$	24,999.00	Total:	_	