

DISCLOSURES: Kahl (Principal Investigator)

Manzanita Pharmaceuticals, Inc.
2995 Woodside Road, Suite 400
Woodside, California 94062 United States

Grant #: 1R44CA295214-01 PI: KAHL, STEPHEN B

I am the designated Investigator of an NIH grant which may be funded (Grant #: 1R44CA295214-01 PI: KAHL, STEPHEN B). I am the Principal Investigator (Investigator) of the above-named NIH-funded grant which is currently undergoing consideration for funding. As defined, my institutional responsibilities to Manzanita Pharmaceuticals, Inc. (Manzanita) include research, research consultation, teaching, professional practice, *etc.* as full or part-time salary, royalties, consulting fees, *honoraria*, paid authorship, reimbursed or sponsored travel, or some other form of financial compensation.

From the date below, and within the last year, I certify as myself as Investigator and on behalf of senior/key personnel identified by Manzanita in the NIH-directed grant application, progress report or any other report to submitted by Manzanita under this regulation and FCOI/SFI Policy that I have disclosed the following:

 X None to disclose.
 Significant Financial Information as required (listed on the next page).

I further certify that in this and every application for NIH-related grant or cooperative agreement funding that falls within the FCOI and SFI Policy requirements, that Manzanita:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI and SFI Policy;
- Has ensured that I as Investigator named in the above NIH-grant currently under consideration have read and understood the requirements set forth on Appendix C;
- Has posted our FCOI Policy on our website, which is publicly accessible, and submitted a copy to the NIH via the eRA Commons Institution Profile Module;
- Shall promote and enforce my Investigator compliance with the regulation;
- Shall manage FCOI and provide as required initial and ongoing FCOI reports to the NIH via the FCOI Module;
- Agrees to make FCOI and Significant Financial Information (SFI), including related Manzanita reviews and determinations, available to the NIH promptly, upon request; and
- Shall fully comply with the regulation’s requirements as shown in Appendix C.



_____ (written signature)

 Stephen B. Kahl (printed name)

 June 10, 2024 (date of certification/signature)

cc: Grants Compliance Officer, Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration
National Institutes of Health

The Significant Financial Information (SFI) Disclosure Policy requires the Investigator or Other Personnel named in the grant to submit the following information:

- Investigator's or Other Personnel's name;
- Entity name in which the Investigator (and spouse and dependent children) or Other Personnel have an SFI;
- Disclosure requirement that is consistent with Manzanita's definition of SFI;
- Disclosure of financial interests in the twelve (12) months preceding the disclosure and value of each equity interest as of the date of disclosure;
- Disclosure of intellectual property (IP) rights and interests not arising from the Investigator's or Other Personnel's interest by and/or employment with Manzanita (e.g., patents, copyrights), upon the receipt of income related to such rights and interests. In accordance with the SFI definition for IP rights and interests as described in the Final Rule on page 53265, Manzanita utilizes the narrative from the regulatory definition of SFI as stated in 42 CFR 50.603, so the threshold for disclosure related to such interests is \$0;
- Disclosure of reimbursed or sponsored travel does not provide a threshold for disclosure as provided in NIH's FAQs E.9. and E.24, so the threshold is \$0. Manzanita's SFI Policy is to specify the details of such travel disclosure, to include, but not limited to, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration;
- Disclosure for SFI is required for all financial interests received from foreign institutions of higher education or the government of another country when such income meets the threshold for disclosure (e.g., income in excess of \$5,000) (see FAQs E.9., E.21., E.24, E.36. and E.37.) Note the 20 U.S.C. Code 1001(a) citation within the SFI definition, refers to institutions of higher education located in the United States or a federal, state, or local government agency within the United States;
- The value of the SFI, and how that value is determined;
- Indicate whether the SFI is from a publicly traded or non-publicly traded entity, either domestic or foreign. Also note that disclosure requirements for equity interest differ for each;
- Describe the nature of the SFI (e.g., salary, royalties, consulting fees, *honoraria*, paid authorship, reimbursed or sponsored travel, or some other form of financial compensation);
- Indicate whether the SFI is related to any NIH application or NIH-funded project and an explanation for the relatedness to assist with Manzanita's review, including (i) Manzanita's designated official(s) making the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research); and/or (ii) per the preamble in the Final Rule (page 53261), "significantly" means "...the financial interest would have a 'material effect on the research'..."

DISCLOSURES: McKee (Project Manager)

Grants Compliance Officer
Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration
National Institutes of Health

RE: Grant #: 1R44CA295214-01 PI: KAHL, STEPHEN B

To whom it may concern:

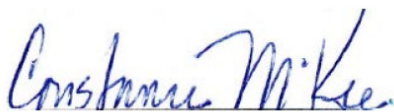
I am the designated official(s) within Manzanita Pharmaceuticals, Inc. (Manzanita). I write to disclose Significant Financial Interests as named Other Personnel (Project Manager) on behalf of Manzanita and the Principal Investigator (Investigator) of (i) the above-listed NIH-funded SBIR Phase II grant which the NIH is currently considering funding; and (ii) any future NIH-funded grant or cooperative agreement that falls within the FCOI and SFI Policy requirements.

From the date below, and within the last year, I certify that I have disclosed the following Financial Conflicts of Interest and/or Significant Financial Information on behalf of Manzanita:

 X None to disclose.
 Significant Financial Information as required (listed on the next page).

I further certify that in this and every application for funding that Manzanita Pharmaceuticals, Inc.:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI and SFI Policy;
- Has ensured that the designated official(s) within Manzanita have read and understood the requirements set forth on Appendix C;
- Has posted our FCOI Policy on our website, which is publicly accessible, and submitted a copy to the NIH via the eRA Commons Institution Profile Module;
- Shall promote and enforce Investigator compliance with the regulation;
- Shall manage FCOI and provide as required initial and ongoing FCOI reports to the NIH via the FCOI Module;
- Agrees to make FCOI and Significant Financial Information (SFI), including related Manzanita reviews and determinations, available to the NIH promptly, upon request; and
- Shall fully comply with the regulation’s requirements as shown in Appendix C.



(written signature)

 Constance McKee
(printed name)

 June 10, 2024
(date of certification/signature)

The Significant Financial Information (SFI) Disclosure Policy requires the Investigator or Other Personnel named in the grant to submit the following information:

- Investigator's or Other Personnel's name;
- Entity name in which the Investigator (and spouse and dependent children) or Other Personnel have an SFI;
- Disclosure requirement that is consistent with Manzanita's definition of SFI;
- Disclosure of financial interests in the twelve (12) months preceding the disclosure and value of each equity interest as of the date of disclosure;
- Disclosure of intellectual property (IP) rights and interests not arising from the Investigator's or Other Personnel's interest by and/or employment with Manzanita (*e.g.*, patents, copyrights), upon the receipt of income related to such rights and interests. In accordance with the SFI definition for IP rights and interests as described in the Final Rule on page 53265, Manzanita utilizes the narrative from the regulatory definition of SFI as stated in 42 CFR 50.603, so the threshold for disclosure related to such interests is \$0;
- Disclosure of reimbursed or sponsored travel does not provide a threshold for disclosure as provided in NIH's FAQs E.9. and E.24, so the threshold is \$0. Manzanita's SFI Policy is to specify the details of such travel disclosure, to include, but not limited to, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration;
- Disclosure for SFI is required for all financial interests received from foreign institutions of higher education or the government of another country when such income meets the threshold for disclosure (*e.g.*, income in excess of \$5,000) (see FAQs E.9., E.21., E.24, E.36. and E.37.) Note the 20 U.S.C. Code 1001(a) citation within the SFI definition, refers to institutions of higher education located in the United States or a federal, state, or local government agency within the United States;
- The value of the SFI, and how that value is determined;
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- Describe the nature of the SFI (*e.g.*, salary, royalties, consulting fees, *honoraria*, paid authorship, reimbursed or sponsored travel, or some other form of financial compensation);
- Indicate whether the SFI is related to any NIH application or NIH-funded project and an explanation for the relatedness to assist with Manzanita's review, including (i) Manzanita's designated official(s) making the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research); and/or (ii) per the preamble in the Final Rule (page 53261), "significantly" means "...the financial interest would have a 'material effect on the research'..."