



STANDARD OPERATING PROCEDURE FOR HLT BREATH ALCOHOL CONTENT

I. INTRODUCTION AND PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the steps for fulfilling the clinical requirements involved in checking breath alcohol content (BAC) and dealing with intoxicated participants. This SOP references BAC limits specific to the HLT study.

2. SCOPE

This SOP applies to the activities involved in checking BAC and dealing with intoxicated participants.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.62
May 9, 1997

Investigator recordkeeping and record retention
International Conference on Harmonisation; Good Clinical Practice: Consolidated
Guideline

4. REFERENCES TO OTHER APPLICABLE SOPS

5. ATTACHMENTS

None

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in ensuring that the BAC is evaluated for all study participants and that intoxicated participants are handled appropriately at the UVA CARE clinic.

7. DEFINITIONS

BAC – Breath Alcohol Content

HLT—High and Low Dose Topiramate for the Treatment of Alcohol-Dependent
Smokers, IRB-HSR 15597

8. PROCESS OVERVIEW

A. Assessing BAC

B. Dealing with Intoxicated Participants

9. PROCEDURES

A. Assessing BAC

Staff Member Responsible

- All Staff

Description of procedure:

A. Assess BAC, using the Intoximeter Alco-Sensor III:

(Instructions for checking BAC are also on the back of the Alco-Sensor)

- **Participants will have their Breath Alcohol Content evaluated at the beginning of each visit, prior to starting any treatment activities.**
- Check temperature on back of Alco-Sensor
 - if any number or symbol shows you may proceed
 - if not, place instrument in pocket, close to body for 2 minutes and re-check
- Attach mouthpiece
- Press READ BUTTON for 10 seconds
 - if display is zero, you may proceed
 - if not, press SET BUTTON and return to pocket
- Depress SET BUTTON
- Instruct participant to blow steadily for as long as possible
- Press READ BUTTON before exhalation ceases (but not less than 3 sec. after blowing starts)
- Keep READ BUTTON depressed until maximum reading is obtained and remains stable for 10 seconds.
- Discard mouthpiece and depress set button.
- Record results.

B. Evaluate BAC Result, and actions for HLT study:

- BAC Results 0.000 % may proceed with *all* study related activities, *including* informed consent
- BAC Results between 0.000- 0.020% may proceed with study related activities, *except* informed consent
- BAC Results > 0.020 Do not proceed with any scheduled activity; patient may wish to wait for BAC to fall to within acceptable levels.
- BAC Results ≥ 0.08 *or* is evaluated as impaired, *do not* proceed with any scheduled activities *and* do not allow the patient to drive. The legal limit of breath alcohol content in the state of Virginia is less than 0.08%. **Refer to B. Dealing with Intoxicated Participants.**

B. Dealing with Intoxicated Participants

<i>Staff Member Responsible</i>	<i>Description of procedure:</i>
<ul style="list-style-type: none">• All Staff	<ul style="list-style-type: none">• The participant will be informed that his/her alcohol breath content is over the legal limit or impaired, and will be escorted to the front waiting area.• The participant may remain in this area provided that they remain non-disruptive to staff and other participants.• The participant will be presented with three options:<ol style="list-style-type: none">1) They can stay at the UVA CARE clinic, getting BAC checked once an hour, until it is below the limit. At that point, depending on the schedule, they can complete the visit or reschedule for another time.2) Participants will be offered the use of a telephone to arrange transportation from friend or family. Participants should be made aware that the person(s) picking them up must present themselves to a UVA CARE staff member upon arrival.3) If participants are unable to find alternate transportation and decide to leave the clinic, UVA CARE clinic staff will offer to call a taxi at the participant's expense or provide them with transportation at no cost using the UVA CARE vehicle. <p>If a participant refuses to wait until he/she is no longer intoxicated and leaves the clinic without permission or against advice, staff may call the Henrico Police Department at 804-501-5000 or the Albemarle Police Department at 434- 977-9041 and report that the participant is driving under the influence of alcohol. Staff will note this in the participant's chart, dating and signing.</p>

