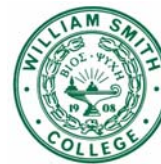




**Hobart and William Smith Colleges
- Colleges of the Seneca -
Form A**



Application to Conduct Research with Human Subjects

Directions: This application is to be submitted to and approved in writing by the IRB *prior* to the initiation of any investigation involving human subjects. If you believe that your research project qualifies for exemption, please complete *Form B: Application for Exemption from IRB Review for Research with Human Subjects*. Please submit a signed, paper copy and an electronic version of your application to the Office of the Provost.

Principal Investigator *Name:* David W. Craig

HWS Department Affiliation: Chemistry
Campus Address: Box 4024
Email Address: craig@hws.edu
Phone Number: 3611

If Principal Investigator is a student:

Name of Faculty/Staff Supervisor:
Supervisor's Campus Address:
Supervisor's Email Address:
Supervisor's Phone Number:

Note: supervisor's signature must appear at the end of this form.

Project *Title:*

Anticipated Starting Date: Assessing the Distribution of Late Night Blood
Alcohol Concentration
Anticipated Completion Date: ongoing

Project Involves: Faculty/Staff research
 Independently conducted student research
 Other: Students in FSEM 060-01 Alcohol in College

For IRB use only:

Application # _____
Submission Date: _____

___ Approved ___ Approved with revisions ___ Not approved

Print Chair's Name

Chair's Signature

Date

Nature of the Project

1. Purpose of the investigation – provide a brief overview of the background for the proposed research and list the overall objectives of the study.

Four fundamental questions, among others, will be addressed in this research. What is the distribution of late night blood alcohol concentrations among a college student population? How accurately can peak blood alcohol concentrations be predicted from anonymous self-report survey data? How accurate are student perceptions of their own BAC and of their degree of impairment? How effective are protective behaviors in reducing peak BAC and harm and how broadly are BAC-reducing protective behaviors used by students at HWS?

Furthermore results from this study will be of particular importance to the social norms alcohol abuse prevention efforts on this campus. Results from breathalyzer measurements will provide another independent data source for social norms messages beyond currently used self-report surveys. By reporting data from biological measurement we can bolster the credibility of data from self-report surveys and possibly enhance the outcomes of this already effective program.

2. Description of methodology – clearly describe the research procedures you plan to use.

Researchers (independent study students, honors students, and students of FSEM 060) will administer blind breathalyzer tests, blind response-time assessments, and anonymous voluntary surveys to randomly selected students entering or leaving randomly selected residence halls every night of the week between the hours of 11pm and 3am. The short survey will contain questions about drinking behaviors for that night and typical use, consequences experienced, and protective factors used. The breathalyzer instrument will report a visible test number that will be recorded on a laptop running a response-time assessment and on a blank two-page survey form. The faculty principal investigator will not be present during data collection activities. Subjects may call the next day to one of the research student's residence hall rooms with the test number and ask for their BAC (a web-based form will be available shortly). Subjects will not be asked their name. The results of these studies will be presented in research reports reporting aggregate data only. No individuals will be identified. In addition, the aggregate data will be used in social norms media messages reporting the positive majorities that have either zero or low blood alcohol concentrations even on nights of perceived heavy alcohol use.

Detailed data collection protocol:

Once a student agrees to participate, they will be asked to participate in three data collection activities: 1) submit a breath sample; 2) play a 35 second response time assessment computer game, and 3) fill out a two page survey. Total data collection time per subject lasts 3 to 4 minutes. The breathalyzer will store the BAC measurements internally and only display a sample test number. BAC data will be downloaded at a later time to the project server in a secured laboratory. Once the breath sample is collected, the test number on the instrument will be entered into a subject identification field on the response time assessment game running on a laptop and onto a blank survey form. The response time assessment game displays a white ball on a black screen. Subjects are asked to click on the ball with a mouse-controlled cursor. Balls initially appear for three seconds before disappearing and reappearing in another random location

on the screen. This is repeated twice more at the three second time interval. If the subject successfully clicks on at least two of the three balls the time is reduced by 25% and three replicates are repeated. This process continues until a subject cannot click on at least two of the three balls. The average time in milliseconds is computed for the time between a ball appearing and a successful click for the fastest successful time trial. Data is recorded in a secured database that can only be opened by the project director at a later time. This game requires about 35 seconds on average to complete. The survey, just as the previous two activities is voluntary and anonymous, only identified by the test number from the breathalyzer instrument. When the survey is returned the participant will be given a card with their test number, a web site URL reporting project results, and a phone number to call to receive their test results at a designated time. Subjects will be given the opportunity to voluntarily return to the measurement station one hour later and submit a second breath test to measure their metabolic clearance rate. To the best of the researcher's ability, no subject will be selected more than once during a single evening data collection session (other than those returning for a time-two measurement).

Subject safety

The following procedure will be used if a subject exhibits symptoms of alcohol poisoning. Researchers as members of the HWS community have the responsibility to help and support peers exhibiting symptoms of alcohol poisoning. Security will be called if any subject enters a residence hall exhibiting symptoms of alcohol poisoning. Symptoms of alcohol poisoning include 1) unconscious or semi-consciousness, 2) cold, clammy, pale, or bluish skin, 3) slow respiration of eight or less per minute, 4) vomiting, or 5) person is not alert to the date, time, or his or her surroundings or location. If researchers are unsure of a subject's condition they will call by cell phone the principal investigator.

The following provisions in our protocol are designed to prevent the mere presence of data collection stations in residence halls from influencing the level of dangerous drinking among students. There was some concern that the mere presence of the BAC testing stations might encourage drinking games or other dangerous drinking activities. This could be dangerous to the residence hall community, to subjects in the study, and to the researchers participating. Therefore, this study has been designed to reduce the likelihood of such activities. Students cannot volunteer to participate in the study, they must be part of the random selection process. Students cannot come back for a repeat test unless they were randomly selected and invited for a metabolic test measurement. Students will not find out their BAC that evening. Finally, students do not know in advance where the stations will be on a given night. All of these factors, we believe, will reduce the chance of the presence of research stations influencing student drinking behaviors. Indeed, the success of this plan seems to be reflected in the results from the previous five terms where 75% of the students had a BAC of 0.05 g/dL or less.

Researcher Safety

Two researchers will be present at all times during survey and breath sample collection. At least one of the researchers will have a cell phone with them.

Researcher Training

In consultation with David Diana, former Director of Alcohol and Other Drug Programs, the following training procedure has been developed to ensure that researchers are aware of the HWS alcohol policy and the appropriate response. A one hour training session is provided to

each researcher reviewing the HWS alcohol policy, reviewing symptoms of alcohol poisoning and rehearsing how to respond given a variety of subject behavior scenarios delivered by the director of alcohol and other drug programs (Prof. Craig will deliver this instruction while this position is vacant). A handout prepared by David Diana describing symptoms of alcohol poisoning is provided to each researcher. Researchers are told to call security immediately if any student exhibiting symptoms of alcohol poisoning comes before them. If they have any questions they are to call the principal investigator immediately by cell phone. All researchers will complete the National Cancer Institute "Human Participant Protections Education for Research Teams" online course. Certificates upon completion will be provided to the principal investigator.

Participant Population

3. Category of participants (check all that apply)

- Adults
- Children and minors (under 18 years old)
- Pregnant women, fetuses, or neonates
- Institutionalized persons (e.g. in prison)
- Cognitively impaired persons (e.g. persons with psychiatric, cognitive or developmental disorders; or under the influence of alcohol or drugs)
- Other:

4. Institutional affiliation of participants (check all that apply and clarify as necessary)

- Hobart and William Smith Colleges
- Schools:
- Hospitals:
- Other:
- None – please explain:

5. Estimated number of participants: 500 per term

6. Participant solicitation (check all that apply and attach examples, scripts, etc. to this form)

- Advertisement
- Telephone
- Letter
- Class announcements
- Other – please describe

Data collection stations will be set up just inside the main entrance of residence halls between the hours of 11pm and 3am. Randomly selected students will be invited to participate as they leave or return to the residence hall. A randomized sequence is generated prior to data collection that selects 25% of those leaving or entering the residence hall for an invitation to participate. If a

person declines to participate the next person to enter is offered an invitation. If they decline as well the next student is chosen from the randomized sequence.

7. Participant incentives – will any inducements (e.g. money or course credit) be offered in exchange for participant involvement in research?

- No
 Yes – please describe the nature of the inducements

Participants will have the opportunity to pick up a BAC card customized for their weight and gender that gives them an estimate of their BAC as a function of number of drinks consumed and time.

Participant Risks

8. Potential harm to participants – could participants incur any psychological, social, physical, or legal risk as a consequence of their involvement in the research (including any psychological distress associated with a) experimental manipulations; b) probing for information that might be considered personal or sensitive; or c) exposure to materials or social interactions that might be considered offensive, threatening, or degrading)?

- No
 Yes – please describe the nature of the potential risk

9. Participant deception – will the participants be deceived or misled in any way?

- No
 Yes – please describe the nature of the deception and attach to this form all written materials and scripted verbal statements that will be misleading or deceptive, as well as debriefing statements.

Voluntary Participation and Informed Consent

Note that this section does not apply to unobtrusive observation of public behavior.

10. Voluntary participation – describe the steps that will be taken to ensure that participation in the research is voluntary. Please attach to this form the script for information provided by research personnel or written materials to be given to the participant.

Randomly selected individuals are invited to participate with the following script:

“Hello. You have been randomly selected to participate in a student research project on alcohol use at HWS. This will only take a few minutes of your time. We will ask you to fill out a short anonymous survey, play a short response-time computer game, and have your blood alcohol, or BAC measured by breathalyzer. The BAC measurement will be stored internally by the instrument. We will not know what your BAC is. You will receive a test number so that you can call a phone number tomorrow and get your BAC results. You should know that as members of the HWS community we have the responsibility to call security should you exhibit symptoms of alcohol poisoning while you are with us. You cannot get into trouble by participating in this project. You must be 18 years old or older to participate. Would you like to participate?”

11. Informed consent – *federal law requires that, except in special circumstances, informed consent must be obtained.*

Will a written consent form be used?

- Yes – please attach the consent form to this application
 No – please provide a justification

We do not wish to have students sign a consent form because we do not want to sacrifice any perceptions of loss of anonymity. We have inserted at the top of the survey form the following statement indicating consent to participate in this project: “Answering questions on this survey form constitutes your tacit agreement to participate in this study.”

It is possible that impaired individuals might give consent to participate in the study and then regret that decision in the morning. To rectify this problem we are setting up a web site that will allow participants to log in with their test number and retrieve their BAC and response time data. At this time they may also click on a check box that will remove their data from the database and discontinue their participation in the study. Until the web site is ready, the card with test number given to students will explain that students may call later and have their data removed from the study should they choose to do so.

For research involving participants who are minors, will consent be obtained from the minors’ parents or guardians?

- Yes
 No – please provide a justification
 Research will not involve participants under the age of 18

Note that information on informed consent and a sample consent form can be downloaded from the Hobart and William Smith IRB web page.

Anonymity and Confidentiality

12. Anonymity – will data be collected and/or recorded in such a way that individual human subjects can be identified by the researcher(s)?

- No
 Yes – please explain the nature of the information and the manner in which it will be collected and recorded.

13. Institutional source of information – will any personal data be drawn from institutional files or archives (e.g. school files)?

- No
 Yes – please explain the source and nature of this data.

14. Data access – explain who will have access to the data you collect.

The principal investigator and independent study students under his direct supervision will have access to the data from this project for the purpose of answering the research questions described above and to supply information to the social norms alcohol prevention program. Students in FSEM 060 will be provided in class aggregate summaries of the research results for their class writing assignments.

15. Confidentiality – describe the steps that will be taken to ensure confidentiality of all personal data collected. Be specific. How will you ensure that research personnel (including students) understand their responsibilities in maintaining confidentiality? How will confidentiality be preserved as data are collected, stored, analyzed, and published? When will data identifying individual participants be destroyed?

Confidentiality and anonymity will be preserved by: 1) not recording any individual identification, 2) collecting the breath sample first and entering the corresponding test number onto the subject identification field of the response time assessment game and onto a survey form prior to the subject filling it out, and 3) having the subject privately fill out the form and place it in a closed survey box with slot when complete.

It is true that researchers may be familiar with a subject but once surveys are placed in the box there will be no way to connect a survey to a particular individual. The instrument that measures blood alcohol concentration (BAC) does not display the BAC. It stores the information internally and displays only a test number. Response times are not displayed by the response time assessment game. Results are stored internally and are not accessible by either the subject or the researchers at the time of data collection. Subjects may voluntarily call one of the researchers during a designated time period with their test number to find out what their BAC and response time was. No names will be revealed or requested. Student researchers will be trained to follow this protocol by the principal investigator.

Assurance Statement

I confirm that the procedures described above are accurate and will be followed in the course of the research project. I will notify the IRB of any changes to procedures and if unanticipated problems arise during the research process.

Signature of PI

Date

For Faculty/Staff Supervisors of Student Research:

Federal guidelines mandate that research be of sufficient merit to justify the participation of human subjects. In the case of student research, the responsibility for determining merit is shared with the student's supervisor. Please sign below and check the appropriate box to help the IRB evaluate the merit of the student application.

Signature of Faculty/Staff Supervisor

Date

- I have discussed the proposed research with the student applicant named above and find the research to be of sufficient merit to justify the use of human participants.
- I have discussed the proposed research with the student applicant named above but have made no determination of merit.
- I have discussed the proposed research with the student applicant named above and find the research is **not** of sufficient merit to justify the use of human participants.

Coming in ___ Heading Out ___ BAC Survey -- Test # _____

This is an **anonymous survey**--- you will not be asked to submit your name. Please read each question carefully. There is no "right" or "wrong" answer—just give your best estimate. This survey is **voluntary**. If you do not wish to respond to a question you may leave it blank and continue on. Answering questions on this survey form constitutes your tacit agreement to participate in this study.

1. Gender

- a. male
- b. female

2. What is your Age?

3. What is your current weight and height?

- a. Weight _____ pounds
- b. Height _____ ft. _____ in.

4. Are you a member (check all that apply)?

- fraternity
- varsity team
- team in season now?

5a. What is your class rank?

- 1st year
- Sophomore
- Junior
- Senior

5b. Do you feel that it would be safe for you to drive an automobile right now?

- yes
- no

6. On how many days in a typical month do you consume alcoholic beverages?

of days _____ (enter zero if you don't drink in a typical month)

7. When you consume alcohol, what is the typical number of drinks you consume? (A drink is a bottle of beer, a glass of wine, a wine cooler, a shot of liquor, or a mixed drink.)

- # of drinks _____
- None, I don't typically consume alcohol

8. Generally speaking, during a typical drinking occasion, what is the length of time you spend drinking?

- _____ Hours
- I don't typically drink

9a. How many alcoholic drinks have you consumed tonight?

of drinks _____ None

9b. Do you think most HWS students tonight are

near your intoxication level? more intoxicated? less intoxicated?

-
-
-

(If you checked none in question 9a above, skip to #14 on the back of this sheet)

10. About what time did you have your first drink tonight? And last drink before this test?

- I have **not** consumed any alcohol in the last fifteen minutes

Start time for first drink: _____ Finished last drink (time): _____

11a. How do you feel right now? (circle one) Sober A little Buzzed Pretty Drunk Wasted

11b. Circle each of the sensations associated with alcohol consumption that you are feeling right now

Relaxed energetic happy giddy lowered inhibitions slurred speech numbness difficulty walking nausea

12. What do you think your blood alcohol concentration is right now?

No idea what BAC scale is BAC _____



Turn the page to the back of this form

13. Have you driven a car tonight after drinking?

No If yes, at what time did you start driving? : _____

14. Which, if any, of the following has occurred as a consequence of your drinking during the last 12 months? (check all that apply)

I did not drink during this academic year. (If checked Skip #14, 15) Thank you for taking survey

	No, not during the last 12 months	Yes, occurred tonight	Yes, occurred once due to my drinking during the last 12 months	Yes, occurred more than once due to my drinking during the last 12 months
a. Physical injury to yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Physical injury to others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Fighting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Damage to property	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Damaged friendships or relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. After drinking could not remember events or actions that occurred while drinking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Impaired driving	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Rode with an impaired driver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Attempted intimate physical/sexual contact NOT desired by other person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Were sexually active when otherwise might NOT have chosen to be	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. Which of the following strategies do you employ to reduce your risk when consuming alcohol? (check all that apply)

	No, I have not used this strategy in the last 12 months	Yes, I used this strategy tonight	Yes, I have occasionally used this strategy in the last 12 months	Yes, I usually used this strategy in the last 12 months
a. Limit consumption to 1 drink/hour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Eat before and/or during consuming alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Limit the amount of money that I bring to spend on alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Alternate alcoholic and non-alcoholic drinks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Have a designated driver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Limit consumption so that my BAC is 0.05 or below	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Test # _____

Dear Hobart and William Smith Student,

Thank you for participating in our research project.
– the Craig research group

You may find out what your BAC was by calling _____ between the hours of _____ and _____ on _____. You do not need to give us your name. Just let us know your test number. You can check out the results of this project on the web at the end of the term at <http://people.hws/craig/bac>. If you wish to discontinue your participation in this study you may request that your test number be removed from the database by calling the number above.

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