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

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

sBLA

## 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.

| investigator involved in the conduct of the  | etween the sponsor of the covered study and the clinical covered study, whereby the value of the compensation to study could be influenced by the outcome of the study; |
|--|---|
|  | ade on or after February 2, 1999, from the sponsor of the ngoing research, compensation in the form of equipment, aria;   |
| any proprietary interest in the product teste  | ed in the covered study held by the clinical investigator;  |
| any significant equity interest, as defined sponsor of the covered study.  | in 21 CFR 54.2(b), held by the clinical investigator in the   |
| Details of the individuals' disclosable financia description of steps taken to minimize the potential arrangements or interests. | al arrangements and interests are attached, along with a ential bias of clinical study results by any of the disclosed  |
| NAME   | TITLE   |
| (b) (6)  | (b) (6)   |
| FIRM/ORGANIZATION Pfizer Inc.  |   |
| signature (b) (6)  | DATE 11/29/2021   |

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

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**FORM FDA 3455** 

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| SUMMARY TABLE                                  |          |  |  |
|--|----------|--|--|
| SIGNIFICANT PAYMENTS OF OTHER SORTS            |          |  |  |
| List of investigators List of Protocol Numbers |          |  |  |
| Dr. Nicola P. Klein                            | C4591001 |  |  |

| ANY SIGNIFICANT EQUITY INTEREST                |          |  |  |
|--|----------|--|--|
| List of investigators List of Protocol Numbers |          |  |  |
| Dr. Jill A. Sangree                            | C4591001 |  |  |
| Dr. Susan Edwards                              | C4591001 |  |  |

| DISCLOSURE DETAILS: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS |        |  |
|--|--------|--|
| Product's Established Name:  | bnt162 |  |

| Name of Clinical Investigator or Related Entity: | Dr. Jill A. Sangree   |
|--|---|
| Clinical Investigator ID:                        | 281831  |
| Product's Established Name:                      | bnt162  |
| 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):                      | C4591001:11/3/2021  |

| DISCLOSURE TYPE: EQUITY SNAPSHOT SUMMARY * |   |             |         |         |         |
|--|---|-------------|---------|---------|---------|
| Investigator Name: Dr. Jill A. Sangree     |   |             |         |         |         |
| Protocol Numb                              | Protocol Number: C4591001   |             |         |         |         |
| Study Number                               | Study Number Disclosure Date Publicly Held Company Number of Shares Value at Disclosure Date Value Disclose |             |         |         |         |
|  |   |             |         | [USD]   | [USD]   |
| C4591001                                   | 08/03/2020  | 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: | Dr. Nicola P. Klein   |
|--|---|
| Clinical Investigator ID:                        | 280164  |
| Product's Established Name:                      | bnt162  |
| 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):                      | C4591001:11/3/2021  |

| Investigator Name: Dr. Nicola P. Klein  |                  |                                      |              |                 |
|---|------------------|--------------------------------------|--------------|-----------------|
| Protocol Number: C4591001               |                  |                                      |              |                 |
| Clinical Investigator or Related Entity | Check Number     | Purpose                              | Payment Date | Amount<br>[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   |                 |
| KAISER FOUNDATION RESEARCH INST         | 0140512813       | CLINICAL AND RESEARCH COLLABORATIONS | 07/26/2021   |                 |
| Payment exceeds threshold amoun         | t of \$24,999.00 |                                      | Total:       | (b) (6)         |

| Name of Clinical Investigator or Related Entity: | Dr. Susan Edwards   |
|--|---|
| Clinical Investigator ID:                        | 51458   |
| Product's Established Name:                      | bnt162  |
| 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):                      | C4591001:11/3/2021  |

| DISCLOSURE TYPE: EQUITY SNAPSHOT SUMMARY * |            |             |         |         |         |
|--|------------|-------------|---------|---------|---------|
| Investigator Name: Dr. Susan Edwards       |            |             |         |         |         |
| Protocol Number: C4591001                  |            |             |         |         |         |
|  |            |             |         |         |         |
| [USD]                                      |            |             |         |         |         |
| C4591001                                   | 11/19/2020 | 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.