

Working Toward Wellness Parent Consent Form for Children

A little over a year ago, you spoke with someone from United Behavioral Health about a project called Working Toward Wellness. The purpose of the study is to learn how to help people who might be feeling depressed. At the time you enrolled in the study, you may have become eligible for extra services, or you may have been told about services available to you in your community. We also mentioned that we may be contacting you for future interviews.

What we are studying

We are interested in asking you some questions about your experiences as a parent and about your child(ren). We will ask you about your child(ren)'s development, your relationship with your child(ren), their school activities, their general health, your child(ren)'s child care experiences (if applicable), and questions about your parenting practices. You will receive \$30 for your time, which is in addition to the \$20 for the survey which asks you questions about yourself. Therefore, if you complete both portions, you will receive a total of \$50.

In addition to asking you some questions, we have selected up to two children in each family to understand more about them and their experiences. For younger children, we will play some games with them to understand their skills and give them a test of their understanding of emotions and their language skills. For older children, we will ask them about their schooling, behavior, activities and interests. The time with each child will be about forty-five minutes, depending on how old they are.

Giving consent means that you will allow us to obtain state and United Behavioral Health records regarding your child(ren)'s use of Medicaid and medical services (i.e. doctor's visits, medications obtained through prescriptions, etc.). We ask you to give us your child(ren)'s social security numbers so we can obtain these records.

Benefits and risks of participation

There are no known risks to completing the interview, or the games and other assessments. If you agree to allow us to talk to your child(ren), we will briefly explain the study to the child so he or she can decide about participating. Your older child(ren) will receive a \$20 gift certificate to show our appreciation for their participation. Your younger child(ren) will receive a toy as a gift that is valued at \$10.

Participation is voluntary

The results of this study can help us understand better how to help people who might be depressed, along with their families and their children. However, it is important that you understand that participation in this study is completely voluntary for you and your child(ren). You and your child(ren) may refuse to answer any questions and still remain in the study. You and your child(ren) may also stop the interview at any time without penalty. Your decision will not affect any services or benefits you might receive now or in the future.

Protecting your information

All the information you and your child(ren) provide will be kept confidential. All study staff are trained to protect privacy and sign a privacy pledge. Your answers will be recorded with an

identification number and your names will be kept in a location separate from your answers. No reports will describe you in a way that would allow you to be identified either.

We will do everything we can to keep others from learning about your participation in the research. We are obtaining a Confidentiality Certificate from the U.S. government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. You should know, however, that we may tell someone if harm to you, harm to others, or child abuse becomes a concern. Also, the federal agency that pays for this study may see your information in an audit, but it too will protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

If you have questions at any time during the study, please call Francisca Azocar or Kathy Sweet at United Behavior Health toll-free at (800) 207-0084. You can also call David Butler or Pamela Morris at MDRC using the toll-free number (800) 221-3165.

Consent for Myself

By my signature, I agree to be interviewed about my experiences as a parent and about my child(ren). I understand that all my responses will remain confidential.

(RESPONDENT'S NAME)

(SIGNATURE OF RESPONDENT)

(INTERVIEWER'S SIGNATURE)

(DATE)

Consent for Children

By my signature, I agree to allow the following child(ren) to participate in the youth interview, games, and/or assessments as described above. I also agree to allow the disclosure of their medical records. I understand that the child(ren)'s answers will remain confidential. A copy of the study description given to my child(ren) will be provided to me.

(CHILD'S NAME)

(SSN)

(CHILD'S NAME)

(SSN)

(SIGNATURE OF PRIMARY CAREGIVER)

(INTERVIEWER'S SIGNATURE)

(DATE)

Working Toward Wellness Parent Consent Form for Physiological Data Collection

A little over a year ago, you spoke with someone from United Behavioral Health about a project called Working Toward Wellness. The purpose of the study is to learn how to help people who might be feeling depressed. At the time you enrolled in the study, you may have become eligible for extra services, or you may have been told about services available to you in your community. We also mentioned that we may be contacting you for future interviews.

Learning about responses to stress

In addition to asking you some questions, we are also interested in learning from you and your child(ren) how daily experiences affect how stressed you feel. One way for us to learn about this is to ask you questions, but another way is to measure a stress hormone your body produces called cortisol. Cortisol is released into your body when you experience stress, and it also is produced at other times of the day as well. Cortisol can be measured in your saliva or spit.

In order to learn more about this, we would like to collect your saliva and saliva from your child(ren) using a simple procedure of spitting through a vial that we will demonstrate with you. The purpose of collecting your saliva is *only* to measure the levels of cortisol in your body. We will not be measuring anything else in these saliva samples. The time spent on the saliva collection should only take about 5 minutes per person.

Unique and different ID numbers will be created for each of your samples and this data will be kept in a location separate from your identifying information. All samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research.

Learning about genes and the environment

In addition to measuring your level of cortisol, we are also interested in understanding more about the link between your genes, the inherited characteristics that distinguish one person from another, and depression. Some people think that there may be some relationship between genes and depression. While we know that what a person is born with does *not* determine whether or not he/she will get depressed, sometimes genetic characteristics can make some people more or less likely to experience depression than others. This kind of information can be really important to learning more about depression. For this reason, we'd like to collect a sample of your genetic material, or DNA, from you. The procedure is very simple: we would only need you to spit into a small container to collect this information from you.

We would *only* look at things in your DNA that are related to family risk for depression and nothing else. We would not be measuring anything drug-related in the samples. The time spent on the DNA collection should only take about 5 minutes per person. And, as with the cortisol samples collected, each DNA sample will be marked with a unique identification number that will be kept separate from your identifying information. These samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research.

Because we are also interested in how what children are born with may affect how they are doing, we are also interested in collecting this same genetic information from your child(ren). As with your sample, we would *only* look at things in your child's DNA that are related to family risk for depression and nothing else. Like your samples, these DNA samples will be labeled with a unique identification, stored separate from any identifying information. All samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research.

Collecting additional samples

Finally, we are interested in seeing what the levels of cortisol are over the course of two full days. Understanding how cortisol levels vary over the course of the day can tell us even more about how people experience stress. For this portion, we will leave you with a home kit for collecting saliva samples to conduct yourself and for your child(ren) (if applicable). You will be asked to mail the samples to us and once received, we will send you a \$20 gift card for the samples collected from you and your young child(ren) (if applicable). Your older child(ren) will also receive a \$20 gift card (if applicable).

Risks of participation

There are no known risks to collecting these samples. To avoid the risk of choking, we will only do the saliva collection with child(ren) over the age of two. We use an extra long cotton roll (approximately 3 inches in length) so that it will not get caught in the child's mouth. The child will also be seated during the saliva collection and we will supervise the first procedure carefully. You will always be present during the saliva collection of your young child(ren) (if applicable).

Participation is voluntary

The results of this study can help us understand better how to help people who might be depressed, along with their families and their child(ren). However, it is important that you understand that participation in this study is completely voluntary for you and your child(ren). You can choose to participate in the saliva collection, the DNA collection, or both. The same applies for the consent you provide for your child(ren). You and your child(ren) may also stop the data collection at any time without penalty. Your decision will not affect any services or benefits you might receive now or in the future.

Protecting your information

All the information you and your child(ren) provide will be kept confidential. All study staff are trained to protect privacy and sign a privacy pledge. Your answers will be recorded with an identification number and your names will be kept in a location separate from your answers. No reports will describe you in a way that would allow you to be identified either.

We will do everything we can to keep others from learning about your participation in the research. We are obtaining a Confidentiality Certificate from the U.S. government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. You should know, however, that we may tell someone if harm to you, harm to others, or child abuse becomes a concern. Also, the federal agency that pays for this study may see your information in an audit, but it too will protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

APPENDIX A.2: Parent Consent Form- Physiological Data Collection

OMB Control No. 0970-0276

Expiration Date: 04/30/08

If you have questions at any time during the study, please call Francisca Azocar or Kathy Sweet at United Behavior Health toll-free at (800) 207-0084. You can also call David Butler or Pamela Morris at MDRC using the toll-free number (800) 221-3165.

Consent for Myself

By my signature, I agree to have the following data collection occur:

Saliva collection to measure stress:

CHECK ONE: YES NO

Saliva collection of DNA to understand family risk for depression:

CHECK ONE: YES NO

(SIGNATURE)

(INTERVIEWER'S SIGNATURE)

(DATE)

Consent for Children

By my signature, I agree to allow the following child(ren) to participate in the following data collection procedures. A copy of the study description given to my child(ren) will be provided to me.

(CHILD'S NAME)

Saliva collection to measure stress:

CHECK ONE: YES NO

Saliva collection of DNA to understand
family risk for depression:

CHECK ONE: YES NO

(CHILD'S NAME)

Saliva collection to measure stress:

CHECK ONE: YES NO

Saliva collection of DNA to understand
family risk for depression:

CHECK ONE: YES NO

(SIGNATURE OF PRIMARY CAREGIVER)

(INTERVIEWER'S SIGNATURE)

(DATE)

Working Toward Wellness Youth Assent Form

Today we'd like to talk to you about what it's like to be a young person these days. We are studying the daily lives and experiences of families and young people. Your mother said it is OK for me to talk with you today, as long as it is OK with you.

What we are studying

We are interested in finding out how young people your age think and feel about different things, such as how you feel about yourself, your family, and friends, and your life at school and home. I am going to ask you some questions about these things. There are no right or wrong answers to my questions. I am interested in your ideas and opinions. If you do not feel like answering a question, that's okay, you can just skip it and go onto the next one. If you decide you don't want to do any more, please tell me and we can stop at any time. It is OK to tell me that you want to stop.

The whole interview will take about 45 minutes and we can take a break if you need to. When we are done with this interview, you will receive a \$20 gift card.

Additionally, by giving us permission to interview you, you will also be giving us permission to get information from the state or United Behavioral Health about your use of Medicaid or medical services, such as visits to see the doctor, or taking medications that the doctor prescribed to you.

Protecting your information

Your name will not be kept in the same file with your answers, so no one will know how you answered these questions. Instead, files with your answers will have a special identification number on them. We keep your name in a separate location so it cannot be linked to your answers.

We will do everything we can to keep others from learning about your participation in the research. We are getting a Confidentiality Certificate from the U.S. government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. You should know, however, that we may tell someone if harm to you, harm to others, or child abuse becomes a concern. Also, the federal agency that pays for this study may see your information in an audit, but it too will protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

If you have questions, ask us!

You can ask any questions that you have about this study. If you have a question later that you didn't think of now, you can ask us later. Signing here means that you have read this paper or someone read it to you and that you are willing to be in this study. If you don't want to be in this study, don't sign. Remember, being in this study is up to you, and no one will be mad at you if you don't sign this, or even if you change your mind later.

APPENDIX A.3: Youth Assent Form

OMB Control No. 0970-0276

Expiration Date: 04/30/08

If you have questions at any time during the study, please call Francisca Azocar or Kathy Sweet at United Behavior Health toll-free at (800) 207-0084. You can also call David Butler or Pamela Morris at MDRC using the toll-free number (800) 221-3165.

When I sign my name here I am saying that I agree to be interviewed for this study. I am also saying that I understand what I am supposed to do and that I may stop the interview at any time.

Print your name _____

Sign your name _____ Date _____

Signature of Interviewer _____ Date _____

Working Toward Wellness Youth Assent Form for Physiological Data Collection

Today we want to talk to you about what it's like to be a young person these days. Your mother said it is OK for me to talk with you today, as long as it is OK with you.

Learning about stress

In addition to asking you some questions, we are also interested in learning from you how your daily life affects how stressed out you may feel. One way for us to learn about this is to ask you questions, but another way is to measure something your body produces called cortisol. Cortisol is released into your body when you experience stress, and it also is produced at other times of the day as well. Cortisol can be measured in your saliva or spit.

In order to learn more about this, we would like to collect your saliva simply by having you spit through a straw into a tube. We will show you how to do this. It will only take a few minutes for us to do this. The purpose of collecting your spit is *only* to measure the levels of cortisol in your body. We will not be measuring anything else in your spit.

A separate number will be created for your spit sample and this information will be kept separate from your name, address, and other information that might identify you. Your name will not be on any of the samples, so even the lab getting the information from your sample for us will not have your name. We will destroy your sample as soon as the cortisol information from it is collected and checked for errors. The sample will only be used for this study and related research.

Learning about genes and the environment

In addition, we are interested in understanding more about your genes, and their link between your genes and how you are doing and feeling. Genes are the characteristics that you inherit that make you who you are. Your hair color and eye color, for example, are determined by your genes. It turns out that some people's genes make them more sensitive to their environments than others, and we want to learn more about this. For this reason, we'd like to collect a sample of your genetic material, or DNA, from you. The procedure is very simple: we would only need you to spit into a small container to collect this information from you. It only takes a few minutes.

We would *only* look at things in your DNA that are related to how sensitive you might be to your environment and nothing else. We would not be measuring anything drug-related in the samples. And, as with the cortisol samples collected, each DNA sample will be marked with an identification number that will be kept separate from your name, address, and other information that might identify you. These samples will be destroyed as soon as the data is collected and checked for errors. The sample will only be used for this study and related research.

Collecting additional samples

Finally, we are interested in seeing what your levels of cortisol are over the course of two full days. To do this, we will leave you with a home kit for collecting saliva samples to conduct yourself. Your parent will be asked to mail the samples to us and once received, we will send a \$20 gift card to you. These samples will also be treated like the others we

APPENDIX A.4: Youth Assent Form- Physiological Data Collection

OMB Control No. 0970-0276

Expiration Date: 04/30/08

collect on the day we are with you—they will be marked with an identification number and destroyed once they are checked for errors. The samples will only be used for this study and related research.

Protecting your information

It is important that you understand that participation in all of these activities are completely voluntary. You can choose to participate in the saliva collection, the DNA collection, or both. There are no known risks to collecting these samples.

We will do everything we can to keep others from learning about your participation in the research. We are getting a Confidentiality Certificate from the U.S. government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. You should know, however, that we may tell someone if harm to you, harm to others, or child abuse becomes a concern. Also, the federal agency that pays for this study may see your information in an audit, but it too will protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

If you have questions, ask us!

You can ask any questions that you have about this portion of the study. If you have a question later that you didn't think of now, you can ask us later. Signing here means that you have read this paper or someone read it to you and that you are willing to do this part of the study. If you don't want to be in this part of the study, check the 'no' boxes. Remember, being in this study is up to you, and no one will be mad at you if you don't participate, or even if you change your mind later.



When I sign my name here, I am saying that I agree to have the following samples taken. I am also saying that I understand what I am supposed to do and that I may stop participating at any time.

Saliva collection to measure stress:

CHECK ONE: YES NO

Saliva collection of DNA to understand how sensitive you are to the environment:

CHECK ONE: YES NO

Print your name _____

Sign your name _____ Date _____

Signature of Interviewer _____ Date _____

PROTOCOL FOR BIOMEDICAL SAMPLES

INTERVIEWER: TO ADMINISTER THIS PROTOCOL, YOU NEED A COMPLETED **“BIOSAMPLE INFORMATION FORM”** WITH INFORMATION ABOUT THE PEOPLE IN THE HOUSEHOLD WHO ARE ELIGIBLE FOR BIOSAMPLES – THEIR ID#, FIRST NAME, AND THE APPROPRIATE KIT FOR THEIR AGE. THE **“BIOSAMPLE INFORMATION FORM”** SHOULD BE FILLED OUT USING THE “INFORMATION FOR BIOSAMPLE” SCREEN THAT APPEARS AT THE END OF THE PARENT INTERVIEW.

STEP 1: INTRODUCE BIOSAMPLING AND OBTAIN CONSENT

TO COLLECT BIOSAMPLES, WE MUST HAVE SIGNED CONSENT FROM THE PARENT FOR HERSELF AND FOCAL CHILD(REN).

WE ALSO MUST HAVE SIGNED ASSENT FROM ANY FOCAL CHILDREN WHO ARE GOING TO USE THE PARENT/ADOLESCENT KIT (OR OLDER YOUTH). SEE BOXES ON PAGE 1 TO DETERMINE WHETHER THERE ARE ANY OLDER YOUTH.

READ PARENT SCRIPT TO PARENT AND OLDER YOUTH (IF ANY).

PARENT BIOSAMPLE SCRIPT

We have a third part of this study. We are interested in learning from you and your child(ren) how daily experiences affect how stressed you feel. One way to do this is to ask questions, but another way is to measure stress levels internally. We can do that by getting a sample of your saliva or spit.

When we are stressed, our bodies produce a hormone called cortisol. If we get a saliva sample, we can measure the level of cortisol.

Another thing we are interested in learning about is the link between genes and depression. Some scientists believe that genes may make a person more or less likely to suffer from depression. Genes are the inherited characteristics that make one person different from another. We would need a second saliva sample. With this sample, we will check for the gene that scientists think may be linked to depression and how you experience your world.

To do this part of the study, we would collect two saliva samples from you and [FOCAL CHILD(REN)] today. It's easy to do and I'll show you how.

I'll take these samples today, but we also need you and [FOCAL CHILD(REN)] to send in samples that you collect in the next two days. I'll explain how to do that. The samples from the next two days help to identify stress levels when you don't have an interviewer in the house, and things are more normal.

Providing these samples will allow scientists to better help people who might be depressed, along with their families.

If you take part, we will send you another \$20 when my office receives your samples. We will also mail out a \$20 gift card to your (child/children) if (he or she/they) also agree to provide samples.

As I said before the interview, your participation in any part is voluntary. Any lab results from these samples will not be linked with your name. As soon as the tests are done, the samples will be destroyed.

Will you and [FOCAL CHILD(REN)] provide samples?

IF YES: HAND **"PARENT CONSENT FORM FOR PHYSIOLOGICAL DATA COLLECTION"** TO PARENT.

Here's a form with more information about these samples. I need your signature on the form before I can take samples from you or [FOCAL CHILD(REN)].

ASSIST PARENT AS NEEDED TO ENSURE THE CONSENT FORM IS FULLY COMPLETED. SIGN WHERE NOTED.

IF PARENT IS HESITANT:

Do you want to see how it is done? It only takes a few minutes.

DEMONSTRATE CORTISOL (SEE STEP 3 BELOW), THEN TRY TO GAIN CONSENT.

IF NO: DO NOT COLLECT BIOSAMPLE FROM PARENT OR FOCAL CHILDREN. STOP BIOSAMPLE PROTOCOL.

IF EITHER FOCAL CHILD IS GOING TO USE THE PARENT/ADOLESCENT KIT, READ OLDER YOUTH SCRIPT. OTHERWISE, SKIP TO STEP 2.

OLDER YOUTH BIOSAMPLE SCRIPT

Are you willing to provide a sample of your saliva or spit? I've talked with your mom and she is going to do it.

These samples will help us measure how stressed out you may feel every day. Your saliva lets us measure something called cortisol. It is a hormone that your body releases when you are stressed.

We are also asking for a second sample to measure if your genes make you more sensitive to stress. Your genes are inside you and make you who you are. Your hair color and eye color are determined by your genes.

We need two samples today and more on the next two days. Your mom will help you remember to do the samples tomorrow.

When you mom sends your samples to my office, we will send you another \$20 gift card for Wal-Mart.

I'll show you and your mom how to make the samples. It's pretty easy.

Will you provide samples?

IF YES: HAND **"YOUTH ASSENT FORM FOR PHYSIOLOGICAL DATA COLLECTION"** TO OLDER YOUTH.

I need to get your signed permission before I can take samples from you.

ASSIST OLDER YOUTH AS NEEDED TO ENSURE THE ASSENT FORM IS FULLY COMPLETED. SIGN WHERE NOTED.

IF NO: DO NOT COLLECT BIOSAMPLES FROM THIS CHILD.

STEP 2: PREPARE BIOSAMPLE MATERIALS

PREPARE THE APPROPRIATE TYPE OF KIT FOR PARENT AND FOCAL CHILD(REN) – AS NOTED ON THE **"BIOMEDICAL INFORMATION FORM"**.

GET LABEL SHEET FROM ASSIGNMENT PACKET FOR THAT CASE. CONFIRM THAT IDs ON LABELS MATCH THE IDs LISTED ON THE **"BIOMEDICAL INFORMATION FORM"**. IF NOT, RECORD CORRECT IDs ON LABELS.

FOR EACH KIT:

- (1) RECORD FIRST NAME AND (P), (FC1), OR (FC2) ON KIT LABEL.
- (2) ATTACH LABELS TO INTERVIEW DAY (SALIVA), DAY 1 AND DAY 2 VIALS AND WRAP THE INTERVIEW DAY (DNA) LABEL AROUND THE BOTTOM OF BLUE PART OF THE ORAGENE SAMPLE CONTAINER. RETURN MATERIALS TO THE CORRECT BAG.
- (3) RECORD FIRST NAME AND ID# ON DAILY DIARY FOR INTERVIEW DAY, DAY 1, AND DAY 2. FOR PARENT/ADOLESCENT KITS, DRAW A LARGE X ON THE WRONG SIDE OF THE DIARY.
- (4) USING A SHARPIE MARKER, WRITE FIRST NAME AND (P), (FC1), OR (FC2) ON STORAGE BOTTLE AND THE ID# ON THE BAG IT COMES IN.
- (5) RETURN ALL BAGS TO THE CORRECT KIT.

STEP 3: DEMONSTRATE CORTISOL SAMPLE PROCEDURE

GET A DEMONSTRATION PACKET. READ SCRIPT AND DEMONSTRATE.

Demonstration Script

Before I get sample from you, I'm going to show you how to do the saliva sample for the cortisol, or stress hormone, test.

IF YOUNG CHILD TO BE TESTED, SAY: This is how adults and older children do the sample. It's a little different for young children. I'll show you that in a minute.

PLACE BOTTOM TIP OF STRAW IN OPEN VIAL. You hold the vial and the straw like this, then spit through the end of the straw. You want to get the vial about 1/3 full. You might have to spit more than once to get enough saliva in the vial.

SPIT INTO VIAL. PLACE CAP TIGHTLY ON VIAL. That's all there is to doing the stress hormone samples!

STEP 4: GET "INTERVIEW DAY" CORTISOL SAMPLES

PARENT/ADOLESCENT SAMPLES

REMOVE INTERVIEW DAY PACKET FROM PARENT KIT AND OLDER YOUTH KIT (IF ANY).

Now it's your turn. Before you do the sample, let's look at the label on this vial. (INDICATE LABEL ON VIAL.) It says "Saliva" and "Interview Day." That tells the people back at the office that this is today's sample for stress hormones. On the ends of the label that stick out, there's a line for you to record the "Date" and "Time" you did the sample. (INDICATE LINES FOR DATE AND TIME ON LABEL.) There's a pen in the bag for you to use to write this information.

OK, take out the vial and straw and go ahead with the sample.

AFTER SAMPLE IS COLLECTED: Be sure to put the cap tightly on the vial. We have to do a couple other things before we're finished with these samples. First, let's record the date and time on the vial label. RECORD DATE AND TIME ON LABEL. Then, I need you to fill out the Daily Diary. This lets us know about some things going on today that might affect the test. When you're done, please put the vial and the diary back in the bag.

YOUNG CHILD SAMPLES

IF YOUNG CHILD TO BE TESTED, CONTINUE. OTHERWISE GO TO STEP 5.

REMOVE INTERVIEW DAY PACKET FROM YOUNG CHILD KIT. DEMONSTRATE AS YOU READ THE FOLLOWING – WITHOUT ACTUALLY OPENING THE KOOL-AID OR CUTTING THE COTTON ROLL.

Now, let's get a sample from [YOUNG FOCAL CHILD(REN)]. Since younger kids can't spit into the straw, we do their sample a little differently. Mom, I'll tell you the steps, but then I'd like you to get your child's sample. First, take out the Kool-Aid packet and the cotton roll. Tear off the top of the Kool-Aid. Touch the end of the cotton roll on your child's tongue, so it gets just a little bit damp. Next, stick the end of the cotton roll in the Kool-Aid packet, so you get just a little bit of Kool-Aid on it. Put the Kool-Aid end of the cotton roll in your child's mouth – about 2 inches in. The Kool-Aid makes (him/her) produce more saliva in (his/her) mouth. After about 30 seconds or so, the end of the cotton should be soaked in saliva, you'll cut the end off with the scissors in the kit and put it in the syringe. Then you'll squeeze the saliva from the syringe into the vial. OK?

REPEAT STEPS AS NEEDED AS PARENT COLLECTS SAMPLE FROM CHILD.
AFTER SAMPLE IS COLLECTED: Be sure the cap is tight and write the date and time

on the label. Then, I need you to fill out a Daily Diary for [YOUNG FOCAL CHILD(REN)]. When you're done, please put the vial and the diary back in the bag.

STEP 5: REVIEW PROCEDURES FOR DAY 1 AND DAY 2 SAMPLES

PARENT/OLDER YOUTH SAMPLES

READ SCRIPT BELOW FOR PARENT AND OLDER YOUTH (IF ANY).

Earlier I mentioned that you'll be collecting samples on your own over the next two days and then sending them to us. [PARENT] and [OLDER YOUTH], each day you'll be collecting three samples – the first one right after you wake up in the morning, the second one 30 minutes after that, and the third one right before you go to bed at night.

REMOVE ALL MATERIALS FROM THE PARENT KIT. OPEN DAY 1 BAG AND REMOVE VIALS.

Here's a bag of supplies for 3 samples on Day 1 – which is tomorrow. Use the vial labeled "Day 1/Sample 1" for your first sample tomorrow – the one you do first thing after you wake up. Use the vial labeled "Day 1/Sample 2" for the sample you take 30 minutes after that. Use the "Day 1/Sample 3" vial for the sample you do right before you go to bed. You'll do the same thing on Day 2. It's best if you do this two days in a row.

RETURN VIALS TO DAY 1 BAG. REMOVE STORAGE BOTTLE FROM KIT. **DO NOT OPEN BOTTLE.**

It's really important that these samples stay cold. After you do the first sample tomorrow and record the date and time on the label, put the vial in this bottle and keep it in the refrigerator. As you do each sample on Day 1 and Day 2, add it to the bottle. At the end, you'll have 6 samples in the bottle.

The cap on the bottle is called a "track cap." The cap records each time it is opened, so it should only be opened when you are putting a completed sample in it. Since you'll have 6 samples, you should only open the bottle 6 times.

Be careful to put the samples in the correct bottle. I wrote each person's name on their bottle to make it easier.

RETURN STORAGE BOTTLE TO ITS BAG. RETURN DAY 1 BAG AND STORAGE BOTTLE TO PARENT KIT.

The time you do the samples each day is **extremely** important, so I want to go over them again.

APPENDIX B: Physiological Sample Protocol

OMB Control No. 0970-0276

Expiration Date: 04/30/08

- Sample 1: Do the first sample immediately after you wake up in the morning, before you even get out of bed. It's probably easiest if you put the materials beside your bed the night before. There's a timer in your kit. Right after you do the 1st sample, set the timer for 30 minutes. Don't brush your teeth or drink or eat anything until after you do the 2nd sample.
- Sample 2: When the timer rings, do the 2nd sample. Again, be sure not to eat, drink, or brush your teeth before you do the 2nd sample.
- Sample 3: That night – just before you brush your teeth and go to bed – do the 3rd sample. At that time, please also fill out the Daily Diary for that day.

REMOVE THE PADDED MAILER AND INCENTIVE CARD FROM THE KIT.

Once you have completed all the samples for both days, take storage bottle from the refrigerator and put it in this brown padded envelope. Also, put the Daily Diary you completed each day in that envelope. As I mentioned, we'll send each of you a \$20 gift for doing these samples. Please fill out this card to tell us where to send the gift and put that in the brown envelope too. Seal the envelope and mail it as soon as possible. It's already addressed and the postage has been paid.

Each person in your family who is providing samples should mail their bottle, diaries, and gift information card in a separate brown envelope.

Do you have any questions?

YOUNG CHILD SAMPLES

IF YOUNG CHILD TO BE TESTED, CONTINUE. OTHERWISE GO TO STEP 6.

REMOVE DAY 1 BAG.

You'll also be collecting samples from [YOUNG CHILD] for the next two days using the same process you did today. (His/her) kit also includes supplies for Day 1 and Day 2, but you see that there are only two vials in the bag for each day. That's because the sample times are different for younger children.

- Sample 1: The first sample should be done right after they wake up – right after you do your own sample.
- Sample 2: The second sample should be done in the afternoon. You can do this 2nd sample anytime between 3:00 PM and 6:00PM – as long as [YOUNG CHILD] hasn't had anything to eat or drink within ½ hour before the sample.

Please fill out a daily diary for your child at the end of each day.

RETURN DAY 1 BAG TO KIT. REMOVE STORAGE BOTTLE FROM KIT. **DO NOT OPEN BOTTLE.**

There's also a storage bottle with a "track cap" for [YOUNG CHILD]. The same rules apply – that is, keep the bottle in the refrigerator and only open it when you're going to put a sample in. When all the samples are collected, put the storage bottle, the diaries, and the gift information card in a brown envelope and mail it as soon as possible.

Do you have any questions?

STEP 6: REVIEW GUIDELINES FOR DAY 1 AND DAY 2 SAMPLES

GET INSTRUCTION/FAQ CARD FROM KIT

I know this is a lot of information. This card has instructions for doing the samples. It also has answers to some questions that you might have over the next two days.

There are some things that can affect the results of the tests. It's important that you know about these so you can avoid doing them right before you do a saliva sample.

- (1) You should **not** eat or drink anything or brush your teeth for at least ½ hour before you do a sample.
- (2) You **should** do samples on days that are typical days in your life – rather than on days when you are sick or have been to the dentist.
- (3) Open the "track cap" **only** when you are putting a sample in the bottle.

This card also has a toll-free number you can call if you have questions about doing these samples. SHOW CONTACT INFORMATION ON CARD.

STEP 7: GET ORAGENE SAMPLES

PARENT/OLDER YOUTH SAMPLE

REMOVE ORAGENE SAMPLE KIT, USER INSTRUCTION SHEET, AND SUGAR PACKET FROM INTERVIEW DAY PACKET FOR PARENT AND OLDER YOUTH (IF ANY). REFER TO INSTRUCTIONS AND PARTS OF KIT WHERE APPROPRIATE.

Now, the last step is the 2nd saliva test – the test that checks for the gene that scientists think may be linked to depression and how you experience your world.

This test also uses saliva, but it's done a little differently. First, rinse your mouth out with water wait about 30 seconds. Then, spit into the blue cup until the saliva is up to the top of the ridges on the sides. You'll probably have to spit more than once to get enough saliva in there. Some people think it's easier to make enough saliva if they put a little bit of sugar on their tongue. Go ahead and do that if you want to.

Once you have enough saliva in there, take the white lid and screw it on tightly. There's fluid inside the lid that will mix with the saliva after you put the lid on, so don't put the lid on until after enough saliva is in the blue cup. When the lid is on, shake the container a little bit and give it to me.

REPEAT INSTRUCTIONS AS NEEDED. ALLOW TIME FOR PARENT/OLDER YOUTH TO FILL CUP. BE SURE THEY CLOSE LID AND SHAKE AS INSTRUCTED.

YOUNG CHILD SAMPLES

IF YOUNG CHILD TO BE TESTED, CONTINUE. OTHERWISE GO TO STEP 8.

REMOVE ORAGENE SAMPLE KIT, SALIVA SPONGE, SCISSORS, AND SUGAR PACKET FROM INTERVIEW DAY PACKET. REFER TO ITEMS AS YOU DESCRIBE THE PROCESS.

Since young children like [YOUNG CHILD] usually can't spit into the blue cup, we do their sample a little differently. First, let's rinse (his/her) mouth out and wait 30 seconds. If (he/she) can't rinse, have (him/her) take a drink of water then we'll have to wait about 10 minutes to do the sample. We'll use this sponge to collect saliva from between (his/her) teeth and (his/her) cheek. Most kids think this is fun because the sponge tickles their mouth a little bit.

ALLOW THE CORRECT AMOUNT OF TIME TO PASS.

[PARENT], I'd like you to help me with this sample. Put this sponge between (his/her) teeth and cheek and move it around a little to soak up as much saliva as possible. You

can also move it to the other side to collect even more saliva. The longer the sponge is in (his/her) mouth, the more saliva the sponge will absorb.

ALLOW TIME FOR PARENT TO COLLECT SAMPLE. IF CHILD'S MOUTH SEEMS TO BE DRY, ASK PARENT TO PUT A LITTLE SUGAR ON CHILD'S TONGUE.

Next, hold the sponge end of the stick over the blue cup and cut the tip off using the scissors so that the sponge falls into the cup. For younger children, we don't have to worry about filling the cup up to the line. The last step is to screw the lid on tightly and shake the container a little bit.

ENSURE THAT PARENT CLOSSES LID AND SHAKES CONTAINER AS INSTRUCTED.

STEP 8: CONCLUDE BIOSAMPLE PROCESS

OK, I have all the samples I need for today. Thank you so much for your cooperation! Please remember to begin the Day 1 samples for yourself and your (child/children) first thing tomorrow morning and to continue doing samples according to the schedule that day and the next day. If you have any questions, the instruction card may have the answer you need.

When you've done samples for both days, remember to mail them as soon as possible in the envelope provided. Once my office gets your samples, we will send you another \$20 and we'll mail out a \$20 gift card to your (child/children) when we receive (his or her/their) samples.

I'd like to give you a call tomorrow to see if you have any questions. What's the best number to reach you? RECORD PHONE NUMBER IN THE PARENT BOX ON THE **"BIOMEDICAL INFORMATION FORM"**.

BEFORE YOU LEAVE THE HOME, CONFIRM THAT YOU HAVE A CORTISOL SAMPLE VIAL, A DAILY DIARY, AND AN ORAGENE KIT FOR EACH PERSON IN THE HOUSEHOLD WHO WAS SELECTED FOR AND CONSENTED TO THE BIOSAMPLES.

STEP 9: MAIL INTERVIEW DAY SAMPLES

AFTER YOU'VE LEFT THE HOME, COMPLETE THE "**BIOSAMPLE SUMMARY FORM**" AND THE "**SHIPPING LOG FOR BIO.**"

MAIL THE FOLLOWING IN A POSTAGE-PAID ENVELOPE AS SOON AS POSSIBLE AFTER YOU LEAVE THE HOME:

- "INTERVIEW DAY" CORTISOL SAMPLE VIAL FOR EACH PERSON INVOLVED IN BIOSAMPLES
- "INTERVIEW DAY" DAILY DIARY FOR EACH PERSON INVOLVED IN BIOSAMPLES
- ORAGENE KIT FOR EACH PERSON INVOLVED IN BIOSAMPLES
- COMPLETED "**SHIPPING LOG FOR BIO**"

STEP 10: PLACE REMINDER CALLS

ON **THE DAY AFTER THE INTERVIEW**, CALL THE PARENT SOMETIME DURING THE DAY/EVENING TO REMIND HER TO COMPLETE THE SAMPLES FOR HERSELF AND YOUNG CHILDREN (IF ANY) AND TO BE SURE THAT OLDER YOUTH DO THEIR SAMPLES TOO. ANSWER ANY QUESTIONS.

ON **DAY 3 POST-INTERVIEW**, CALL THE PARENT TO REMIND HER TO MAIL COMPLETED SAMPLES FOR HERSELF AND ANY FOCAL CHILDREN AS SOON AS POSSIBLE. REMIND HER TO INCLUDE DAILY DIARIES AND THE GIFT INFORMATION CARD FOR EACH PERSON.

Instructions for Day 1 and Day 2 Saliva Samples

Parent / Adolescent Samples

On Day 1 and Day 2, do three (3) samples at the following times:

- Sample 1: Do this sample right after you wake up – before you eat, drink, or brush your teeth. (When you're done, set the timer for 30 minutes.)
- Sample 2: Do this sample 30 minutes after Sample #1 – before you eat, drink, or brush your teeth.
- Sample 3: Do this sample at the end of your day – right before you brush your teeth and go to bed – and at least 30 minutes after you last ate or drank.

For each sample, do the following:

- (1) Choose the correct vial for the Day (1 or 2) and Sample (1, 2 or 3).
 - (2) Place one end of the straw into the open vial and then spit through the other end of the straw until the vial is about 1/3 full. You might have to spit more than once. Put the cap tightly on the vial.
 - (3) Record the date and time you did the sample on the vial label.
 - (4) Put the vial in the storage bottle in the refrigerator.
 - (5) On each day, after you do Sample #3, fill out the Daily Diary for that day.
-

Young Child Samples

On Day 1 and Day 2, do two (2) samples at the following times:

- Sample 1: Do this sample right after your child wakes up – before he/she eats, drinks, or brushes his/her teeth.
- Sample 2: Do this sample anytime in the afternoon between 3:00 PM and 6:00 PM – at least 30 minutes after he/she last ate or drank.

For each sample, do the following:

- (1) Choose the correct vial for the Day (1 or 2) and Sample (1 or 2).
 - (2) Dip a cotton roll in the open Kool-Aid packet to pick up a little bit of Kool-Aid powder. Place the Kool-Aid end of the cotton roll in your child's mouth to soak up his/her saliva.
 - (3) Cut off the wet end of the cotton roll, put it in the syringe, and squeeze the saliva into the open vial. Put the cap tightly on the vial.
 - (4) Record the date and time you did the sample on the vial label.
 - (5) Put the vial in the storage bottle in the refrigerator.
 - (6) On each day, after you get Sample #2 from your child, fill out the Daily Diary for him/her for that day.
-

Remember...

- You should **not** eat or drink anything or brush your teeth for at least ½ hour before you do a sample.
- You **should** do samples on days that are typical days in your (or your child's) life – rather than days when you are sick or have been to the dentist.
- Only open the cap on the refrigerator storage bottle, when you are putting a sample in it.
- Once you have completed all the sample for both days, each person in the family who is providing samples should put his/her storage bottle, Daily Diary from both days, and gift instruction card in a separate brown postage-paid envelope addressed to HumRRO. Mail the envelope(s) as soon as possible. HumRRO will send a \$20 gift to each person who provided samples. We don't actually send \$20 for the young kid, only another present.

If you have any questions about doing these samples, please call Gwen Van Trieste at HumRRO toll-free at 1-888-880-2966, extension 3708.

Frequently Asked Questions

Q: I've had a change in medication, health, or had a major stressful life event in the past week, what should I do?

Please make a note of this on the Daily Diary that you received with your materials.

Q: I am supposed to start my saliva sampling today but I am feeling sick, what should I do?

If you have a serious cold, the flu, or another illness, please wait and do your sampling once you are feeling better. The stress hormone we are measuring is affected by the changes in your body and to your immune system when you are sick, which makes the data not able to be interpreted. Therefore, it doesn't make sense to collect information when you are sick.

Q: I missed taking one of my samples, what should I do!?

In general, if you miss taking any one sample, please take it at the same time on another day. Record **the exact time and date** you actually took each sample, **not** the time and date you were supposed to take it.

Q: If I missed my first sample, should I finish the rest today or start over tomorrow and do all the samples on the same day?

We prefer that you do the samples on the same day, so if you miss the first morning sample it is better to wait until the next day and do the samples together that day.

Q: I missed a couple of samples, should I still send you my data?

You should send us all your samples even if some of the requested samples are missing, and even if they were done across multiple days. We can use the information as long as we know the exact time and date it was taken.

Q: Do I really have to do my sampling the moment that I wake up? Can't I wait just 15 or 30 minutes so I'm more awake when I do it?

You really must do it right away. Your stress levels change a lot in the first half hour or so after wakeup, so we would really like to know what your stress levels are at the moment you open your eyes.

Q: Can I have my morning cup of coffee before sampling, or a little bit of breakfast? How about my morning shower? Should I brush my teeth?

Both of the morning samples should be done before eating and before brushing your teeth and before drinking coffee. If you absolutely have to have a cup of coffee right after you get up, please have it right **after** your first sample and rinse your mouth out with water afterwards.

Q: Does it matter if I forget to write the time on the label of the vial?

This is really important information for us. Please try to remember to record the time. But if you can't remember the time, still send the sample to us.

Q: Why do you need to collect separate saliva samples for cortisol and DNA?

The saliva quantities are not large enough for DNA in the cortisol saliva sampling protocol, and the preservative in the DNA protocol will prevent us from using that to analyze for cortisol.

Q: What will you be looking at in my saliva?

The samples you did during the interview, Day 1, and Day 2 will be tested for stress hormones – in particular the stress hormone, cortisol. No other substances will be testing without your explicit permission.

Q: Can you tell me the results of my saliva samples?

This study and the data we are collecting from you are exploratory and it won't help to give out information on each person individually. Cortisol is affected by many factors in a day and the sample will not be exact enough for any one person for the levels to be medically meaningful. If we group enough people together, the "noise" will be cancelled out and we'll get meaningful information. Additionally, there are no clear cut medical standards for what is "too high" or "too low" or "normal" levels of cortisol, so we are not able to provide participants with meaningful guidance on how to read their personal levels. Similarly for the DNA samples, we are still learning a lot about what these variations in genetic patterns mean. Your information will help us learn about that. But having or not having this genetic profile won't tell you about a diagnosis—only a clinical can tell you that. If you are worried, seek clinical advice.

**Daily Diary for Home Saliva Collection
Parents**

Please complete this diary on each day you provide a saliva sample, when taking the last (third) sample of the day.

Please do not eat, drink, or brush your teeth in the ½ hour before doing each sample. Thanks!

1. Today's Date: Month _____ Day _____ Year _____

2. Time you went to sleep last night: _____ : _____ 1 am 2 pm

3. Time you woke up this morning: _____ : _____ 1 am 2 pm

4. Approximately how long did it take you to fall asleep after going to bed last night (check one) ?
1 1-15 min 2 16-30 min 3 > 30 min

5. How well did you sleep last night?
1 Not well at all 2 Ok 3 Very well

6. Did you use any medications today? 1 Yes 2 No
(Include prescription drugs, over-the-counter medication, or inhaler for asthma)

If yes, what is the name of the medication(s) (or kind of inhaler)?

7. Did you have any of the following today? (**check all that apply**):

___ Cigarettes (if yes, how many? _____)

___ Alcohol (if yes, how many drinks? _____)

___ Caffeinated drinks (coffee, tea, soda) (if yes, how many cups, bottles, or cans in ALL ? _____)

8. Do you currently use birth control pills or a birth control implant, injection, or the patch?

1 Yes 2 No

If yes, please indicate type: _____

9. Did you get into an argument with someone today that lasted more than a few moments?

1 Yes 2 No

10. Did anything happen today that upset or worried you? 1 Yes 2 No

If yes, please describe: _____

11. How were you feeling today? (**Circle** the word that describes your feelings today)

Happy	Not at all	A little	Somewhat	Very
Sad	Not at all	A little	Somewhat	Very
Angry/Irritable	Not at all	A little	Somewhat	Very
Anxious/Worried	Not at all	A little	Somewhat	Very

**Daily Diary for Home Saliva Collection
Older Children (ages 9-15)**

Please complete this diary on each day you provide a saliva sample, when taking the last (third) sample of the day.

Please do not eat, drink, or brush your teeth in the ½ hour before doing each sample. Thanks!

1. Today's Date: Month_____ Day_____ Year_____

2. Time you went to sleep last night: _____:_____ 1 am 2 pm

3. Time you woke up this morning: _____:_____ 1 am 2 pm

4. Approximately how long did it take you to fall asleep after going to bed last night (check one) ?

1 1-15 min 2 16-30 min 3 > 30 min

5. Did you wake up in the night? 1 Yes 2 No

6. Did you use any medications today? 1 Yes 2 No

(Include prescription drugs, over-the-counter medication, or inhaler for asthma)

If yes, what is the name of the medication(s) (or kind of inhaler)?

7. Please indicate what you did today (**check all that apply**):

- ___ Went to school
- ___ Went to summer day camp
- ___ Visited with friends outside of school
- ___ Did a sports activity (baseball, basketball, soccer)
- ___ Quiet activity at home (tv, playing, doing homework)
- ___ Special event (school field trip, school event, special family trip)
- ___ Other activity (what was it? _____)

8. Did you get into an argument with someone (a parent, sister or brother, friend, other adult) today that lasted more than a few moments?

1 Yes 2 No

9. Did anything happen today that upset or worried you? 1 Yes 2 No

If yes, please describe: _____

10. How were you feeling today? (**Circle** the word that describes your feelings today)

Happy	Not at all	A little	Somewhat	Very
Sad	Not at all	A little	Somewhat	Very
Angry/Irritable	Not at all	A little	Somewhat	Very
Anxious/Worried	Not at all	A little	Somewhat	Very

**Daily Diary for Home Saliva Collection
Young Children (ages 2-7)**

Please complete this diary on each day your child provides a saliva sample, when taking the last sample of the day.

Please do not let child eat, drink, or brush their teeth in the ½ hour before doing each sample. Thanks!

1. Today's Date: Month_____ Day_____ Year_____

2. Time child went to sleep last night: _____:_____ 1 am 2 pm

3. Time child woke up this morning: _____:_____ 1 am 2 pm

4. Approximately how long did it take your child to fall asleep after going to bed last night (check one) ?
1 1-15 min 2 16-30 min 3 > 30 min

5. Did child wake up in the night? 1 Yes 2 No

6. Did your child use any medications today? 1 Yes 2 No
(Include prescription drugs, over-the-counter medication, or inhaler for asthma)

If yes, what is the name of the medication(s) (or kind of inhaler)?

7. Please indicate what your child did today (**check all that apply**):

- ___ Went to school
- ___ Went to day care center, preschool, nursery school, or family day care center
- ___ Went to summer day camp
- ___ Visited with friends outside of a center or school
- ___ Did a sports activity (baseball, basketball, soccer)
- ___ Quiet activity at home (tv, doing homework)
- ___ Played at home
- ___ Special event (school field trip, school event, special family trip)
- ___ Other activity (what was it? _____)

8. Did your child get into an argument with a parent or another child today that lasted more than a few minutes?
 1 Yes 2 No

9. Did anything happen today that upset or worried your child? 1 Yes 2 No

If yes, please describe: _____

10. How was your child feeling today? (**Circle** the word that describes your child's feelings today)

Happy	Not at all	A little	Somewhat	Very
Sad	Not at all	A little	Somewhat	Very
Angry/Irritable	Not at all	A little	Somewhat	Very
Anxious/Worried	Not at all	A little	Somewhat	Very

[Federal Register: September 20, 2006 (Volume 71, Number 182)]
[Notices]
[Page 54992-54993]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr20se06-59]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: DHHS/ACF/ASPE/DOL Enhanced Services for the Hard-to-Employ Demonstration and Evaluation: Rhode Island 15-Month Survey Amendment.

OMB No.: **0970-0276**.

Description: The Enhanced Services for the Hard-to-Employ Demonstration and Evaluation Project (HtE) seeks to learn what works in this area to date and is explicitly designed to build on past research by rigorously testing a wide variety of approaches to promote employment and improve family functioning and child well-being. The HtE project is designed to help Temporary Assistance for Needy Families (TANF) recipients, former TANF recipients, or low-income parents who are hard-to-employ. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Labor (DOL).

The evaluation involves an experimental, random assignment design in four sites, testing a diverse set of strategies to promote employment for low-income parents who face serious obstacles to employment. The four include: (1) Intensive care management to facilitate the use of evidence-based treatment for major depression among parents receiving Medicaid in Rhode Island; (2) job readiness training, worksite placements, job coaching, job development and other training opportunities for recent parolees in New York City; (3) pre-employment services and transitional employment for long-term TANF participants in Philadelphia; and (4) home- and center-based care, enhanced with self-sufficiency services, for low-income families who have young children or are expecting in Kansas and Missouri.

Materials for follow-up surveys for each of these sites were previously submitted to OMB and were approved. The purpose of this submission is to add physiological measures to the follow-up effort to the Rhode Island study.

Respondents: The respondents to this component of the Rhode Island follow-

[[Page 54993]]

up survey will be low-income parents and their children from the Rhode Island site currently participating in the HtE Project. As described in the prior OMB submission, these parents are Medicaid recipients between the ages of 18 and 45 receiving Medicaid through the managed care

provider United Behavioral Health (UBH) in Rhode Island who meet study criteria with regard to their risk for depression. Children are the biological, adopted, and stepchildren of these parents, between 1 and 18 years of age.

The annual burden estimates are detailed below, and the substantive content of each component will be detailed in the supporting statement attached to the forthcoming 30-day notice.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
RI 15-month, parent physiological component.	400	8	5 minutes or .08 hrs.	266.66
RI 15-month, young child physiological component.	160	8	5 minutes or .08 hrs.	106.66
RI 15-month, youth physiological component.	242	8	5 minutes or .08 hrs.	161.33

Estimated Total Annual Burden Hours: 534.65.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 13, 2006.

Robert Sargis,
 Reports Clearance Officer.
 [FR Doc. 06-7763 Filed 9-19-06; 8:45 am]
 BILLING CODE 4184-01-M

SECOND FEDERAL REGISTER NOTICE TEMPLATE



This template is used to prepare the second Federal Register notice which offers copies of the information collection to the public and solicits comments to OMB. Comments submitted will be considered by OMB prior to their determination which must occur between thirty and sixty days from submission.

This notice should be submitted to OIS, and needs to be included in each of the four sets of request packages. Be sure to carefully review this notice prior to sending it to OIS since this is what will appear in the Federal Register. Please refer to the “overview” document on the information collection intranet Web site for a list of items required for each request package. It

is located at the following URL: <http://intranet/offices/oa/ois/irm/security/index.htm>. The four sets of request packages need to be delivered to OIS at 334 F in the Humphrey Building.

This notice will be delivered to the Federal Register at the same time the request packages are sent to the Department. The Federal Register usually publishes three or four days after receipt, and the Department has up to ten days to review and submit to OMB.

This document contains text form fields which are indicated by the gray areas. You enter your specific information in each of these areas. Pressing the tab key will move the insertion point forward and pressing the shift-tab keys will move it backward. With the exception of the table area, all other parts of the form are protected.

OMB allows closely related information collections to be bundled in a single request, and therefore multiple rows are often needed to account for each collection. The number of rows can be adjusted with the buttons on the tool bar to the right once a cell is selected. In addition, this document contains guidance that can be seen by holding the pointer (I beam) over the areas shaded in yellow.

Please direct any questions to Bob Sargis at 690-7275.

APPENDIX E.2: Federal Register 30-Day Draft Notice

OMB Control No. 0970-0276

Expiration Date: 04/30/08

4184-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB review; comment request

Title: DHHS/ACF/ASPE/DOL Enhanced Services for the Hard-to-Employ Demonstration and Evaluation: Rhode Island 15-Month Survey Amendment

OMB No.: 0970-0276

Description: The Enhanced Services for the Hard-to-Employ Demonstration and Evaluation Project (HtE) seeks to learn what works in this area to date and is explicitly designed to build on past research by rigorously testing a wide variety of approaches to promote employment and improve family functioning and child well-being. The HtE project is designed to help Temporary Assistance for Needy Families (TANF) recipients, former TANF recipients, or low income parents who are hard-to-employ. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Labor (DOL).

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Materials for follow-up surveys for each of these sites were previously submitted to OMB and were approved. The purpose of this submission is to add physiological measures to the follow-up effort to the Rhode Island study.

Respondents: The respondents to this component of the Rhode Island follow-up survey will be low-income parents and their children from the Rhode Island site currently participating in the HtE Project. As described in the prior OMB submission, these parents are Medicaid recipients between the ages of 18 and 45 receiving Medicaid through the managed care provider United Behavioral Health (UBH) in Rhode Island who meet study criteria with regard to their risk for depression. Children are the biological, adopted, and step-children of these parents, between the ages of 1 and 18 years of age.

The annual burden estimates are detailed below, and the substantive content of each component will be detailed in the forthcoming supporting statement.

ANNUAL BURDEN ESTIMATES

APPENDIX E.2: Federal Register 30-Day Draft Notice

OMB Control No. 0970-0276

Expiration Date: 04/30/08

Instrument	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
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RI 15 month young child physiological component	160	8	5 minutes or .08 hrs	106.66
RI 15-month, youth physiological component	242	8	5 minutes or .08 hrs	161.33

Estimated Total Annual Burden Hours:

534.65

Additional Information:

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget
Paperwork Reduction Project
725 17th Street, N.W.
Washington, D.C. 20503
Attn: Desk Officer for ACF

DATED: _____

Bob Sargis
Reports Clearance
Officer

202 205 3598 P.02

DHS/RCF/DFRE

JUL-11-2002 11:29

108th Congress 1st Session	COMMITTEE PRINT	WMCP- 108-5
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COMPILATION
OF THE
SOCIAL SECURITY LAWS

INCLUDING THE SOCIAL SECURITY ACT,
AS AMENDED, AND RELATED ENACTMENTS
THROUGH JANUARY 1, 1993

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THE SOCIAL SECURITY ACT
SELECTED PROVISIONS OF THE INTERNAL REVENUE CODE
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SOCIAL SECURITY ACT—§ 1110(b)

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AMOUNTS DISREGARDED NOT TO BE TAKEN INTO ACCOUNT IN
DETERMINING ELIGIBILITY OF OTHER INDIVIDUALS

SEC. 1109. [42 U.S.C. 1309] Any amount which is disregarded (or set aside for future needs) in determining the eligibility of and amount of the aid or assistance for any individual under a State plan approved under title I, X, XIV, XVI, or XIX, or part A of title IV, shall not be taken into consideration in determining the eligibility of and amount of aid or assistance for any other individual under a State plan approved under any other of such titles.

COOPERATIVE RESEARCH OR DEMONSTRATION PROJECTS¹⁷

SEC. 1110. [42 U.S.C. 1310] (a)(1) There are hereby authorized to be appropriated for the fiscal year ending June 30, 1957, \$5,000,000 and for each fiscal year thereafter such sums as the Congress may determine for (A) making grants to States and public and other organizations and agencies for paying part of the cost of research or demonstration projects such as those relating to the prevention and reduction of dependency, or which will aid in effecting coordination of planning between private and public welfare agencies or which will help improve the administration and effectiveness of programs carried on or assisted under the Social Security Act and programs related thereto, and (B) making contracts or jointly financed cooperative arrangements with States and public and other organizations and agencies for the conduct of research or demonstration projects relating to such matters.

(2) No contract or jointly financed cooperative arrangement shall be entered into, and no grant shall be made, under paragraph (1), until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed projects as to soundness of their design, the possibilities of securing productive results, the adequacy of resources to conduct the proposed research or demonstrations, and their relationship to other similar research or demonstrations already completed or in process.

(3) Grants and payments under contracts or cooperative arrangements under paragraph (1) may be made either in advance or by way of reimbursement, as may be determined by the Secretary; and shall be made in such installments and on such conditions as the Secretary finds necessary to carry out the purposes of this subsection.

(b)(1) The Secretary is authorized to waive any of the requirements, conditions, or limitations of title XVI (or to waive them only for specified purposes, or to impose additional requirements, conditions, or limitations) to such extent and for such period as he finds necessary to carry out one or more experimental, pilot, or demonstration projects which, in his judgment, are likely to assist in promoting the objectives or facilitate the administration of such title. Any costs for benefits under or administration of any such project (including planning for the project and the review and evaluation of the project and its results), in excess of those that would have been incurred

¹⁷See Vol. II, P.L. 96-265, §505, as amended by P.L. 101-239, §10103(a)(1)(A)(3) and P.L. 101-508, §1200(f), with respect to authority for demonstration projects and requirements for reports to Congress.

See Vol. II, P.L. 99-190, §126, and P.L. 99-272, §2216, as amended by P.L. 101-239, with respect to the extension of approval of certain Medicare municipal health services demonstration projects. See Vol. II, P.L. 101-508, §5120, with respect to vocational rehabilitation demonstration projects.

without regard to the project, shall be met by the Secretary from amounts available to him for this purpose from appropriations made to carry out such title. The costs of any such project which is carried out in coordination with one or more related projects under other titles of this Act shall be allocated among the appropriations available for such projects and any Trust Funds involved, in a manner determined by the Secretary, taking into consideration the programs (or types of benefit) to which the project (or part of a project) is most closely related or which the project (or part of a project) is intended to benefit. If, in order to carry out a project under this subsection, the Secretary requests a State to make supplementary payments (or makes them himself pursuant to an agreement under section 1616), or to provide medical assistance under its plan approved under title XIX, to individuals who are not eligible therefor, or in amounts or under circumstances in which the State does not make such payments or provide such medical assistance, the Secretary shall reimburse such State for the non-Federal share of such payments or assistance from amounts appropriated to carry out title XVI.

(2) With respect to the participation of recipients of supplemental security income benefits in experimental, pilot, or demonstration projects under this subsection--

(A) the Secretary is not authorized to carry out any project that would result in a substantial reduction in any individual's total income and resources as a result of his or her participation in the project;

(B) the Secretary may not require any individual to participate in a project; and he shall assure (i) that the voluntary participation of individuals in any project is obtained through informed written consent which satisfies the requirements for informed consent established by the Secretary for use in any experimental, pilot, or demonstration project in which human subjects are at risk, and (ii) that any individual's voluntary agreement to participate in any project may be revoked by such individual at any time;

(C) the Secretary shall, to the extent feasible and appropriate, include recipients who are under age 18 as well as adult recipients; and

(D) the Secretary shall include in the projects carried out under this section such experimental, pilot, or demonstration projects as may be necessary to ascertain the feasibility of treating alcoholics and drug addicts to prevent the onset of irreversible medical conditions which may result in permanent disability, including programs in residential care treatment centers.

(3) All reports of the Secretary with respect to projects carried out under this subsection shall be incorporated into the Secretary's annual report to the Congress required by section 704.

PUBLIC ASSISTANCE PAYMENTS TO LEGAL REPRESENTATIVES

SEC. 1111. [42 U.S.C. 1311] For purposes of titles I, X, XIV, and XVI, and part A of title IV, payments on behalf of an individual, made to another person who has been judicially appointed, under the law of the State in which such individual resides, as legal representative of such individual for the purpose of receiving and managing

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