

Informed Consent

ELIZABETH K. BROWN

FOR IRB USE ONLY

IRB ID #: [REDACTED]

APPROVAL DATE: 01/31/2000

INFORMED CONSENT DOCUMENT

Project Title: [REDACTED]

Research Team: [REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

If you are the **parent or guardian** of a child under 18 years old who has been invited to be in this study, the word “you” in this document refers to your child. If you are a **teenager** reading this document because you have been invited to be in this study, the word “you” in this document refers to you. If you are **over 18 years old**, your parents will not have access to information regarding your willingness to participate in this study.¹

This consent form provides important information about **what you will be asked to do** during this research study, about the **risks and benefits** of the study, and about **your rights** as a research subject.

1 It's the year 2000, and you are now thirteen years old. You will continue to participate in this study, roughly every other year, up through your thirtieth birthday, at which point you will request a copy of the materials used to administer this study. Some of these materials may give insight into your experience as a research subject.

- If you have any questions about or do not understand something in this document, you should ask the research team for more information.²
- You may discuss your participation with anyone you choose, such as family or friends.³
- Finally, do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of the study.⁴

What Is the Purpose of This Study?

This is a research study. The purpose of this research study is to identify genes associated with drinking. Iowa is one of seven medical centers that the National Institute of Alcohol Abuse and Alcoholism (NIAAA) is funding to study families in which some family members have had “drinking problems.”⁵

-
- 2 Though we will not be able to tell you why, specifically, you have been selected to participate in this research study, we will be able to help with directions to the site location—a small, brown, one-story building that looks identical to your dentist’s office—over the phone. We will also be able to suggest a nearby restaurant where you can get a meal for less than the allotted five-dollar meal reimbursement for which you qualify as a result of your participation in this study. McDonald’s is right up the street.
 - 3 However, you may want to avoid bringing it up with your father. We understand he is suspicious of doctors, lawyers, bankers, insurance agents, telemarketers, professors, pharmacists, credit card companies, the government, etc. We are not certain how he feels about researchers, but it is likely he will feel threatened by our questions. Is it true that, in general, your father does not like questions?
 - 4 You are desperate to be a part of things—at thirteen, this is normal—and so we’re confident that you’ll sign your name on the dotted line. You are practicing a new signature and you are eager to use it. We are aware you may not yet know the type of questions to ask here. Please note that the questions you will have later in life may be questions we will not be able to answer.
 - 5 A note on “drinking problems”: We understand that the Drug Abuse Resistance Education program (D.A.R.E.), adopted by millions of elementary and junior high schools across the country in the 1990s, actually worked for you. You even still remember some of the songs:

People can tell me what they’ve done / Maybe some things, maybe none / But people can’t tell me what to do / I will choose a way that’s true—for me // Don’t want to fall into the trap / Don’t want to be somebody’s sap / I’m better than that! / I’ll go to the mat! / To prove I can be . . . DRUG FREE! // Yeah, yeah. (Chorus, in a round) // D—I won’t do Drugs / A—I won’t have an Attitude / R—I will Respect myself / E—I will Educate me now.

How Long Will I Be in This Study?

If you agree to take part in this study, the interview, questionnaires, and brain wave tests will take between 4 and 6 hours. We plan to continue following study participants for at least 5 years.

Will I Be Paid for Participating?

You will be compensated for time and inconvenience involved in participating in this research in the amount of \$75 for the interview, \$75 for the brainwave test, and \$50 for the blood or saliva sample.⁶

How Many People Will Participate in This Research Study?

Approximately 4,000 people will take part in this study at the University of Iowa. The total number of people who participate at all sites nationwide will be approximately 14,000.⁷

Not only have you chosen not to drink, but you are against all “drugs,” including tobacco. In fifth grade, you were shown photos of a former professional baseball player dubbed “The Man without a Face.” He had to have part of his tongue and jaw removed as a result of his snuff habit. You hadn’t known that the pouch of Red Man your dad kept in his front shirt pocket was tobacco. (“You kids want some raisins?” he’d ask you and your sisters, a wad of “raisins” protruding from his lower lip, the bulge somewhat concealed by his thick beard.) For a while, you gave your dad the silent treatment. And then you began to look for patterns in the adults around you. You assumed the police officers and teachers leading the D.A.R.E. training didn’t dip or smoke cigarettes or drink alcohol, and you decided right then that you’d rather end up more like them than your father. They were all so nice.

- 6 We know that your babysitting and lawn-mowing money doesn’t add up very fast. You will likely save most of the two hundred dollars earned for participation in this study for your future, which is something you already spend a great deal of time thinking about.
- 7 By 2016 you will be one of more than 17,702 members of more than 2,255 families from around the United States who have agreed to be research subjects for this study. Thank you!

What Will Happen during This Study? (Please initial on the line provided.)

_____ Interview: We will conduct a 1- to 2-hour interview with you which will contain questions about drinking and experiences that can affect “drinking behavior.”^{8,9}

If necessary, we will conduct this interview over the phone, direct from your “early home environment.”¹⁰

-
- 8 What is “drinking behavior”? We spent a lot of time trying to agree on a neutral term that would encompass the myriad expressions of individual drunken mistakes, spanning from despair (e.g., suicidal thoughts and/or attempts) to rage (e.g., physical abuse of loved ones) to pleasure (e.g., engaging in unprotected sex), etc. In the end, “drinking behavior” was chosen. Other terms considered included: “drinking conduct,” “drinking performance,” “drinking phenotypes,” “drinking practices,” “drinking habits,” and “drinking customs.”
- 9 While you are vaguely aware of the actual effects alcohol could, hypothetically, have on your life were you to partake, you are concretely aware of the effects alcohol has had on your mother’s life. You—the fact that you exist—are proof of her “drinking behavior.” You’ve done the math. Your maternal grandmother died young, after a brief battle with leukemia, in *July*. You were born the following *April*. When you’re older, your mother will tell you she didn’t realize she was pregnant for the first couple of months. You will wonder then how her “drinking habits” might have affected you, specifically, the development of your brain. Your mother’s “coping mechanism” for all that grief was an impressive “drinking performance.” She got married in *November* and gave you her mother’s name. In about fifteen years, you will begin to feel guilty for being alive, for ruining her life. Try not to dwell on these feelings for long.
- 10 Because you are too young to make the trip to Iowa City on your own and your mother has her hands full with your younger brother and all his health problems, we will conduct the interview over the phone.

Here’s a scene: You sit in the corner opposite the basement door with the phone pressed to the side of your face. The phone has a long curly cord and is located in the center of your house, in a small cubby just off the hallway that connects the kitchen to the living room. This hallway is filled with tools and building materials: a circular saw and sawhorses and power drills, stacks of sheetrock and buckets of mud, and boxes of nails and screws in all shapes and sizes. Strewn about the tools are small piles of clothing and coats, dirty dishes, construction-paper craft projects, and letters from your teachers that are supposed to be signed and returned, but which will inevitably be lost. Your younger sisters and brother run circles around you, screaming and laughing and arguing over the remote control. The television is blasting *Roseanne*. Your mother is in the kitchen placing a tray of fish sticks in the oven. Your father is asleep, lying face-down in the middle of the floor in the hallway, still in his work clothes: grease-stained Wrangler jeans and a solid navy blue Hanes T-shirt with a front pocket, Redwing steel-toed boots still attached to his feet, his toes splayed out on the kitchen linoleum.

Many of these questions about drinking and experiences that can affect “drinking behavior” may not be applicable to you.¹¹ Next to these questions you may write N/A.¹² Other questions in the interview are concerned with your *moods* and *feelings*.¹³

_____ Questionnaires: We would like you to complete some or all of the several questionnaires, which measure (a) your early home environment; (b) levels of stress; (c) social support system; (d) how you might react in particular situations; (e) your attitudes about drinking; (f) relationship with your parents and family rules;¹⁴ (g) coping skills;¹⁵ and (h) important people in your life.

-
- 11 Abstaining from alcohol is only part of the equation, but we want to applaud you for your efforts, both now and in the future. However, we recognize that you are currently at work constructing the scaffolding for a lifelong practice of extreme self-control. Please note that this type of vigilance will serve you well in academic and athletic endeavors but not necessarily in social situations. As an adult, you may attempt to impose on others the self-restraint on which you will come to pride yourself. This will likely be especially true for the men in your life. A few of these men will have a “drinking practice” of their own.
 - 12 While N/A may be the appropriate answer now, we anticipate that this will change as you grow.
 - 13 Later in life, you will recognize that your participation in this research study was the closest thing to therapy you’d ever experienced, and for this you will be grateful.
 - 14 While completing the over-the-phone interview from your “early home environment,” you may experience a “level of stress” due to your “social support system.” Just try to focus on the questions, on the sound of the researcher’s voice coming through the hard, white plastic telephone receiver. While it is not our job to determine how you are “reacting in *this* particular situation,” we might be taking notes. By now we’ve covered your “attitudes about drinking,” and we understand that your “relationship with your parents” is somewhat reversed from what is typical. We have also observed that there isn’t much in the way of “family rules.” We’re fairly certain you will create rules of your own to establish a sense of order for yourself. For example, strict rules around food and exercise may prove highly effective in providing relief from the feeling you have that nothing is within your control. We will be asking about this when you’re a little older.
 - 15 During the section about your “coping skills,” the term <<suicide>> might come up. You have never talked about this word with anyone; it isn’t talked about. This research study may prompt you to begin thinking about things you have not previously thought about. Merely thinking about the word <<suicide>> may cause you to feel as though you have done something wrong. (You have been trained to feel this way. This is not your fault. We have been notified of your father’s oft-repeated rhetorical question: *What the hell is wrong with you?*) In response to the question, “Do you ever have thoughts of harming yourself or others?” it’s okay to say, “No.” We will not question you, or the question we hear in your voice.

NOTE: You may skip any questions in the interview or personality questionnaires that you do not want to answer.¹⁶

_____ Brainwave Tests: These tests (electroencephalograms, known as EEGs) involve no radiation or pain. You will sit in a comfortable chair in a private room for 2 to 3 hours and wear a cap to which wires are attached.¹⁷ To improve the recording quality, a special paste will be applied to the scalp. This paste will wash out easily.¹⁸

During this portion of the study, you will be asked to respond to computer-generated stimuli by pressing a button.¹⁹

16 However, keep in mind that you cannot skip any parts of your life. We are sorry, but this is simply the hand you have been dealt. You do not get much of a choice when it comes to the “important people in your life.” That will come later.

17 Here’s another scene: You are sitting in a closet-like structure large enough for the chair, about three feet of legroom, and a small TV on a desk. The chair will be brown and hold the bodily odors of other “research subjects.” You are young and so you do not yet have body odor like that—like stale bread and coffee breath and twice-worn slacks; your stink is that of a little girl who sweats when she is nervous, who picks her nose, who does not wash her hands often enough. In addition to the cap and wires, you are wearing a headset that covers your ears entirely. The room is completely dark except for the glow of the television. Even with a shrill beeping noise penetrating the fuzzy silence, you fall asleep within minutes. “Try to stay awake,” we say to you through a speaker, startling you awake. For a few minutes, your heart pounds and you feel as if you’ve let us down, but soon your eyelids grow heavy again.

You are chronically sleep deprived, and this will go on for years, a decade, even longer. This has something to do with all the nighttime bedwetting and the device you are supposed to sleep on that buzzes whenever you have an accident. (We hear an echo: *What the hell is wrong with you?*) It may also have to do with nerves, and possibly the lack of “family rules.” You and your siblings do not have a bedtime, for example. An additional complicating factor is that you and your siblings all sleep in the same bed with your mother, and who can sleep with limbs on top of limbs, a sweat-sticky mess of unwashed feet and tangled sheets?

18 You may wash your hair in the bathroom sink in the front waiting area. Towels will be provided, as well as Suave shampoo, the Vanilla Bean kind, which we know is your favorite.

19 For first portion of the test, you will hear a beep in the right or left ear of the headset and will be asked to click the button on the corresponding side of the Nintendo-like controller. The next portion of the test will involve rapid flashes of words on the screen. The word RED will flash in red letters, GREEN in blue letters, YELLOW in red letters, BLUE in blue letters, and so on. For each of these fraction-of-a-second flashes of words, you are to indicate whether the color and word matched (left button) or did not match (right button.) There are many, many tests of this sort, but after two hours you probably won’t be able to remember much past the colors and the beeps.

_____ Neuropsychological Tests: You will be given 2 computerized tests that measure your ability to remember patterns, to plan ahead, and to respond accurately.²⁰ These tests will take about 20 minutes to complete.²¹

_____ Relatives: We may ask your immediate relatives (sisters, brothers, parents, spouse and children) to participate in this research study.²²

_____ Return Visits: We may invite you to participate in an additional phase of this study. In this phase, we would invite participants to return every 2 years for the interview and brainwave test described above. To help us contact you in the future, we would like the names of 2 or 3 people who are likely to know where you are in 2 or 3 years.

_____ I allow you to contact others for the purpose outlined above.

_____ I do NOT allow you to contact others for the purpose outlined above.

_____	_____
Name	Phone Number
_____	_____
Name	Phone Number
_____	_____
Name	Phone Number

20 You will still be working on these skills by the time you are thirty. You will have certainly proven your ability to “plan ahead” at that point—and you will do this with gusto, even when it is not necessary. But as for your ability to “remember patterns” and “respond accurately,” you will continue to show room for improvement. Take, for instance, all those older men you will date, or spend time with, whatever it is you will ultimately decide to call it. They will comprise a pattern in shades of gray. Will you be able to say that you “responded accurately” to their advances? We understand that it will be easy to keep on believing that these father-figure types are only trying to help. You may need the help, but not from them.

21 One of the tests is just like Tetris but with exploding jewels. Another consists of a bouncing ball and a platform you must move to strategically knock out bricks. The ball bounces back faster and faster until you are unable to keep up and it zooms past your tiny platform. While you complete these tests, we will sit in the office with you sipping pop from a Styrofoam cup and paging through loose files. Because we remain in the room, you might believe that we will be impressed if you score high, and so you do your very best. You have learned by now that high scores and good grades tend to get you the attention you crave from grown-ups. Please remember: your performance is not being graded, only recorded.

22 Your sisters and brothers have been invited to participate in this study as well. Your mother has not been invited. Your father has most likely declined.

What Are the Risks of This Study?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- *Inconvenience of the interviews and brainwave tests.*²³
- *Loss of confidentiality of the information you give us.*²⁴
- *Some of the questions are personal and could make you uncomfortable, but you do not have to answer any questions you do not want to answer.*²⁵
- *Discomfort of the blood draw and possibility of bruising around the site of a blood draw.*²⁶

23 Because you are young, you do not think of things in terms of being convenient or inconvenient. As for your mother, participating in this study may prove to be an inconvenience. After all, she will have to shuttle you, and possibly your siblings, to our offices in the family van and wait for you in the waiting area for hours.

24 Confidentiality is akin to keeping secrets or having privacy. We know you're good at keeping secrets. However, you are quite unfamiliar with the experience of privacy. A few examples:

Secrets: You don't mention it to your father when your mother buys you a new pair of basketball shoes or a new curling iron because you know it will make him yell at your mother. You aren't yet aware of how credit cards work but will later learn that your mother is responsible for paying the bills, and so your father never knows exactly where his money goes; he won't know this until it's all gone.

Privacy: You are used to your sisters and brother and mother and father walking into the bathroom to look for Vaseline, a Scrunchie, or ibuprofen while you are on the toilet; brushing your teeth while someone else is taking a shower; or streaking through the house nude after showering, searching for something to wear in the pile of laundry on the scratchy green recliner.

In fact, respecting the privacy of others is another area in which you will continue to demonstrate room for improvement for years to come. As an adult, your boyfriend will have to ask you to please stop entering the bathroom while he is on the toilet enjoying his morning bowel movement. You will leave the bathroom door open at all times. "But I just need to grab my tweezers," you'll protest, and he'll tell you that you have to wait. This may hurt your feelings; you may feel left out. Doesn't he love you? Doesn't he feel comfortable with you? Your therapist will be able to help you with this, as will the many self-help books that have been recommended to you by well-meaning friends.

25 Refraining from answering any such questions in your real life, outside of this study, might be defined as having boundaries. Setting healthy boundaries will likely prove to be a difficult practice for you. However, you may want to answer all of the questions we ask you. You will most likely not have another opportunity to talk about these things with anyone else for a very long time.

26 We understand that you've never been squeamish about needles. In fact, it's been reported that you never cry at all.

What Are the Benefits of This Study?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from the data collected in this study.²⁷

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. Please retain a copy of this document for your records.²⁸

(Signature)

(Date)

27 While we will not be contacting you to share the results of this study with you, you will be able to find information about it online. You may have ideas about how to improve the study: Why don't they ask about what sort of benefits you've found through psychotherapy or meditation? Why aren't there questions about sexual abuse? Please understand that there are limitations to the work that we do.

28 Every couple of years, you'll receive an email from one of us, with whom you will eventually be on a first-name basis. We will ask you about your life. What are you studying in graduate school? How are your sisters? How do you like Saint Louis? We will ask if you are interested in participating again. Most likely, you will be interested. You could still use the extra cash.