Center Liaison Transmittal Form

Please indicate the submission type:

New Submission

RIHSC Protocol Number (to be filled if new submission):

I concur that:

A. For protocols applying for RIHSC review:

1. The protocol as submitted, has undergone scientific review for technical merit and programmatic relevance by the Center or Office and has been approved by the Center Director or Office Director or designee.

2. The principal investigators are qualified to do the research.

3. The study site has been documented to be adequate.

4. The FDA sponsor and investigators have completed the required training in human subject's protection and the sponsor understands his/her obligations under the regulations and is qualified to provide adequate oversight of this protocol.

5. The potential risks to the subjects are appropriate for the potential benefits.

6. The informed consent document conveys the risks and benefits in a clear, scientifically accurate and balanced manner.

7. The completed submission form (Form RIHSC-PROT)) and, if appropriate, the request for expedited review form (Form RIHSC-EXPD) are accurate and the supporting information have been attached.

8. IDE/IND required?

An IDE/IND is not required.

B. For protocols requesting exemption from RIHSC review and for Continuing Review Submissions:

1. The protocol has undergone scientific review for technical merit and programmatic relevance by my Center/Office and has been approved by the Center Director/Office Director or designee

2. The completed exemption form (Form RIHSC-EXT) is accurate and supporting information have been attached.

C. For amendments to an existing study:

D. For continuing review submissions or continuing review form (Form RIHSC-CR)

Upload center specific review materials.

Please Upload IRB Authorization Agreement

By checking this box I attest that I have conducted a review all of the information above.

IRB Chair Letter

IRB Chair Letter

Check here to enter IRB Chair LetterComment: *MEMORANDUM*
Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: December 26, 2017

FROM: Chair, Research Involving Human Subjects Committee

SUBJECT: RIHSC Study # 17-091CTP
Study Title: "Qualitative Study on Nicotine Exposure Risk Knowledge, Beliefs, Perceptions, and Behaviors"
Principal Investigator: Jennifer Alexander, MPH; RTI International
FDA Sponsor: Anh Zarndt, PhD; CTP

TO: Anh Zarndt, PhD; CTP
Cathy Backinger, PhD, CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your study, entitled, "Qualitative Study on Nicotine Exposure Risk Knowledge, Beliefs, Perceptions, and Behaviors." Your study proposes to conduct focus groups with youth, young adults and adults who are using or have used electronic nicotine delivery systems. The focus groups will be conducted to gain information on subjects' knowledge of e-cigarettes and the risks associated with nicotine exposure. This research will inform on labels that may be used on future e-cigarettes and their packaging.

Because your study is no greater than minimal risk, it could be reviewed using the expedited procedure outlined in 45 CFR 46.110.

The RIHSC waives the requirement for documentation of informed consent for subject assent and parental permission, under 45 CFR 46.116(d), before the subjects are screened for eligibility.

The RIHSC determined your study satisfies the criteria outlined in 45 CFR 46.404 for research not involving greater than minimal risk to children. Assent and parental permission will be obtained prior to the start of the study.

*Your study is **APPROVED**.*

EFFECTIVE PERIOD OF APPROVAL:
This study has been approved December 26, 2017 – December 25, 2018.

FDA IRB:
Research Involving Human Subjects Committee, FWA #00006196
Chair: Jeffrey DeGrasse, PhD
Office of the Commissioner
Food and Drug Administration

RESPONSIBILITIES:
The Principal Investigator is responsible for ensuring that the investigation is conducted according to the investigational plan and applicable regulations and for protecting the rights, safety, and welfare of subjects. The Principal Investigator is also responsible for complying with the following requirements:
1. Promptly reporting to the RIHSC all changes in the research activity including any modifications to the Study Protocol or Informed Consent. 45 CFR 46.103(b)(4)(iii) Changes in approved research may not be initiated without RIHSC review and approval except when necessary to eliminate apparent immediate hazards to the subjects. 45 CFR 46.103(b)(4)(iii)
2. Promptly reporting to the RIHSC all unanticipated problems involving risk to human subjects or others. 45 CFR 46.103(b)(5)(i)
3. Providing periodic reports to the RIHSC, as required. 45 CFR 46.109(e)

PROGRESS OR FINAL REPORT:
If you wish to continue your study beyond December 25, 2018, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than October 15, 2018.

If your study is completed or terminated within the next year, please submit a FINAL REPORT to the RIHSC Executive Director. This report should contain the following information, if applicable:
1. RIHSC FILE Number/Study Title/Study Investigator(s)/Institution where study is being/was conducted.
2. Brief summary of the project status, including a description of all changes, amendments, or supplements to the previously approved protocol and consent form.
3. Number of subjects initially approved by the RIHSC for inclusion in the study and the number actually entered into the study.
4. Number of subjects whose participation was completed as planned.
5. Number of subjects that dropped out of the study.
6. Summary of Adverse Events that can reasonably be attributed to the study.
7. List of abstracts or publications, and/or a brief description of any available study results.

If you have questions, or would like further information, please do not hesitate to contact the RIHSC Program Management Staff by email at RIHSC@fda.hhs.gov, or by phone at (301) 796-9605.

Signed By: 

IRB Chair

Active Protocol Qualitative Study on Nicotine Exposure Risk: Knowledge, Beliefs, Perceptions, and Behaviors	IRB	Case Number 17-091CTP	
Sponsor Zarndt, Anh	**Organization** CTP-White Oak	**Email** anh.zarndt@fda.hhs.gov	**Phone** 240-402-5875
Approved		**Date Submitted** 12/19/2017	**Expiration Date**

Doc Ver: 281-311

Laboratory Not in List

Laboratory: N/A

Recommendations

Liaison: Focus groups in youth and adults for warning label understanding for ENDS and nicotine. Will email the Stimuli because file was too large for SIPS/HealthRX. 12/19/2017

Point of Contact

None

Inventory Requests

None

Associated Researchers

None

Associated Registrations

None

Minimal Risk

Please read the definition below and answer the following question.

Minimal Risk: the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Can this study be classified as minimal risk based on the definition above?

Yes, please continue to next step

Registration Document Approved by Admin	Registration Document Approved by Chair, IRB	Registration Document Approved

12/27/2017

Carefully read the following statement and indicate by checking the box that you agree. This registration cannot be submitted without affirming the statement.

I assure that the information above is accurate.

Category Checklist

Please indicate which of these categories apply to your study/project/protocol (more than one may apply).

Please note that the following 9 categories pertain to both INITIAL and CONTINUING IRB REVIEW.

Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

No

Research on medical devices for which (I) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

No

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows (Circle a or b, whichever applies):
(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

No

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (I) mucosal and skin cells collected by buccal scraping or swab, skin swab,

No

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscul

No

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

No

Collection of data from voice, video, digital, or image recordings made for research purposes.

Yes

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Yes

Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects, research will not involve stress to subjects.

Yes

The last 2 categories pertain to CONTINUING REVIEW only.

Continuing review of research previously approved by the convened IRB as follows (Circle a, b, or c, whichever applies):
(a) Where (I) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) Where no subjects have been enrolled and no additional risks have been identified; or
(c) Where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Upload center specific review materials.

Qual_Study_on_Nicotine_Exposure_Risk_12.19.17_final.zip

Please have your FDA Sponsor (or if you are the Sponsor) sign-off this submission by clicking the red 'PI E-Signature' button located at the bottom right of the screen. Please note your registration must be complete.

This application has been carefully reviewed by the proper personnel.