DISTRICT OF COLUMBIA
COURT SERVICES AND OFFENDER SUPERVISION AGENCY &
PRETRIAL SERVICES AGENCY
RESEARCH REVIEW COMMITTEE

RECOMMENDATION ACCEPTANCE/REJECTION

I. RESEARCH SUMMARY:

Principal Researcher: R. Sam Niedbala, Ph.D.

Title: Collection of UP*link*™ Oral Fluid Specimens

Institution: OraSure Technologies, Inc., Bethlehem, PA

II. RRC RECOMMENDATION:

The RRC recommendation is for **CSOSA/PSA not to support this study**, as discussed in the Recommendation Statement (03-03-OraSure-Niedbala).

III. RESPONSE OF DIRECTOR(s)

The RRC recommendation requires the acceptance or rejection of the directors of CSOSA and PSA:

Paul A. Quander, Jr., CSOSA

☑ Accept recommendation

☐ Reject recommendation

Signature 4/28/03 Date

Susan W. Shaffer, PSA

☑ Accept recommendation

☐ Reject recommendation

Signature 4/25/03 Date

DISTRICT OF COLUMBIA
COURT SERVICES AND OFFENDER SUPERVISION AGENCY &
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MEMORANDUM

DATE: April 17, 2003

TO: Paul A. Quander, Jr.
Susan W. Shaffer

FROM: Claire Johnson

RE: Collection of UP*link*™ Oral Fluid Specimens

The Research Review Committee (RRC) has reviewed the research proposal submitted by R. Sam Niedbala, Ph.D., to collect oral fluid samples from defendants/offenders. Our recommendation is for CSOSA/PSA not to support this study. The RRC's recommendation statement is enclosed.

The proposed study indicates no direct benefits to CSOSA/PSA, and presents several risks, which are discussed in the recommendation statement. Although the Drug Lab has worked on similar projects with OraSure and other companies in the past, our new status as a Federal agency requires compliance with numerous regulations that restrict such research activities as the one proposed.

Please indicate your acceptance or non-acceptance of this recommendation as soon as possible so that we may inform the researcher of the outcome of our review. If you have any questions or would like a copy of the complete review file, please feel free to contact me at 202-220-5553 or *claire.johnson@csosa.gov*.

Thank you.

Enclosures: RRC Recommendation Statement
Researcher's proposal

DISTRICT OF COLUMBIA
COURT SERVICES AND OFFENDER SUPERVISION AGENCY &
PRETRIAL SERVICES AGENCY
RESEARCH REVIEW COMMITTEE

FULL REVIEW RECOMMENDATION STATEMENT

April 17, 2003

I. RESEARCH PROPOSAL SUMMARY

Principal Researcher: R. Sam Niedbala, Ph.D.

Title: Collection of UP*link*™ Oral Fluid Specimens

Institution: OraSure Technologies, Inc., Bethlehem, PA

Type of Data: Oral fluid samples

Subjects: 250 defendants/offenders

Description: The researcher wants to collect UP*link* oral fluid specimens from defendants/offenders and use these samples to evaluate the UP*link* system for detection of drugs use in oral fluids (which include amphetamines, methamphetamines, cocaine metabolites, opiates, marijuana and phencyclidine) and compare this to GC/MS/MS oral fluids drug use detection system.

Other Information: OraSure, as well as other companies, have conducted sample collection activities at CSOSA/PSA in the past (*e.g.*, sweat induction analysis, sweat patch collection, and intercept oral fluid procedures), prior to the implementation of the current research and evaluation policy.

II. RECOMMENDATION

The RRC recommendation for this study:

☐ Support ☐ Support with Conditions ☒ **Do Not Support**

III. SUPPORTING INFORMATION

Regulatory:

The proposed study presents the following regulatory issue:

- The researcher has not obtained IRB approval for this study, but indicates that this will be obtained if requested by the RRC. In his proposal, Dr. Niedbala indicates that, "since the technology being tested has already been approved by the FDA, and the proposed study is an extension of technological capabilities to add indications for *Uplink*, no IRB approval was pursued for this project." However, the proposed research must be regarded as a new and distinct study and, therefore, requires IRB approval.

Otherwise, the proposed study shows no evidence of non-compliance with Agency policies pertaining to research.

Benefits to Agency:

The proposed study indicates no direct benefits to the Agency, and presents several risks:

- The study as proposed does not provide a reasonable rationale for allowing a private company to collect samples from defendants/offenders. The proposal states the benefits of testing the new device in relation to advancement of this technology in general, but not with regard to any benefit to the Agency directly. Although the Agency is interested in knowing the usefulness and reliability of oral fluid testing as an alternative to urine testing; advancement of the technology is not dependant on accessing persons under the Agency's supervision, and development of Up*link* will not directly support, improve or advance any particular Agency function or operation.

- There are two ways in which the proposed study potentially could benefit the Agency, but neither of these is advisable. Any value for this study to the Agency rests in being able to compare the oral fluid samples with urine tests for the same cases. The two approaches for accomplishing this and their limitations are as follows:

    1. Agency staff coordinate urine collection of defendants/offenders with OraSure's oral fluid samples by establishing a procedure whereby the Agency could ultimately link OraSure's data with the defendant/offender's urine test result. This essentially would require that the Agency and OraSure each establish independent data collection procedures that account for the confidentiality of the defendants/offenders, while creating an identification system that enables linkage of the data sets. In addition

to presenting various challenges in ensuring confidentiality, this approach would yield data with limited usefulness (*e.g.*, participants would be identified via convenience sampling rather than stratified random sampling).

2. Agency staff redesign the study as an internal research project that would enable internal sampling of cases to be tested and simultaneous collection of urine and oral fluids samples. This would permit direct oversight by and involvement of Agency staff, enable stratified random sampling of participants for the most meaningful analysis, reduce confidentiality concerns, and produce a more reliable data set for both the Agency and OraSure. The PSA Director of Forensic Research indicated support for this approach, but noted that the resources necessary to administer such an internal study are not available at this time.

- The proposal states that no Agency resources are required to collect the samples. However, Agency staff would be required to coordinate the activities associated with OraSure's access to volunteers and OraSure staff will require on-site accommodations for sample collection. The necessary Agency resources required for this study would not be commensurate with any benefits to the Agency.

- There is some potential for negative publicity should it become known that the Agency is cooperating, without a reasonable rationale, in allowing a private for-profit company to sample defendants/offenders in an effort to develop its product.

OraSure Technologies, Inc.

diagnostic solutions for the new millennium

March 28, 2003

Claire M. Johnson
Director of Community Justice Program
District of Columbia Pretrail Services Agency
633 Indiana Avenue
NW Room 1145
Washington, DC 20004-2903

Dear Claire,

Enclosed, for your review and consideration by the RRC, are six (6) copies of the Proposed Protocol and background information for the Collection of *UPlink*™ and Intercept Oral Fluid Specimens.

Thank you for all your help with this submission and for your time and consideration. If additional information is needed or if you have any questions, please do not hesitate to contact me.

R. Sam Niedbala

R. Sam Niedbala, Ph.D. BCFE
OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA
(610) 882-1820

Requirements For Non-Agency Research

PART 1

(a) Names and current affiliations of the researchers

R. Sam Niedbala, Ph.D.
OraSure Technologies, Inc. (OTI)
150 Webster St.
Bethlehem, PA 18015
610-882-1820

(b) Title of the Study

COLLECTION OF UP*link*™ and Intercept ORAL FLUID SPECIMENS

(c) Purpose of the Project

OBJECTIVE: Collect UP*link*™ and Intercept oral fluid specimens from individuals who are participants in defendant and offender testing programs. These samples will be used to evaluate the UP*link*™ system for detection of drugs of abuse in oral fluids which include Amphetamines, Methamphetamines, Cocaine Metabolites, Opiates, Marijuana and Phencyclidine. **UP*link*™** along with matching Intercept sample test results will be compared to GC/MS/MS for detection of drugs of abuse in oral fluids. No comparison is being made in this study with urine unless desired by CSOSA/PSA.

(d) Location of the Project

DC Pretrial Sites, Washington DC

(e) Duration of the Study

Expected Duration not more than one week.

(f) Research Methods to be Employed

SUBJECTS:
INCLUSION CRITERIA:

1. Healthy male and female volunteers 18 years of age or over.

2. Volunteers who are participants in a defendant or offender testing programs.

3. Volunteers who have read, understood, and signed an informed consent document as required by United States Food and Drug Administration, Code of Federal Regulations Title 21, part 50.20 to 50.27 regulations. Consent forms will be kept on file at OTI.

EXCLUSION CRITERIA:

1. Volunteers under 18 years of age.

INFORMED CONSENT DOCUMENT: Prior to sample collection, a signed informed consent will be obtained from each volunteer describing reasons for the study, possible adverse effects, associated risks, and potential benefits of the product under investigation and their limits of liability, in accordance with CFR 21 Part 50, Subpart B Section 50.20-50.27. Each volunteer will be assigned a unique identification number. The signed consent forms will be available for inspection at OTI.

Additionally, volunteers will be informed that their participation is entirely voluntary and that they may decline to participate without prejudice.

Finally, volunteers will be informed that the investigator may, at his discretion, disqualify an individual at any time during the course of the study for reasons that may include, but are not limited to, lack of volunteer cooperation, safety considerations, or failure to follow the procedures indicated. Such reasons for disqualification shall be recorded on the volunteer's consent form.

METHODS: Upon entrance into the study, volunteers will be assigned a unique identification number and will be asked to read and sign a consent form. If qualified and willing to participate, an UP*link*™ and Intercept oral fluid specimen will be collected according to the procedures outlined below.

Any deviations from the protocol will be recorded on the consent or data forms.

UP*link*™/Intercept oral fluid samples – For each subject, one sample will be collected using the UP*link*™ Collection Device and one sample with the Intercept oral fluid collection device. For each sample, the subject will continuously swab their mouth with the collection device for a minimum of 1-2 minutes.

After collecting the sample, the UPlink and Intercept collection devices will be placed in individual bags labeled with the volunteer ID for further testing on-site or after shipment back to OraSure Technologies(OTI). GC/MS/MS analysis of the each sample collection device will be performed at OTI for the full panel of drugs of abuse.

All sample costs, shipping, testing and analysis will be performed by OTI. All data will be shared with the study site supervisor.

(g) Sample size required and/or time frame for sample collection;

Specimens will be collected from up to 250 subjects. An incentive will be provided with a cash value of $5.00. This may be in the form of cash or a meal certificate at McDonald's.

(h) Agency staff and/or resources needed to support the study and description of the support needs:

All collection support and testing will be done by Orasure Technologies staff who will be present on-site during the study. PreTrial services staff would not be required to participate in any aspect to support the study.

(i) Indication of risk or discomfort to subjects as a result of participation.

RISKS/BENEFITS: The Collection Pad used on the UPlink collector is made from a sponge material while the stick is made from plastic. It is not treated with any chemicals or salts. Therefore the only risk may be the discomfort of the collector placed into the mouth. The Intercept collector is an FDA approved collection device for drugs of abuse in oral fluids.

(j) Anticipated Results

The outcome of this work will be the first determination of a full panel of drug of abuse found in saliva specimens using the Uplink and Intercept collectors. The UPlink collectors will ultimately be used as part of an integrated on-site drug testing system. This new technology will allow drug testing using the convenience of saliva with the same accuracy as urine testing.

(k) List of Deliverables

1. Collection of up to 250 Uplink/Intercept specimens for drugs of abuse analysis
2. Analysis of these specimens by immunoassay and GCMSMS
3. Data summary and analysis
4. Final report of results to DC Pretrial and Orasure Technologies, Inc.
5. Publication with Mutual Consent by DC Pretrial and OraSure Technologies, Inc.

PART 2

(a) Review of the related literature:

A summary is attached of the literature along with specific articles of relevance. The attached articles include recent publications by the investigators as well as submitted abstracts to be presented this year at scientific meetings.

(b) Detailed description of the research method:

INFORMED CONSENT DOCUMENT: Prior to sample collection, a signed informed consent will be obtained from each volunteer describing reasons for the study, possible adverse effects, associated risks, and potential benefits of the product under investigation and their limits of liability, in accordance with CFR 21 Part 50, Subpart B Section 50.20-50.27. Each volunteer will be assigned a unique identification number. The signed consent forms will be available for inspection at OTI.

Additionally, volunteers will be informed that their participation is entirely voluntary and that they may decline to participate without prejudice.

Finally, volunteers will be informed that the investigator may, at his discretion, disqualify an individual at any time during the course of the study for reasons that may include, but are not limited to, lack of volunteer cooperation, safety considerations, or failure to follow the procedures indicated. Such reasons for disqualification shall be recorded on the volunteer's consent form.

METHODS: Upon entrance into the study, volunteers will be assigned a unique identification number and will be asked to read and sign a consent form. If qualified and willing to participate, an UP*link*™ and Intercept oral fluid specimen will be collected according to the procedures outlined below.

Any deviations from the protocol will be recorded on the consent or data forms.

UP*link*™/Intercept oral fluid samples – For each subject, one sample will be collected using the UP*link*™ Collection Device and one sample with the Intercept oral fluid collection device. For each sample, the subject will continuously swab their mouth with the collection device for a minimum of 1-2 minutes.

After collecting the sample, the UPlink and Intercept collection devices will be placed in individual bags labeled with the volunteer ID for further

testing on-site or after shipment back to OraSure Technologies(OTI). GC/MS/MS analysis of the each sample collection device will be performed at OTI for the full panel of drugs of abuse.

All sample costs, shipping, testing and analysis will be performed by OTI. All data will be shared with the study site supervisor.

(c) Significance of anticipated results and their contribution to the advancement of knowledge:

Just a few years ago the concept of using an oral fluid saliva specimen for routine testing for drugs of abuse was a foreign. New technologies have now been developed, reviewed and cleared by the FDA, and are now gaining acceptance as a method for drug detection and ultimately deterrence.

The initial technologies for oral fluid drug testing utilize unique collection technologies that require the sample to be sent back to a laboratory for analysis (Intercept). The next step for technologists was to develop an on-site method to detect drugs of abuse.

This proposed study is critical to the development and implementation of this new generation of on-site tests with oral fluid. The collection of these samples is helping to determine the concentrations found in a probation and parole population for a variety of drugs. The knowledge gained will help speed the determination of cutoff's for both screening and confirmation testing with oral fluids.

(d) Benefits of research and/or participation to CSOSA/PSA:

One of the largest problems with routine urine testing is the inability to determine the approximate time of dosage by an individual. Using urine as a matrix is limited because individuals may have taken drugs long ago and are still positive. Some of the programs CSOSA use frequently test individuals for drugs. Any positives may be punished and therefore clients object stating that they took the drug long ago and are being re-punished for a previous infraction. The drug of abuse that can typically create this scenario is marijuana.

Using oral fluids the problem may be eliminated. The metabolism/excretion of THC into the mouth mimic's closely the timing of blood. Therefore, oral fluids provides a window into the drug patterns of the previous 24 hours versus the last few days to weeks using urine.

The bottom line benefit would be a first hand evaluation of oral fluid and it's potential use to all programs within CSOSA/PSA

(e) Specific Resources and/or participation from the Agency:

The investigators will supply all needed materials. Participants routinely giving their specimens would be asked if they would like to participate in this study. Once done with their normal routine urine collection, volunteers would be directed to a separate area where representatives of Orasure Technologies would be available to collect the oral fluid specimens.

(f) Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur:

-Population to be tested: Individuals who are defendants or offenders may participate in this study.
-Risks: The oral fluid collector is intended to be inserted between the cheek and gum, however it may be possible that someone may try to put it into their throat causing a gag reflex. Otherwise all materials used in the collector have been tested for biocompatibility and pose no chemical risks to humans.
-Discomforts: Aside from a risk of a gag reflex, it may be possible that the collector causes some discomfort as it is placed between the cheek and gum.
-Possibility of Risks or Discomforts: Since instruction will be given in person, it is felt that volunteers will have little chance to improperly place the collector in the mouth and encourage a gag reflex. As far as discomfort, the UPlink collector is not large and has been tested with over 1,000 individuals to date. No reports of extreme discomfort have been documented. No adverse reactions or extra-ordinary events have been reported.

(g) Description of steps taken to minimize any potential risks or discomforts:

Each person will be given a personal explanation of the procedure for collection which includes pictograms. Additionally, the investigators will be present to assure proper procedures are followed.

(h) Description of physical and/or administrative procedures to be followed to 1) ensure the security of any individually identifiable data that are being collected for the project; and 2) destroy research records or remove individual identifiers from those records when the research has been completed;

In this study no data is being collected to identify individuals. Volunteers are only providing oral fluid specimens which are numbered in random

sequence. The data generated will therefore be unlinked from any volunteers personal information.

(i) Description of any anticipated effects of the research project on Agency programs and operations:

The research project's outcome will offer the agency a potential alternative to urine testing. The potential benefit to operations will be first-hand exposure to the new technology being evaluated from in-program populations.

(j) Relevant research materials such as vitae, endorsements, descriptions or similar work undertaken, sample informed consent statements, questionnaires, and interview schedules:

Appendix 2 contains the principle investigators vitae as well as a copy of the letter from the FDA approving the use of this technology for detection of opiates in oral fluids. Additionally also included is a copy of the informed consent. There are no additional questionnaires or interview schedules.

(k) Statement indicating that copies of all deliverables will be provided to CSOSA/PSA; and
(l) Statement that copies of any data sets will be provided to CSOSA/PSA at the conclusion of the project:

For both k and l, letters of commitment to supply CSOSA/PSA with results of all deliverables and data set from the study are included in appendix 3.

PART 3

(a) Copy of application for review to IRB; and
(b) Copy of certification statement from IRB

Since the technology being tested has already been approved by the FDA, and the proposed study is an extention of technological capabilities to add indications for UPlink, no IRB approval was pursued for this project. However, if it is seen as a requirement by the RRC, the investigators will obtain IRB approval prior to initiation of the study.