

ALTOLD

Assessing Long Term Outcomes of Living Donation

Manual of Operations

Overview

This manual of operations is intended to be a guide for the Local Study Coordinator at each ALTOLD Study site. Since each site will evaluate living donors differently, how potential participants will be contacted, consented, and enrolled in the ALTOLD Study will vary from site to site. Similarly, the Research Center at each site will operate differently, and how they will interact with the Local Study Coordinator will also vary. In the end, it is the responsibility of the Local Study Coordinator to recruit patients, obtain informed consent, obtain screening information, schedule visits, complete the Case Report Forms (including the Quality of Life SF36 Scores), email a data report form to the Central Coordinator, and record the Food Frequency Questionnaire responses on the web site (for Visits 0, 6, and 36 months only).

Recruitment and Enrollment

Identifying Potential Participants

In general, all living donors will be approached for possible participation in ALTOLD. The Study Coordinator will be contacted by a clinical coordinator whenever there is a potential living donor that appears to be a likely candidate for donation. The potential donor will be mailed or hand delivered a brochure about the ALTOLD Study (possibly included with other materials mailed by the center to the potential donor). The Study Coordinator will contact the potential donor, by telephone or at the Transplant Center. If the potential donor is interested in participating in ALTOLD and has a healthy control available, the Study Coordinator will ask the potential donor participant if he/she will contact the control and ask permission for the Study Coordinator to contact the control, or if permitted by your IRB that the study coordinator can contact the control directly with permission from the potential donor.

The Study Coordinator will contact the potential donor participant back after a few days and ask if the control was "ok" with being contacted. If it is ok to proceed, the Study Coordinator will contact the control and ascertain whether the control would be healthy enough to donate, if he or she were the donor at that center. If this appears to be the case (the Study Coordinator may wish to consult with the site Co-Investigator), then the Study Coordinator may obtain telephone consent, complete the Screening Visit Case Report Form history, and arrange for screening labs to be obtained locally or at the Transplant Center. If no control participant can be identified by the donor participant the Study Coordinator may seek a matched control from a control pool at the local site if permitted by the local IRB.

Obtaining Informed Consent

Consent for the donor's control will need to be obtained before screening labs.

Consent from the potential donor will need to be obtained at or before Visit 0. Since screening labs for the donor are to be the labs used as part of the clinical donor evaluation, consent for the donor can be obtained at any time at or before Visit 0.

It is important that this study not influence the donor's decision to donate. As part of the consent process, donors should be told that they may decide against being a donor. If this is the case, then the site will inform the donor's friends and family (including the control if potential donor desires) that the donor is not suitable for donation, or for this study. Their participation in the study should in no way influence their decision to donate or not to donate. They may withdraw from either at any time.

Account for Control Screening Labs

The Local Study Coordinator should have an account to pay the cost of screening labs for the control (the donor's labs are obtained as part of usual care and will not be paid by this study). It may be that the control has a local physician who will obtain the necessary labs (as part of routine care) and this local physician may choose not to deal with the hassle of having the study pay for the labs if they are indicated for routine care. Controls who are near the site may opt to have the labs obtained at the Research Center. In any case, the Local Study Coordinator should have an account that the local lab or Research Center can bill when necessary.

Financial Support for Donors and Controls

The study budget includes money for travel and other expenses that the donor and control may incur due to their participation in the ALTOLD Study. Travel expenses will be reimbursed as allowed by each center (i.e. lowest coach airfare, mileage, lodging, etc). Participants will also be given a modest compensation for each visit to help defray the cost of meals, time off work and other expenses. The amount budgeted is \$150 for the 0, 6, 12, 24 and 36 month visits to the CRC, \$250 for the 36 month visit if it includes a FSIVGTT or \$50 for labs drawn at home. Some participants who live near the Research Center may not need financial support. Some participants may need more than the above amounts. The Local Study Coordinator should have a discretionary account that can be used to cover reasonable costs for participants.

Scheduling the First Study Visit

The Study Coordinator may opt to schedule Visit 0 for both the donor and control in conjunction with a planned visit to the Transplant Center for the usual donor evaluation. Alternatively, this could be scheduled separately. In any case, Visit 0 will need to occur before donation in the case of the donor, and ideally at the same time as the donor, before donation or at the time of donation, in the case of the control. Visit 0 for the control should never occur more than 2 weeks after donation. Exceptions may be made in extreme circumstances; please contact the Central Study Coordinator for assistance if this occurs.

Record Reasons for Not Participating

The Study Coordinator will record each potential living donor considered for ALTOLD in an Excel spreadsheet "ALTOLD Participant List" under the tab labeled "Donor List". Whenever a potential donor does not participate in ALTOLD (Enter "N" in this column), the Study Coordinator will record the reason(s) in the spreadsheet with an "X" in the appropriate column(s) for:

1. Donor failed screening (not a suitable donor for whatever reason)
2. Donor not interested (indicate reason, e.g. distance, cost, time)
3. No Control
4. Donor did not want to contact control
5. Other (specify)-**type reason in this cell**
6. Control not interested (indicate reason, e.g. distance, cost, time)
7. Control failed screening
8. Other (specify)-**type reason in this cell**

Contact Information

For donors and control participants, record contact information on the tab labeled "Participant Contact Info" in the Excel spreadsheet "ALTOLD Participant List" .

Record and Track Visits

Record the dates of scheduled visits in the tab labeled "Visits" in the Excel spreadsheet "ALTOLD Participant List".

Back Up Computer Data Files!

The Excel spreadsheet "ALTOLD Participant List" is designed to facilitate the tracking of participants. It is wise to back this file up on a separate diskette (or some other device) whenever new data are entered. Data from study visits will be backed up by printed Case Report Forms and by forwarding data to the Central Coordinator (Tracy Anderson-Haag) **after each visit**.

Data Collection and Case Report Forms

For Each Screening and Study Visit

1. Each participant should have a separate, Excel spreadsheet named with the study participant's name (last name, then first name). These can be kept in a separate directory on a computer, and sorted by file name (participant name) to easily locate a given participant's spreadsheet.
2. Fill out only those cells that are highlighted in gray (electronic version shows lavender).
3. **NOTE:** much of the information will not change between visits. Permanent information will only need to be entered once, and will automatically appear on forms for subsequent visits, e.g. the participant's name and other identifying information.

4. For each visit, data should be collected on a printed version, then carefully entered on the computer spreadsheet. This should be done as soon as possible after the visit:
 - a. Screening Visit , Visit 0, etc., are each accessed by clicking on the tabs at the bottom of the spreadsheet. Each tab is a separate spreadsheet page.
 - b. Each of these visits (tabs) prints out as a 3-page form by clicking on the print icon in the tool bar at the top of the spreadsheet (or by clicking on “File” in the tool bar and “Print”). You may have to select print only pages 1-3 to avoid blank pages.
 - c. Save the paper version in a secure file for future reference.
5. **After data has been entered for each study visit, the last tab of the participant’s spreadsheet (which automatically collects data as they are entered), should be re-saved (to email to Tracy Anderson-Haag) as a separate file as follows:**
 - a. Create a new spreadsheet named with the participant’s Study ID:
 - i. Click “File” in the upper left hand corner of the tool bar
 - ii. Click “New” and “ok”
 - iii. You are in a new spreadsheet probably called “Book 2”. You will need to rename this new spreadsheet with the participant’s Study ID.
 - iv. Click “File”
 - v. Click “Save as”
 - vi. Type the participant’s Study ID, e.g. “7D 001”
 - vii. Click “ok” and you have renamed the new spreadsheet
 - b. Go back to the participant’s original spreadsheet to copy the data on the DATA tab to the new spreadsheet as follows:
 - i. Return to the participant’s spreadsheet by clicking on the tab in the very bottom Window’s tool bar.
 - ii. Click “DATA” tab
 - iii. Highlight the DATA spreadsheet page by clicking on the gray cell in the corner between “1” and “A”.
 - iv. Click “Edit” in the upper tool bar, expand the menu by clicking on the arrows at the bottom of the menu.
 - v. Click “Copy” .
 - vi. Now return to the new spreadsheet by clicking on the tab in the Window’s toolbar, e.g. “7D 001”
 - vii. Highlight the blank spreadsheet page by clicking on the gray cell in the corner between “1” and “A”.
 - viii. Click “Edit”
 - ix. Click “Paste Special”. **It is important to select “Paste Special” and not just paste or the data calculated by formulas within the cells of the data report form will not carry forward!**
 - x. Choose “Values”, then click “ok”. The data from the DATA page of the participant’s spreadsheet should appear on this new spreadsheet.
 - xi. Click “Save” (the diskette icon on the spreadsheet toolbar).
 - c. Email the new spreadsheet (without participant identifiers) to Tracy Anderson-Haag at teresa.andersonhaag@hcmcd.org by either:

- i. Opening your email browser and attach and email the new spreadsheet, or more simply
- ii. Clicking “File”, “Send To”, and “Mail Recipient”.

Screening Visit

Med. Record No.: medical record number at the participating institution.

Date: mo/da/yr (of the visit)

Study number: Each study participant has a unique study number.

The first digit indicates the site:

- 1=Hennepin County Medical Center
- 2=University of Minnesota
- 3=Mayo Clinic
- 4=Ohio State University
- 5=Johns Hopkins Medical Center
- 6=University of Maryland
- 7=University of California San Francisco
- 8=University of Iowa
- 9=Iowa VAMC

The next letter indicates if the participant is a donor (D) or control (S).

This is followed by a space.

The 3rd, 4th, and 5th digits are sequential numbers for the donor-control pairs.

Note that both the donor and the control share the same last 3 digits.

Example: the first 2 participants (donor and control) at the University of California San Francisco will be assigned the numbers 7D 001 and 7S 001. These 2 study identification numbers indicate that these 2 participants are a donor-control pair and enrolled at the University of California San Francisco.

Last Name: the participant’s last name.

First Name: the participant’s first name.

M.I.: the participant’s middle initial.

DOB: the participant’s date of birth

Sex: “M” if male, “F” if female

Ethnicity: “W” if white, “B” if black, “H” if Hispanic, “A” if Asian, “N” if Native American, and “O” if of some other ethnic background.

Relationship to recipient: “S” if Spouse, “I” if in-law, “D” if distant blood relative (e.g. cousin, uncle, etc.), “P” if parent, “B” if brother or sister, “C” if child, “F” if friend or acquaintance, “N” if altruistic. Leave this blank if this is the control data collection form.

Major Illnesses or Hospitalizations (Date): after the screening visit, only new major illnesses or hospitalizations need to be added to the list, e.g. ask patient: “Since the last visit has there been any new major illnesses or hospitalizations?”

Ever treated for hypertension (Y): “Y” if yes, “N” if no, dyslipidemia, gout, diabetes or Hi-BG (“high blood glucose”, “high blood sugars”), kidney disease, proteinuria (“protein in the urine”), stroke, heart disease.

Current Medications, dose, and times per day. For example, a patient taking Metoprolol 100 bid, would be entered as dose = 100, times per day = 2.

Family History:

1st column: “So” if son, “D” if daughter, “B” if brother, “S” if sister

2nd column: age at enrollment or screening visit (if living)

3rd column: age at death (if died)

4th column: cause of death (avoid “cardiac arrest” if possible)

Enter approximate age (do best that you can) at first occurrence of:

5th column: “MI” myocardial infarction

6th column: “CABG/PTCA” coronary artery bypass or angioplasty/stent

7th column: “DM” diabetes mellitus

8th column: “HTN” hypertension (high blood pressure)

9th column: “CKD” chronic kidney disease

Radioccontrast Allergy (Y/N): “Y” if yes, “N” if no (generally “N” if “felt funny”)

Desc: Describe as “hives” “broke out” “skin rash” “asthma” “short of breath” etc.

Seafood allergy: “Y” if yes, “N” if no (generally “N” if only nausea, vomiting, etc.)

Desc: Describe as “hives” “broke out” “skin rash” “asthma” “short of breath” etc.

Cigarettes:

1st column: place an “X” under either Never, Former, or Current (only one)

2nd column: “packs per day” indicate an “on average” value

3rd column: year began

4th column: year quit (if smoked once and now quit)

Alcohol:

1st column: place an “X” under either Never, Former, or Current (only one)

2nd column: “drinks per week” indicate an “on average” number

3rd column: year begun

4th column: year quit (if smoked once and now quit)

Las line: place an “X” for either: “Mostly wine”, “Beer”, “Both” or “Other”

Number of pregnancies: single digit (include all pregnancies even if aborted)

Number of deliveries: single digit

Weight in kg: (leave blank if entering weight in lb), use one decimal if possible

Weight in lb: (leave blank if entering weight in kg), need only to nearest pound

Height in cm: (leave blank if entering height in inches), round to nearest cm without shoes

Height in inches: (leave blank if entering height in cm), round to nearest 0.5 inch without shoes

Waist circumference in inches: (leave blank if entering in cm), use only one decimal

Waist circumference in cm: (leave blank if entering in inches), use only one decimal

To measure waist circumference, locate the upper hip bone and the top of the right iliac crest. Place a measuring tape in a horizontal plane around the abdomen at the level of the iliac crest (the natural waist = smallest point between the end of the ribs and the iliac crest) . Ensure the measuring tape is snug, but does not compress the skin, and is parallel to the floor. The measurement is made at the end of a normal expiration.

Hip circumference in inches: (leave blank if entering in cm), use only one decimal

Hip circumference in cm: (leave blank if entering in inches), use only one decimal

To measure hip circumference, locate the distance around the largest extension of the buttocks. Ensure the measuring tape is snug, but does not compress the skin, and is parallel to the floor.

Systolic BP #1: to nearest mm Hg

Systolic BP #2

Systolic BP #3

Diastolic BP #1: to nearest mm Hg

Diastolic BP #2

Diastolic BP #3

Heart rate #1: beats per minute

Heart rate #2

Heart rate #3

Laboratory Screening: enter appropriate values. Calcium, white blood count, hemoglobin, serum creatinine and serum albumin require at least one decimal.

Pre-Donation Surgery “Visit 0” (for control no later than 2 weeks after the transplant surgery)

Most cells should already have data (from the Screening Visit).

Major illnesses or Hospitalizations: add only those that are new since the last visit. Do not delete any previous entries!

Current Medications: delete any that are no longer taken. Add new medications patient is taking.

Family History: briefly review and update any new illnesses or deaths in the family.

Review and update the following: “since the last visit have you had any:”

Radiopaque Allergy (Y/N): “Y” if yes, “N” if no (generally “N” if “felt funny”)

Desc: “hives” “broke out” “skin rash” “asthma” “short of breath” etc.

Seafood allergy: “Y” if yes, “N” if no (generally “N” if only nausea, vomiting, etc.)

Desc: “hives” “broke out” “skin rash” “asthma” “short of breath” etc.

Cigarettes:

1st column: place an “X” under either Never, Former, or Current (only one)

2nd column: “packs per day” indicate an “on average” value

3rd column: year begun

4th column: year quit (if smoked once and now quit)

Alcohol:

1st column: place an “X” under either Never, Former, or Current (only one)

2nd column: “drinks per week” indicate an “on average” number

3rd column: year begun

4th column: year quit (if smoked once and now quit)

Las line: place an “X” for either: “Mostly wine”, “Beer”, “Both” or “Other”

Number of pregnancies: single digit (include all pregnancies even if aborted)

Number of deliveries: single digit

Weight in kg: (leave blank if entering weight in lb), use one decimal if possible

Weight in lb: (leave blank if entering weight in kg), need only to nearest pound

Systolic BP #1: to nearest mm Hg

Systolic BP #2

Systolic BP #3

Diastolic BP #1: to nearest mm Hg

Diastolic BP #2

Diastolic BP #3

Heart rate #1: beats per minute

Heart rate #2

Heart rate #3

SF36 Scores

Quality of Life Survey

At each study visit, participants will be asked to fill out the Medical Outcomes Survey Short Form 36 (SF36) for Quality of Life. The Study Coordinator should make sure the Research Center administers the SF36 during those visits. If this is missed, the Study Coordinator should mail the SF36 to the participant and ask the participant to return the completed SF36 as soon as possible. The Study Coordinator will then record the participant’s SF36 scores on the Case Report Form.

Report Forms for Visits at 6, 12, 24, and 36 mo are handled as for “Visit 0”

Role of the Study Coordinator in Research Clinic Visits

Scheduling the Visit

Visits to the Research Center should be scheduled as far in advance as possible. The Research Center may have a scheduling form that needs to be mailed or faxed to them.

Confirming the Visit

Approximately 1-2 weeks before a scheduled visit, the Study Coordinator should call to remind the participant of the upcoming visit. The participant should be reminded to come fasting, and to avoid taking non-steroidal anti-inflammatory drugs, e.g. naproxen, ibuprofen, etc. During this phone call, the medical history for the upcoming visit can be updated.

Updating the Case Report Form for the Visit

When calling to remind the participant of the upcoming visit, the Case Report Form for that visit can be reviewed with the participant for new major illnesses or hospitalizations since the last visit, changes in medications, changes in the family history (deaths or illnesses), allergies to radiocontrast or seafood, changes in cigarette or alcohol consumption, or pregnancy. The updated Case Report Form for the upcoming visit can then be sent to the Research Center for completion at the visit (vitals, etc.).

Visit to the Research Unit

After the participant's visit to the Research Center, the Study Coordinator will complete or pick up the completed Case Report Form for that visit, enter the new data on the Excel spreadsheet, and email the DATA page to the Central Coordinator (Tracy Anderson-Haag; see page 4).

Food Frequency Questionnaire

At Visits 0, 6, and 36 months, participants will be asked to fill out the National Institutes of Health Food Frequency Questionnaire (FFQ). The Study Coordinator or the Research Center should administer the FFQ during those visits. If this is missed, the Study Coordinator should mail the FFQ to the participant and ask the participant to return the completed FFQ as soon as possible. The Study Coordinator will then transcribe the participant's answers on the web page:

https://apps.qcrc.umn.edu/dhq_p1062/

Username: lurds

Password: lurds2006

Once logged in, you will need to enter a study ID number for the participant that is specific to the visit related to the FFQ form that you are entering. The ID code will consist of the study participant ID number (i.e. 1D001) followed by "FFQ00" for the visit 0 questionnaire, "FFQ06" for the 6 month visit questionnaire, or "FFQ36" for the 36 month visit questionnaire. The study ID code for entering the FFQ will be a 10-digit number (i.e. 1D001FFQ00 for patient 1D001 on visit 0). Please contact Tracy Anderson-Haag if you have problems accessing this site.

The FFQ form has been emailed to you in a .pdf file for reproduction if necessary. It can also be downloaded from the NIH website at: <http://riskfactor.cancer.gov/DHQ/dietcalc/password.html>. Click on DHQ forms, then the English version.

Role of the Research Center in Clinic Visits

Brief Description

The Research Center will collect the following:

1. Fasting laboratory samples at each visit.
2. Glomerular filtration rate determination at each visit.
3. Quality of Life (SF36) survey at each visit.
4. Food frequency questionnaire at visits 0, 6, and 36 months.
5. Frequent sampling intravenous GTT at 36 months, if participating.

Sample Research Center Orders for Each Visit:

- Admit as an outpatient to the Research Center.
- If the participant has a fever or acute illness, contact the Study Coordinator before proceeding.
- Order 5 mL of Omnipaque (300 mg iodine/mL) containing Iohexol 3.235 g from the research pharmacy.
- Activity – Up ad lib.
- Vitals – Height, weight, hip circumference and waist circumference. BP and P after resting for at least of 5 minutes: 3 BP's at ~1 minute intervals using right arm (raised to heart level) while sitting with feet flat on the floor and resting quietly. Record on flow sheet.
- Medication – Participant may self-medicate any prescribed medications. Record on the flow sheet any medication(s) that patient has taken since the last GFR visit.
- Medical history – record on the flow sheet any hospitalizations, illnesses, or medical tests since the last GFR visit, unless this has already been done by the ALTOLD Study Coordinator.
- Diet – participant's usual diet, but no caffeinated beverages, carbonated beverages, or concentrated carbohydrates on morning of GFR. Ask if the participant is following any special diet and why, e.g. vegetarian, low protein, caloric restriction (for weight reduction), low fat and low cholesterol (for dyslipidemia), low salt (for hypertension), low carbohydrate index (for diabetes), or any other special diet. Record diet on the flow sheet.
- Have the participant fill out a Food Frequency Questionnaire (at visits 0, 6 and 36 months only) and a quality of life survey (visits time 0, 6, 12, 24 and 36 months).
- Allergy kit (epinephrine, anti-histamine, Solu-cortef) – available for an anaphylactic reaction.
- Ask if s/he has an allergy to iodine or to seafood (if yes, do not inject Iohexol).
- Process a pregnancy test on all premenopausal women before injecting Iohexol.

Spot (morning) urine sample:

Collect urine and perform/record multistix results. Aliquot ~4 mL into each of 4 clear-capped plastic tubes: 1 for urine protein:creatinine and albumin:creatinine ratios, and 3 saved specimens. Label and send with blood samples to the Fairview (Central) Laboratory.

Glomerular Filtration Rate Study (See ALTOLD Lab Specimen Collection and Processing Manual for details)

Injection arm – Start heparin lock (18-20 gauge) and draw fasting bloods (before locking with heparin).

- Serum pregnancy screen on premenopausal women—2 mL red top tube. Process in CRC using pregnancy test procedure kit. If a weak positive result is obtained, send the remainder of the serum to the lab for a quantitative HCG. Do not administer iohexol until a negative result is obtained. Urine pregnancy screens are also acceptable if blood tests cannot be processed within a reasonable time frame to facilitate convenience of visit.
- Draw two 8.5 mL red/gray top SSTs, one 2 mL lavender top tube, one 1.8 mL blue top tube, three 6 mL lavender top tubes and two 7 mL green top tubes. Collect and process as directed in the ALTOLD Laboratory Specimen Collection and Processing manual and flowsheet. Label and send to the Fairview Laboratory for a comprehensive metabolic panel (including fasting glucose, serum electrolytes, calcium, albumin, blood urea nitrogen, and creatinine), lipid panel (total, HDL, and LDL cholesterol and triglycerides), lipoprotein (a), homocysteine, HbA_{1c}, insulin, phosphorous, parathyroid hormone, uric acid, high-sensitivity C-reactive protein, fibrinogen and storage of the remainder at – 70°C.

Slowly, but within 2 minutes, inject five (5) mL of Omnipaque; flush the catheter with 10 mL of normal saline. Keep the IV line patent with saline in case the other line will not draw blood samples – DO NOT use the injection arm for draws unless blood cannot be drawn from the sampling arm. Record the exact time the injection is completed and use the same clock for timing throughout the procedure.

Sampling arm – Start heparin lock (18-20 gauge) and keep patent with saline.

- Draw and discard adequate blood from start of each blood draw to avoid dilution with saline. Draw blood samples at 120, 150, 180, 210 and 240 minutes after iohexol injection. It is extremely important to accurately record the time of each of these blood draws. Completely fill each 2 mL green top tube (sodium heparin anticoagulant). Samples should be centrifuged at 3000 rpm for 10 minutes, aliquoted into labeled tubes, and frozen at - 70° C. Place a copy of the flow sheet with samples.

After the last collection period (240 minutes), remove IV's. Encourage fluids for the remainder of day to flush Iohexol from system. Discharge to home.

IOHEXOL GLOMERULAR FILTRATION RATE (GFR) FLOW SHEET

Pre-donation Visit Visit 1 (6 mo post) Visit 2 (12 mo post)

Visit 3 (24 mo post) Visit 4 (36 mo post)

Participant is a premenopausal woman: No Yes (if yes, perform pregnancy test)
 Pregnancy test: Negative Positive Allergy to iodine or seafood: No Yes
 If pregnancy test is positive or there is an allergy to iodine or seafood, do not inject
 iohexol or do GFR, but page <Insert name & page number of Site Investigator here
 or if not available < Insert name & page number of back-up here >.

Participant is on a diet: No Yes. If yes, type/reason: _____
 Medications taken since last GFR, including OTC drugs (name, dose, start date,
 stop date):

Multistix: S.G. _____ pH _____ Protein _____ Glu _____ Ket _____ Blood _____ Bili _____ Urobil _____ Nit _____ LE _____

ALTOLD (LURDS)



Pt ID label

ALTOLD (LURDS)



Lab ID Label

Date:		BP#1:		Height:	cm
Weight:	kg	BP#2:		Waist circumference:	
Heart rate:		BP#3:		Hip circumference:	

Iohexol GFR Blood Draws		
Target Time	Actual Time (hour, minute)	Blood Draw
0 (injection)		-----
120 minutes		2 mL green top tube
150 minutes		2 mL green top tube
180 minutes		2 mL green top tube
210 minutes		2 mL green top tube
240 minutes		2 mL green top tube

Make 2 copies: send one with the blood samples and provide the second along with the Food Frequency Questionnaire and Quality of Life survey to the ALTOLD-LURDS Study Coordinator.

FREQUENT SAMPLING INTRAVENOUS GLUCOSE TOLERANCE TEST (FSIVGTT) ORDERS

- Admit as an outpatient to the Clinical Research Center (CRC).
- If the participant has a fever or an acute illness, contact the Study Coordinator before proceeding.
- Activity – recumbent, or with head of bed at 45 degrees, during the procedure.
- Medication – Participant may self-medicate any prescribed medications.
- Record weight, BP, fasting blood glucose (per BG meter) and heart rate on the FSIVGTT flow sheet.
 - **If fasting blood glucose is abnormal, contact MD. If fasting blood glucose is > 126 testing should not proceed.**
- Place two 18-20 gauge intravenous catheters, one in each arm; a heparin lock (preferably in an antecubital vein) for infusion and a catheter (preferably in a hand vein) for blood drawing.
- Attach a 3-way stopcock to the catheter used for blood drawing and continuously infuse 0.9% Normal Saline TKO.
- Have two stop watches, labeled tubes, and the FSIVGTT flow sheet at bedside before starting blood draws.
- Draw baseline blood samples for insulin (2 mL red-top tube) and glucose (1 mL gray-top tube) at -15, -10, -5, and -1 minutes before glucose infusion is begun at “time 0”.
- At time 0 inject 0.3 g/kg body weight glucose (50% solution) over 1 minute (flush catheter with saline).
- Draw blood samples for insulin (2 mL red-top tube) and glucose (1 mL gray-top tube) at 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 19, 22, 25, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, and 180 minutes after the start of the glucose infusion (time 0).
- Give regular insulin **0.02 U/kg** body weight intravenously at 20 minutes.
- After the last collection period (240 minutes), remove IV’s. Discharge to home.

FREQUENT SAMPLING INTRAVENOUS GLUCOSE TOLERANCE TEST (FSIVGTT) FLOW SHEET

- Is the participant fasting (NPO after midnight)? Yes No If the participant is ill or not fasting, contact the Study Coordinator before proceeding.

Date _____

Fasting Blood Glucose _____ Weight: _____ kg BP: _____ mm Hg Heart rate: _____

FSIVGTT Blood Draws		
Time (min)	Place (✓)	Remarks
-15		
-10		
-5		
-1		
0	No blood	Infuse glucose
2		
3		
4		
5		
6		
8		
10		
12		
14		
16		
19		
20	No Blood	Give Insulin
22		
25		
30		
40		
50		
60		
70		
80		
90		
100		
120		
140		
160		
180		

Make 2 copies: send one with the blood samples and provide the second to ALTOLD Study Coordinator.