Financial Conflict of Interest Policy

National Institutes of Health, Public Health Service-Sponsored Research Grants & Subawards

Introduction

This policy governing financial conflict of interest applies to all PHS-sponsored Investigators of Evidence-Based Practice Institute, Inc. (EBPI). This policy satisfies the institutional compliance with the 2011 revised Federal regulation on Financial Conflict of Interest (FCOI) for grants and cooperative agreements [42 CFR Part 50 Subpart F](), Promoting Objectivity in Research.

Institutions are required to develop a FCOI Policy or revise an existing policy that will be maintained and enforced, and that meets or exceeds the regulatory requirements. This policy applies to each Investigator, as defined by the regulation, who is planning to participate in or is participating in Public Health Service (PHS)-funded research. The President/Chief Scientific Officer and Chief Executive Officer/Signing Official are responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional officials is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

Definitions

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

***Conflict of Interest Committee* (*COI Committee*)** means EBPI's committee or individual that advises the Institutional Officials on conflict of interest matters. The committee consists of Behavioral Health Research Collective's Institutional Review Board (BHRC IRB) Chair, Travis Osborne, PhD, other members of BHRC's IRB and/or others appointed by Dr. Osborne.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- salary, royalties, or other remuneration from EBPI;
- income from the authorship of academic or scholarly works;

- income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for US Federal, state or local governmental agencies; US institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, **Financial Interest** also includes any reimbursed or sponsored **travel** undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. *It excludes travel reimbursed or sponsored by US Federal, state or local governmental agencies, US. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.*

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000; or
b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds $5,000; or
c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
d) is income exceeding $5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional Official means the individuals within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Officials are designated as the President/Chief Scientific Officer, Linda Dimeff, PhD, and Chief Executive Officer/Signing Official, Kelly Koerner, PhD.

Institutional Responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as Principal Investigator or Co-Investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service* or *PHS means the Public Health Service of the US Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Conflict of Interest:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Officials.

1) Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests as defined above to EBPI on an annual and on an ad hoc basis, as described below. The Institutional Officials are responsible for the distribution, receipt, processing, review and retention of disclosure forms. The COI Committee will assist with the review of the forms and processes as needed.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the Investigator's institutional responsibilities to the Institution, through the Institutional Officials, on an annual basis. All forms should be submitted to the Institutional Officials or designee by July 1 for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to EBPI, through the Institutional Officials or designee, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her

Significant Financial Interests with the outside entity. EBPI will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Officials or designee an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) Review and Decision of The Institutional Officials

Prior to expenditure of funds awarded for PHS-sponsored research, at least annually thereafter, and when new Financial Conflicts of Interest are reported, the Institutional Officials will:

a) Review Investigators' Financial Conflict of Interest forms
b) Determine if any significant financial interests relate to the PHS-sponsored research
c) Determine if a Financial Conflict of Interest exists (significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research)
d) Develop and implement written management plans, as needed, to manage conflicts

If the Financial Conflict of Interest Disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Officials or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Officials will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate. The Institutional Officials may consult the COI Committee for guidance in specific cases, or in the application of the policy to particular situations.

A Financial Conflict of Interest will exist when the Institutional Officials or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Officials determine that there is a Financial Conflict of Interest that can be managed, they will develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Officials will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3) Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Conflict of Interest related to the clinical trial. All Investigators are required to disclose their outside financial interests as defined above to EBPI on an annual and on an ad hoc basis, as described above. If a Financial Conflict of Interest exists, EBPI will take action to manage the Financial Conflict of Interest including the reduction or elimination of the conflict, as appropriate. If the Financial Conflict of Interest can be managed, EBPI will develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose the Financial Conflicts of Interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

4) Reporting to PHS

EBPI will report Financial Conflicts of Interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

5) Investigator Non-Compliance

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, EBPI may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Officials is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator, COI Committee , and, where applicable, the Institutional Review Board (IRB), and will notify the individual of the right to appeal the decision. EBPI will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

In addition, if the Institutional Officials determine that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Officials will complete a retrospective review of the Investigator's activities and the PHS-sponsored Research to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. Retrospective reviews will be completed and documented within 120 days of EBPI's determination of noncompliance for Significant Financial Interests not disclosed timely or previously reviewed or whenever a Financial Conflict of Interest is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

Documentation of the retrospective review shall include:

- the project number,
- project title,
- name of the Principal Investigator,
- name of Investigator with the Financial Conflict of Interest,
- name of the entity with which the Investigator has the Financial Conflict of Interest,
- reason(s) for the retrospective review,
- detailed methodology used for the retrospective review, and
- findings and conclusions of the review.

The Institutional Officials will update any previously submitted report to the PHS (or the prime PHS-awardee relating to the research), specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, EBPI will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

6) Training

Each Investigator must complete training on this Policy, the Investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators must also complete training immediately in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Training consists of

- reading and signing this policy to document that the Investigator understands the policies contained herein; and
- completing the NIH Financial Conflict of Interest Training and providing EBPI with a certificate of completion. NIH Financial Conflict of Interest Training can be found here: https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

7) Record Retention

EBPI will retain all disclosure forms, conflict management plans, and related documents for a period of no less than three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, EBPI may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to EBPI, if requested or required. If EBPI is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) Public Accessibility

Prior to the expenditure of funds, EBPI will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

10) Regulatory Authority

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94, where applicable; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

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DISCLOSURE OF FINANCIAL INTERESTS FORM

Member Identification:

Investigator Name: Linda Dimeff, PhD

Email Address: linda.dimeff@jasprhealth.com

Filing (ad hoc): First time

Grant Number(s): R44MH126819

Section 1 – Disclosure of Financial Interests

In compliance with Federal law and regulation and EBPI policies, disclosure of all relevant and significant financial interests is required of all investigators who are responsible for the design, conduct, or reporting of research. The interests which must be disclosed include those of the investigator, his or her spouse, dependent children, and other members of his or her personal household.

"Significant Financial Interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). It does not include any of the following:

a. salary, royalties or other remuneration from EBPI, or any ownership interests in the EBPI;

b. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

c. income from service on advisory committees or review panels for public or nonprofit entities;

d. financial interests in business enterprises or entities if the value of such interests, when aggregated with interests owned by the investigator's spouse or dependent children, do not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 5 percent ownership interest for any single entity; or

e. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $5,000 during the next twelve month period.

A. IDENTIFICATION OF POSSIBLE CONFLICT OF INTEREST

Please describe the relevant research activities that may be affected by the financial or ownership interest that you, your spouse, your dependent child(ren), or other members of your personal household may have. Complete the remainder of this section with this possible conflict of interest in mind.

Please insert additional pages as necessary to complete this section.

B. OWNERSHIP INTERESTS

List any corporation, partnership, proprietorship, trust, joint venture, and every other business interest, including land used for income in which either you or other members of your household own or have owned within the preceding 12 months that constitute a legal or equitable interest exceeding $5,000 or five percent of total ownership, whichever is less, which **actually or potentially influences or conflicts with any of your research** at the EBPI. Ownership of intellectual property, e.g., patents, royalties, and copyrights, is also included and must be disclosed. If you or member(s) of you

household own more than five percent of the total ownership interests of a business, you must disclose the percentage held.
Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☐.

Business Name and Address	Type of Business	Description of Interest*	Held by (you/spouse/other)	% Interest Held	Value
Portland DBT Institute, Inc.		Equity Interest - Non-publicly traded entity	Self	56%	$280,000
Health Thrive Grow Behavioral Health, Inc.		Equity Interest - Non-publicly traded entity	Self	56%	$16,800
Dimeff and Associates	PLLC	Equity Interest - Non-publicly traded entity	Self	100%	$40,000

*****Please use one of the following answer categories for Description of Interest here and in items below involving a description of interests:
- Equity Interest – Publicly traded entity (e.g., stock, stock option, or other ownership interest)
- Intellectual property rights (e.g., royalties, patents copyrights) not from the awardee institution
- Investment vehicles, such as mutual funds and retirement accounts, controlled by the Investigator
- Payment for servcies (e.g., consulting fees, honorria, paid authoriship)
- Reimbursement or sponsored travel
- Other (provide an explanation that describes the significant financial interest)

For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for how the financial interest conflicts with such research.

Neither Portland DBT Institute nor Health Thrive Grow Behavioral Health, Inc. or Dimeff and Associates, PLLC will be engaging in any research related activities of this project, thus there is no financial conflict of interest.

C. RECEIPT OF COMPENSATION

List all places of employment and other business (excluding EBPI) from which you or any member of your household expect to receive $5,000 or more in compensation per year as to which an independent observer could conclude could **actually or potentially influence or conflict with any of your research activities** at EBPI.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☐.

Business Name and Address	Type of Business	Recipient of Compensation (you/spouse/other)	Description of Interest*	Annual Value
Portland DBT Institute		Self	Salary not from the awardee institution	$40,000-$59,999
Health Thrive Grow Behavioral Health, Inc.		Self	Salary not from the awardee institution	$0
Health Thrive Grow Behavioral Health, Inc.		Self	Salary not from the awardee institution	$0

*****Please use definitions of ***Description of Interest*** provided above.

For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for how the financial interest conflicts with such research.

Compensation is for activities completely unrelated to and does not conflict with this project. Neither Portland DBT Institute nor Health Thrive Grow Behavioral Health, Inc. or Dimeff & Associates PLLC will be engaging in any research related activities in Phase II of this project, thus there is no financial conflict of interest.

D. OFFICER OR DIRECTOR OF ORGANIZATION OR BUSINESS

List any organization or business in which you, your spouse, or any other member of your household, hold the position of officer, director, partner, or proprietor for which more than an aggregate of $5,000 in compensation is received per year or more than five percent ownership interest is held which **actually or potentially influences or conflicts with any of your research** at EBPI.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☒.

Business Name and Address	Position Held	Position Held by (you/spouse/other)	Description of Interest*	Annual Value

*****Please use definitions of ***Description of Interest*** provided above.

For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for how the financial interest conflicts with such research.

(2000 character limit on eRA Commons)

E. RECEIPT OF FEES AND COMMISSIONS

List each client or customer from whom you, your spouse, or any household member receives an aggregate of $5,000 or more per year which could **actually or potentially influences or conflicts with any of your research** at EBPI. In the case of a partnership, it is the proportionate share of the fee or commission that is significant, without regard to the expenses of the partnership. An individual who receives a salary as opposed to portions of fees or commissions is generally not required to report in this section, but may be required to report in Section C, above.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☒.

Business Name and Address	Position Held	Position Held by (you/spouse/other)	Description of Interest*	Annual Value

*Please use definitions of ***Description of Interest*** provided above.

For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for how the financial interest conflicts with such research.

(2000 character limit on eRA Commons)

Section 2 –Declaration

I, Linda Dimeff, hereby declare that this statement of significant financial interests (including accompanying additional pages and statements) has been examined by me and that to the best of my knowledge and belief is a true, correct, accurate, and complete statement of all such interest required to be disclosed by law, regulation, or policy. I have read and agree to comply with EBPI on Conflicts of Interest and Investigator Financial Disclosure and the EBPI policy implementing the same. I have complied with Federal conflict of interest policies and regulations. Also, I understand that failure to file this statement as required or intentionally filing a false statement may result in disciplinary action. Any changes with regard to information provided on this statement will be reported when it becomes known to me.

Linda Dimeff

Signature

04/28/21

Date

Confirmed no changes during initial iKSA RCT submission to IRB 3/6/2025 (AKB)

Submit this form to EBPI for review and signature.

For each possible conflict of interest, please include a description of how the financial interests relates to the funded research/grant-funded project identified above and the basis for EBPI's determination that the financial interest conflicts with such research. If financial interest does not conflict with the research/project, please note below.
The financial interests listed above do not conflict with the research study. Neither Portland DBT Institute nor Health Thrive Grow Behavioral Health, Inc. will be engaging in any research related activities in Phase II of this project.

REVIEW NOTES:

EBPI VERIFICATION: I have reviewed the potential or actual conflicts of interest with the above named individual. CHECK, AS APPROPRIATE: There is no conflict ☒. There is an actual ☐ /potential ☐conflict of interest, and a copy of this disclosure form and signed mitigation/resolution will be/has been agreed upon and saved in appropriate files.

KEY ELEMENTS OF MITIGATION/MANAGEMENT PLAN: Include a description of the following elements in the mitigation plan:

A. Role and principal duties of the conflicted Investigator in the research project
B. Conditions of the management plan
    a. All investigators involved with EBPI's grants must manage conflicts of interest with the following management plan. [see VW facepage for BHRC financial disclosure. Use for all projects and all investigators]

C. How the management plan is designed to safeguard objectivity in the research project [see above]
D. Confirmation of the Investigator’s agreement to the management plan [signed copy of the version to be submitted with the FCOI forms in era commons]
E. How the management plan will be monitored to ensure Investigator compliance [annual reporting, investigator required to report if new SFI arises]
F. Other information as needed

There is no conflict of interest at this time. A management plan will be developed and executed if a financial interest poses conflict to the research study.

DOES THE FCOI REPORT INCLUDE A FAILURE TO COMLY WITH THE REGULATION? ____Yes___X_No

______________________________________ 04/28/21

EBPI Designated FCOI Official Date

BHRC DISCLOSURE OF FINANCIAL INTERESTS FORM

Member Identification:

Investigator Name: Cindy Schaeffer, PhD

Email Address: Cschaeff@som.umaryland.edu

Filing (Annual, First Time, ad hoc): First Time

Section 1 – Disclosure of Financial Interests

In compliance with Federal law and regulation and BHRC policies, disclosure of all relevant and significant financial interests is required of all investigators reviewed through the BHRC IRB who are responsible for the design, conduct, or reporting of research. The interests which must be disclosed include those of the investigator, his or her spouse, dependent children, and other members of his or her personal household.

"Significant Financial Interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). It does not include any of the following:

a. salary, royalties or other remuneration from BHRC, or any ownership interests in the BHRC;

b. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

c. income from service on advisory committees or review panels for public or nonprofit entities;

d. financial interests in business enterprises or entities if the value of such interests, when aggregated with interests owned by the investigator's spouse or dependent children, do not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 5 percent ownership interest for any single entity; or

e. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the next twelve month period.

A. IDENTIFICATION OF POSSIBLE CONFLICT OF INTEREST

Please describe the relevant research activities that may be affected by the financial or ownership interest that you, your spouse, your dependent child(ren), or other members of your personal household may have. Complete the remainder of this section with this possible conflict of interest in mind.

Please insert additional pages as necessary to complete this section.

B. OWNERSHIP INTERESTS

List any corporation, partnership, proprietorship, trust, joint venture, and every other business interest, including land used for income in which either you or other members of your household own or have owned within the preceding 12 months that constitute a legal or equitable interest exceeding $10,000 or five percent of total ownership, whichever is less, which **actually or potentially influences or conflicts with any of your research** at the BHRC. Ownership of intellectual property, e.g., patents, royalties, and copyrights, is also included and must be disclosed. If you or member(s) of you household own more than five percent of the total ownership interests of a business, you must disclose the percentage held.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☐.

Business Name and Address	Type of Business	Description of Interest	Held by ((you/spouse/other)	% Interest Held
Cindy M. Schaeffer, Ph.D.	Independent contractor	Intellectual property (IP) rights for the iKinnect mobile app and royalties from the sales of the product being evaluated in this application, once it goes to market.	self	Not yet determined - in negotiations now.

C. RECEIPT OF COMPENSATION

List all places of employment and other business (excluding the BHRC) from which you or any member of your household expect to receive $10,000 or more in compensation per year as to which an independent observer could conclude could **actually or potentially influence or conflict with any of your research activities** reviewed by the BHRC.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☒.

Business Name and Address	Type of Business	Recipient of Compensation ((you/spouse/other)

D. OFFICER OR DIRECTOR OF ORGANIZATION OR BUSINESS

List any organization or business in which you, your spouse, or any other member of your household, hold the position of officer, director, partner, or proprietor for which more than an aggregate of $10,000 in compensation is received per year or more than five percent ownership interest is held which **significantly affects or will be affected by any of your research activities** reviewed by BHRC.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☒.

Business Name and Address	Position Held	Position Held by (you/spouse/other)

E. RECEIPT OF FEES AND COMMISSIONS

List each client or customer from whom you, your spouse, or any household member receives an aggregate of $10,000 or more per year which could constitute an **actual or potential conflict of interest with any of your research activities** reviewed by the BHRC. In the case of a partnership, it is the proportionate share of the fee or commission that is significant, without regard to the expenses of the partnership. An individual who receives a salary as opposed to portions of fees or commissions is generally not required to report in this section, but may be required to report in Section C, above.

Please insert additional pages as necessary to complete this section.

If you have nothing to report in this section, check here ☒.

Business Name and Address	Position Held	Position Held by (you/spouse/other)

Section 2 –Declaration

I, Cindy Schaeffer, PhD, hereby declare that this statement of significant financial interests (including accompanying additional pages and statements) has been examined by me and that to the best of my knowledge and belief is a true, correct, accurate, and complete statement of all such interest required to be disclosed by law, regulation, or policy. I have read and agree to comply with the BHRC on Conflicts of Interest and Investigator Financial Disclosure and the BHRC policy implementing the same. I have complied with Federal conflict of interest policies and regulations. Also, I understand that failure to file this statement as required or intentionally filing a false statement may result in disciplinary action. Any changes with regard to information provided on this statement will be reported when it becomes known to me.

Verified no changes 10/10/25 continuing review
for iK2.0 Summative (AKB)

3/1/2011

Signature

11/7/17
Date

Submit this form to the BHRC IRB for review and signature.

VERIFICATION: I have reviewed the potential or actual conflicts of interest with the above named individual. CHECK, AS APPROPRIATE: There is no conflict ☐. There is an actual ☐ /potential ☐conflict of interest, and a copy of Disclosure Form B will be/has been sent to the BHRC IRB for resolution.

Chair of IRB

11/13/17
Date

4/28/21

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