

I-CONNECT MANUAL OF PROCEDURES UPDATE:**V03.2020**

Section	Change
Document Footer	The version date was updated for this amendment.
Table of Contents	Page numbers modified appropriately for update summary.
Title Page	Title page updated to reflect version change.
Throughout Document	1. Updated fax number and room number.

**Internet-based Conversational Engagement Clinical Trial
(I-CONNECT)**

in collaboration with

**The National Centralized Repository for Alzheimer's Disease
and Related Dementias (NCRAD)**

Manual of Procedures

Version 4.1

March, 2020

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1.0 ABBREVIATIONS

APOE	Apolipoprotein E
DNA	Deoxyribonucleic Acid
I-CONNECT	Internet-Based Conversational Engagement Clinical Trial
IU	Indiana University
NCRAD	National Centralized Repository for Alzheimer's Disease and Related Dementias
USPS	United States Postal Service

2.0 PURPOSE

The collection of biofluids is an important part of the I-CONNECT study. These samples will be used to:

- Obtain APOE data
- Facilitate sample sharing

The purpose of this manual is to provide study staff (PIs, study coordinators, and study assessors) at the various study sites with instructions for collection and submission of biological samples for I-CONNECT study visits. It includes instructions for biospecimen submission to NCRAD located in Indianapolis at Indiana University (IU).

The following samples will be sent to NCRAD:

- Saliva sample

This manual includes instructions for collection of saliva, labeling, storage prior to shipping, and shipping to NCRAD.

These procedures are relevant to all study personnel responsible for processing saliva specimens entering NCRAD.

3.0 NCRAD INFORMATION

3.1 NCRAD Contacts

Tatiana Foroud, PhD, NCRAD Leader

Phone: 317-274-2218

Kelley Faber, MS, CCRC, Project Manager

Phone: 317-274-7360

Email: kelfaber@iu.edu

Colleen Mitchell, Laboratory Manager

Phone: 317-278-9016

Email: mitchecm@iu.edu

General NCRAD Contact Information

Phone: 1-800-526-2839

Fax: 317-321-2003

Email: alzstudy@iu.edu

Website: www.ncrad.org

Kristi Wilmes, MS, CCRP, Study Coordinator

Phone: 317-274-7546

Email: wilmesk@iu.edu

Sample Shipment Mailing address

I-CONNECT at NCRAD

Indiana University School of Medicine

351 West 10th Street

TK-217

Indianapolis, IN 46202

3.2 Hours of Operation

Indiana University (IU) business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

Check weather report to make sure impending weather events (blizzards, hurricanes, etc.) will not affect the shipping or delivery of the samples.

3.3 Holiday Schedules

- Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday.

3.4 Holiday Observations

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
4 th Monday in May	Memorial Day
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas Day

Please note that between December 24th and January 2nd, Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2nd. If at all possible, biological specimens for submission to Indiana University should **NOT** be collected and shipped to Indiana University after the second week of December. Saliva samples are very stable after collection. Therefore, all samples should be able to be stored and shipped after this holiday period. However, should it be absolutely necessary to ship samples for DNA extraction to Indiana University during this period, please contact the Indiana University staff before December 20th by e-mailing alzstudy@iu.edu, so that they can arrange to have staff available to receive incoming samples.

Please see: https://ncrad.org/holiday_closures.html for additional information.

4.0 NCRAD SALIVA COLLECTION INSTRUCTIONS

4.1 Labeling Instructions

Two labels will be sent in the kit. One will be for the tube, one to place on the Sample and Shipment Notification Form.

In order to ensure the label adheres properly and remains on the tube, please follow these instructions:

- Using a fine point permanent marker, fill-in label before placing on the tube.
- The tube label contains a 2D barcode on the left hand side of the label. Place this barcode toward the tube cap.
- Place label horizontally on the tube just below the “fill to” line and place so as not to cover the tube information.
- Place label before sample collection. This should help to ensure the label properly adheres to the tube before exposure to moisture or handling.
- Place additional label provided with kit on I-CONNECT Sample and Shipment Notification Form.



Blank Tube Label





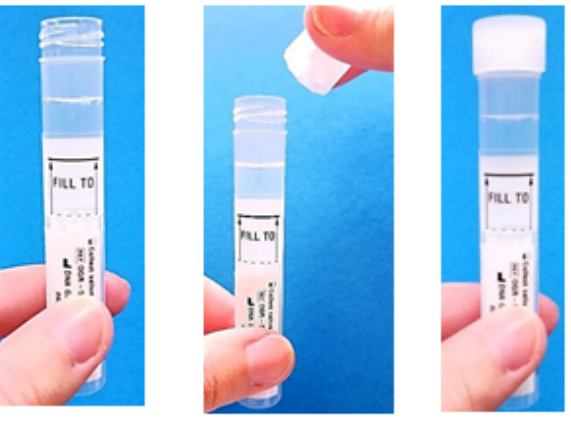
Label on Tube



4.2 Preparation for Saliva Collection

Remember: Do NOT remove plastic film from the lid.

Subject should not eat, drink, smoke, chew gum or brush teeth for 30 minutes prior to giving sample.

Subject does NOT need to rinse their mouth prior to giving the sample. Most people take between 2 and 5 minutes to deliver a saliva sample following steps 1 to 5 below. Before spitting, ask subject to relax and rub their cheeks gently for 30 seconds to create saliva.

<p>STEP 1</p> <ul style="list-style-type: none"> Do NOT remove the plastic film from the lid of the container. Spit directly into the funnel at the top of the tube until the amount of liquid saliva (not including bubbles) reaches the fill line shown in picture #1. The saliva tube has a false bottom, so you will only need to provide 2 milliliters (less than ½ teaspoon) of saliva to reach the fill line. Do NOT fill above the line. 	
<p>STEP 2</p> <ul style="list-style-type: none"> Once the saliva level reaches the fill line, hold the tube upright with one hand. Close the lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the saliva. Make sure that the lid is closed tightly. 	
<p>STEP 3</p> <ul style="list-style-type: none"> Hold the tube upright. Unscrew the funnel from the tube. Pick up the small cap for the tube. Use the small cap to close the tube tightly. 	

<p>STEP 4</p> <ul style="list-style-type: none"> • Shake the capped tube for 5 seconds. • Discard or recycle the funnel. • Place sample in provided specimen bag for shipment to Indiana University (IU). 	
<p>STEP 5</p> <ul style="list-style-type: none"> • Peel off blue plastic liner at the top of the specimen bag to expose the adhesive. • Seal bag by pressing down across the top of the bag. 	

To review a video of the saliva collection procedure, please visit:

<http://www.dnagenotek.com/ROW/support/ciOG500.html>

Intended Use: This product is designed for the safe collection of human saliva samples.

Contents: The funnel lid contains 2 mL of Oragene® DNA liquid. The solution should be clear and colorless.

Warnings: Do not ingest the Oragene® DNA liquid. Wash with water if the Oragene® DNA liquid comes in contact with eyes or skin.

Storage: Store at room temperature 15-30°C (59-86°F).

5.0 NCRAD SPECIMEN COLLECTION KITS, SHIPPING KITS, AND SUPPLIES

NCRAD will provide saliva sample collection kits for research specimens as part of the I-CONNECT Study. Collection and Aliquot Tube Labels will be pre-printed with study information. Please ensure that all tubes are properly labeled during processing and at the time of shipment according to [Section 4.1](#).

5.1 Specimen Collection Kit Contents

Collection kits contain the following (for each subject) and provide the necessary supplies to collect saliva samples from a given subject. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NCRAD Study team to do so. Please store all kits at room temperature until use.

I-CONNECT Saliva Kit

Quantity	I-CONNECT Saliva Kit Components
1	Saliva kit (DNA Genotek) OGR-500
1	Address label
1	Small bubble mailer
1	Saliva kit biohazard bag
2	Cryohold label
1	Human Exempt label
1	Large resealable bag

Individual Supplies

Quantity	I-CONNECT Saliva Kit Components
By Request	Saliva kit (DNA Genotek) OGR-500
By Request	Address label
By Request	Small bubble mailer
By Request	Saliva kit biohazard bag
By Request	Cryohold label
By Request	Human Exempt label
By Request	Large resealable bag

5.2 Kit Supply to Study Sites

Each site will be responsible for ordering and maintaining a steady supply of kits from NCRAD. We advise sites to keep a supply available. Be sure to check your supplies and order additional materials before you run out or before supplies expire so you are prepared for study visits.

Please go to <https://is.gd/ICONECT> to request additional kits and follow the prompts to request the desired supplies. Options include ordering a specific number of kits or simply ordering the desired amount of extra supplies.

Please allow **TWO weeks** for kit orders to be processed and delivered.

6.0 NCRAD SALIVA KIT SHIPPING INFORMATION

6.1 General Saliva Kit Information

6.1.1 Please fill and seal the saliva kit as directed in [Section 4.0](#). Be sure to place completed label on the tube.

6.1.2 Please send the samples to NCRAD as soon as 5 kits have accumulated or at least every 3 months, whichever is sooner.

6.2 Saliva Sample Shipping Instructions

- 6.2.1** Please fill in the date of sample collection where indicated on the ***I-CONNECT Biological Sample and Shipment Notification Form***. Please also fill in your contact information on this form so we can ensure your record remains updated. **Also, please ensure that the 2nd label provided in the kit is placed in the designated spot on the form.** Place this form into the padded shipping envelope.



- 6.2.2** Place the specimen bag, with the saliva tube sealed separately inside, into the padded shipping envelope.
- 6.2.3** Peel off the white paper at the top of the envelope to expose the adhesive, fold this flap down and press firmly to seal envelope.



- 6.2.4** Send the envelope via U.S. Mail. The envelope may be placed in

6.2.5 your mailbox with any outgoing mail or mailed through any USPS drop box or post office location. Thank you!

If you have any questions, please contact the study coordinator at (800) 526-2839 or (317) 274-7546.

7.0 **APPENDICES LIST**

[Appendix A: Biological Sample and Shipment Notification Form](#)



APPENDIX A

Biological Sample and Shipment Notification Form

Please email or fax the form on or prior to the date of shipment.

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To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839

General Information:

Study Staff Name: _____ Site (circle): UM OHSU

Phone: _____ Fax: _____

Email: _____ Date Mailed: _____

Subject ID #: _____ **Subject Year of Birth:** _____

Subject Sex: M F

Ethnicity: Does subject report Hispanic/Latino Ethnicity? Y N

Race: White Black or African American American Indian or Alaska Native Asian
 Native Hawaiian or other Pacific Islander Other (specify): _____
 Unknown

Saliva Collection:

Date Collected: _____

Specimen Label #: Place Specimen Label here

Notes: _____

Internal NCRAD Use-Do Not Complete Volume (ml)
 Saliva: _____

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