

**Supporting Statement for  
OMB Clearance Request:  
Appendices**

**Innovative Strategies for  
Increasing Self-Sufficiency  
(ISIS)**

**Contract #  
HHSP23320072913YC**

April 11, 2011

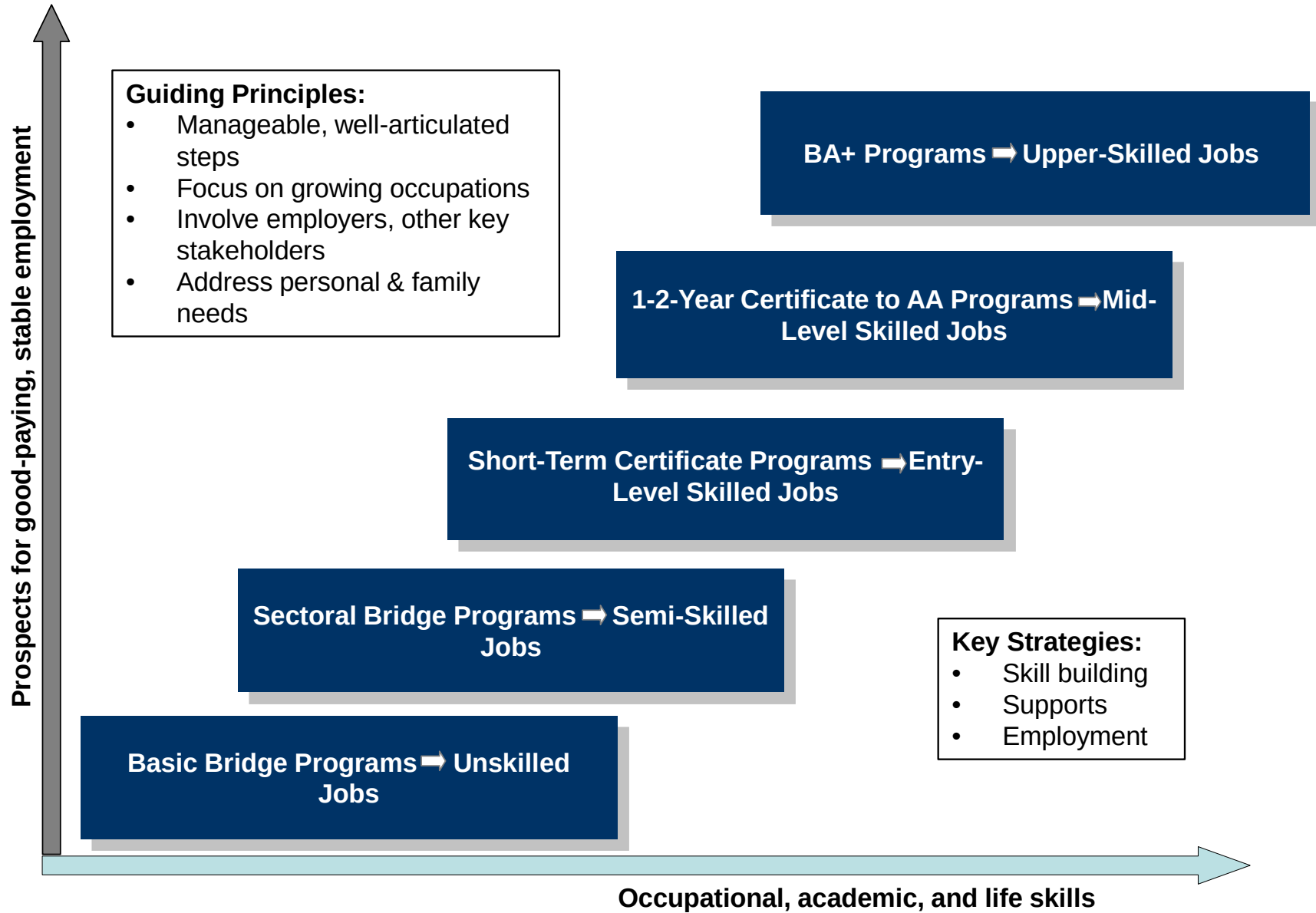
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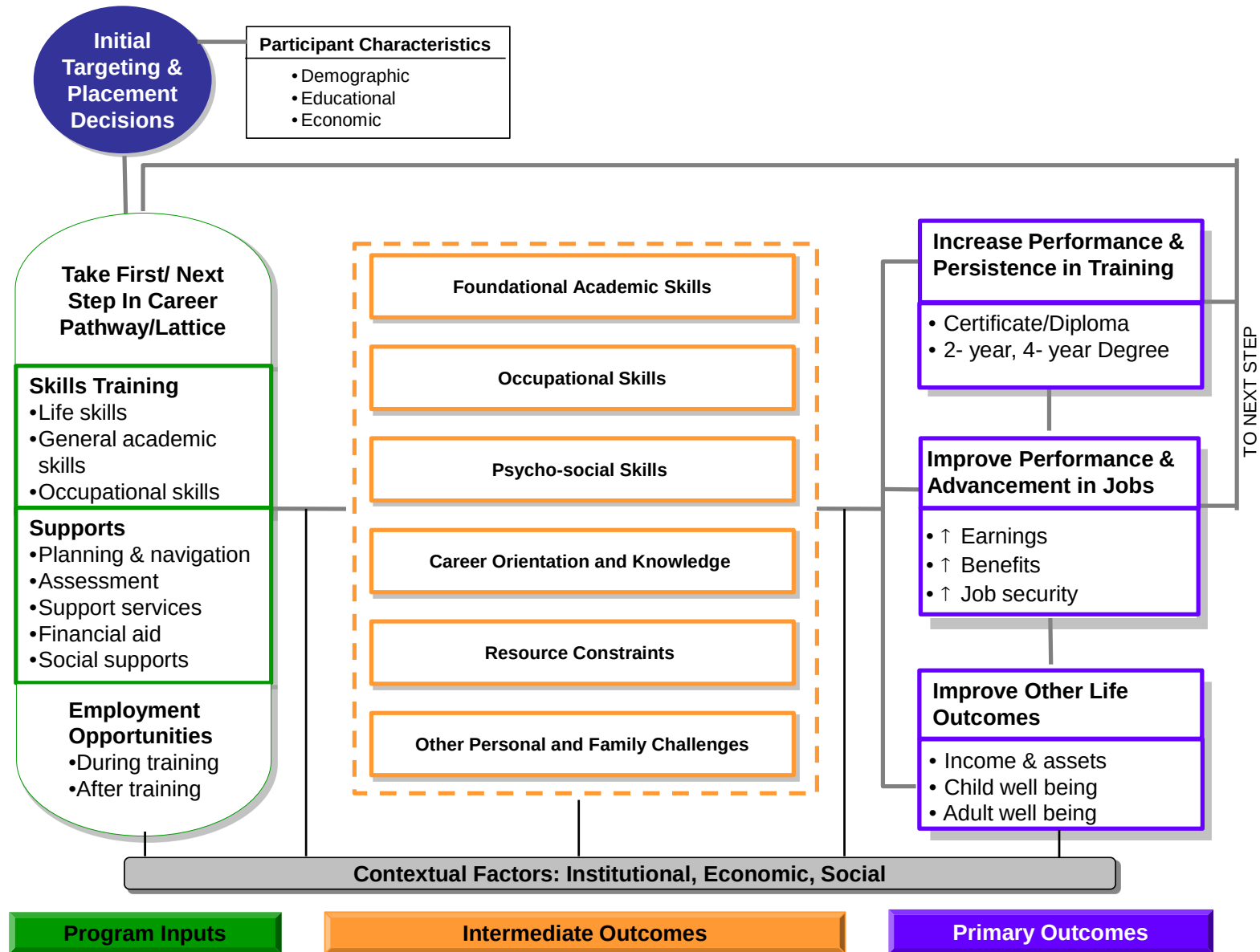
## **Appendix A:**

### **Exhibits Describing Career Pathway Program**

Exhibit AA-1: The Basic Career Pathways Model



**Exhibit AA-2: Theory of Change for Comprehensive Career Pathways Programs**



**Appendix B:**

**ISIS Participation Agreement (Informed  
Consent Form)**

**Agreement to Take Part in the Innovative Strategies for Increasing Self-Sufficiency (ISIS) Study**

We invite you to take part in an important study of services that may help people improve their skills, find a job, and advance in their careers. The study is the Innovative Strategies for Increasing Self-Sufficiency (ISIS) project. The U.S. Department of Health and Human Services is funding the project. A research company called Abt Associates is conducting the study.

[Name of site] is trying innovative approaches to help individuals improve their education and employment outcomes. To learn about how well the program is working, we will compare participants who receive the innovative program services to those who receive other services. Your participation in ISIS is voluntary. You can end your participation at any time. There are no penalties for declining to participate. We hope you will agree to be in this study. It will help us learn how well the program is working and how to improve services for future participants.

**What Does Participation Mean?**

If you agree to be in the study, we will assign you to one of two groups. One group will be able to participate in [Program Name]. The other group will not be able to participate in this program but may be eligible for other services in the community. We will use a lottery-like procedure to determine which group you will be in. This procedure makes sure that assignments are fair. Everyone who agrees to join the study has the same chance of receiving [Program Name] services. People who are not selected for this program can re-apply after a period of 48 months. If you decide not to participate in the study, you will not be able to get these services at [name of site]. We expect to recruit 10,800 participants across several programs to be in this study.

If you agree to be in the study, ISIS and program staff will collect information from you to help understand how well the services you receive are working. We will ask you to fill out two forms today. They will take about 40 minutes to complete. They will ask about your educational background, family structure, work history, and other experiences. You may feel that some questions are personal or sensitive. The information will help us to understand what contributes to peoples' success, and we encourage you to provide it. You may refuse to answer any question. Your answers will not affect your placement into the program or non-program group.

The ISIS team will collect additional information about you in the future, regardless of which group you are in. This information will help us understand how well the program is working.

- 1) We are likely to ask you to participate in one or more additional surveys sometime in the next few years. You will receive a payment for your time completing each survey. You can refuse to participate in the interviews or answer any of the questions.
- 2) We will collect information about your job earnings from data maintained by this program and government agencies. This information may include information about government services you have received, such as TANF or SNAP (food stamps), and school records. To do this, we need to collect your Social Security Number.

3) We are interested if programs like [name of site] benefit children. If you have children, we may collect information about them from school records and other agencies. We also may ask your permission to talk with or observe your children. Your participation in these activities is voluntary. You or your children can choose to stop participating at any time.

### **Potential Risks**

We are committed to keeping your personal information private. However, there is a small risk of a breach of confidentiality. We will take strong precautions to make sure this does not happen. We will keep any paper that includes your name and other personal identifiers in a locked storage area and destroy the files after the study ends. We will password protect any computer files with personally identifiable information and will store them on a secure network. We will provide the Department of Health and Human Services with a copy of the data set. The data set will not be available to the public. Your personally identifiable information will not appear in the data set or any public document produced as part of the study. Your information will be used only for the purpose of the study and will be kept confidential to the extent allowed by law.

### **Questions about participation**

If you have any questions about the study, contact [name of site contact or liaison to be added] at ISIS@abtassoc.com (email) or [contact information to be added] (phone). If you have any questions about your rights as a study participant, contact Teresa Doksum with the Abt Associates Institutional Review Board at IRB@abtassoc.com (email) or 877-520-6835 (toll-free).

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### **Agreement to Participate**

By signing this participation agreement, I confirm that I have read and understand the description of the ISIS study. I have had the opportunity to ask questions. I understand I will be put into one of two groups at random. One group will get the innovative program services. The other group will have access to other services. I understand that my participation is voluntary. I understand that I can refuse to answer any questions or stop being in the study at any time without penalty. I understand that I will be given a copy of this consent form to keep. I understand that Abt Associates will get information about me as described above. I understand this information will be used only for the purpose of the study and will be kept confidential to the extent allowed by law.

**Participant:**

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Name of Participant (Printed)

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Signature of Participant                  Date



**Appendix C:**  
**Item-by-Item Justification for the Baseline  
Information Form**

Q #	Question	Source	Justification
<b>Identifying Information</b>			
1.	What is your name?	Adapted from Census	To be used with other contact information for tracking purposes.
2.	What is your date of birth?	Adapted from Census	Respondents are asked to identify their dates of birth to verify that programs have enrolled adults and because age may be an essential factor affecting adult learning. At some point, people may become too old to effectively change learning habits, potentially limiting the effectiveness of career pathway programs. <sup>1</sup> On the other hand, some qualities conducive to learning, such as self-discipline, increase with age. When determining program impacts, it will be important for researchers to see if career pathway programs are more effective for some age groups than others.
3.	What is your social security number?	Adapted from Census	Researchers will use Social Security Numbers to link individuals to other administrative data sets. These data will include individuals' earnings and use of government programs.
4.	What is your sex?	Adapted from Census	There is a substantial body of literature on occupational and wage discrimination based on sex. It is possible that women will not see the same earnings outcomes as men.
<b>Background and Family Characteristics</b>			
5.	What is your marital status?	American Communities Survey (ACS)	Family structure could play an important role in both training and employment outcomes. Those who are married could have more support at home to allow them to focus more on training activities.
6.	Are you of Hispanic, Latino, or Spanish origin?	ACS	There is a substantial literature on occupational segregation and wage discrimination on the basis of race and ethnicity, and career pathway programs may benefit certain groups more than others. <sup>2</sup> There is evidence that shows some education and labor force attachment programs are especially effective for minorities. <sup>3</sup> Some of the potential ISIS programs specifically focus on increasing the number of specific populations in a given industry. For example, one of Carreras en Salud's core missions is to increase the number of Latinos in the health care profession, where they currently compose less than 2% of all LPNs and RNs. <sup>4</sup>
7.	What is your race?	Question from ACS; response categories from Supporting Healthy Marriages (SHM)	

<sup>1</sup> See Leininger & Kalil (2008) for a quick summary of the literature.

<sup>2</sup> For a debate as to the prevalence of racial discrimination see Darity & Mason (1998) and Heckman (1998).

<sup>3</sup> The NEWWS evaluation showed that, in general, African American and Hispanic participants in human capital development and job search activities had higher earnings impacts than white participants in the same programs. Hamilton et al. (2001).

<sup>4</sup> See Estrada & DuBois (2008).

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Q #	Question	Source	Justification
8a.	Were you born in one of the 50 US States or Washington, DC?	SHM Baseline	Being a recent immigrant to the United States presents unique challenges to individuals trying to complete career pathway programs and find employment. Recent immigrants' comfort with cultural norms and expectations could have an impact on program outcomes. The BIF asks two questions about English language speaking and ability because individuals who have difficulty with English may have an especially hard time completing training programs offered in English and finding employment in English language environments. <sup>5</sup> A demonstration of the I-BEST model in Washington revealed that higher-skill ESL students are more likely to benefit from the program. <sup>6</sup> If ISIS finds similar results, it will be important for career pathway programs to target those who are most likely to succeed to maximize their impacts.
8b.	In what year did you come to live in the United States?		
9a.	Do you speak a language other than English at home?	ACS	
9b.	If yes, how well do you speak English?		
9c.	If yes, how well do you read English?		
10.	Which of the following live in your household at least half the time?	Adapted from SHM	
11.	How many adults age 18 or older live in your household at least half the time?	SHM	
12a.	How many children under age 18 live with you at least half the time?		
12b.	For how many of these children are you or your spouse the legal guardian?	Adapted from Employment, Retention, Advancement (ERA) Study	
13.	Do you have any children under age 18 who do not live with you at least half the time?	National Job Training Partnership Act (JTPA) Study	
<b>Educational Background</b>			
15.	What is the highest degree or level of school you have completed?	ACS	Educational attainment is often associated with the basic academic skills necessary to find employment. Basic math and language skills are essential for most occupations, and numerous studies have shown that education is a significant predictor of employment outcomes. Evidence suggests that high school graduates who engage in job search activities do better both in
16.	Have you received a vocational or technical certificate or diploma?	New Item	
17.	Have you ever attended any of the following education and training programs?	Adapted from Fragile Families	

<sup>5</sup> See Carnevale, Fry, & Lowell (2001) found that English language has a significant impact on employment outcomes.

<sup>6</sup> See Washington State Board for Community and Technical Colleges (2005).

<sup>7</sup> See Crew & Davis (2006), Danziger, Kalil, & Anderson (2000), Olson & Pavetti (1996), Riger, Staggs, & Schewe (2004), and Seefeldt & Orzol (2005).

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<b>Q #</b>	<b>Question</b>	<b>Source</b>	<b>Justification</b>
18.	What is the highest level of education that you eventually expect to complete?	Adapted from New Visions	terms of employment rates and on-the-job earnings than non-graduates. <sup>8</sup> Additionally, educational attainment could be a sign of other skills associated with better educational outcomes. Individuals who complete high school may demonstrate more persistence in accomplishing tasks or may be better at socializing or working in group environments. Such “soft” skills could affect both training and employment outcomes. While there are additional questions on the SAQ that specifically address some of these soft skills, education is still a useful proxy to identify any soft skills that cannot be measured on the SAQ.
19a.	What is the highest level of school completed by your mother (or guardian #1)?	Adapted from the Community College Survey of Student Engagement and the Student Strengths Inventory	It is possible that having family members who have had exposure to higher education could have a positive effect on individuals own educational outcomes. If someone else in their family has attended college, an adult learner may have a better idea of how to navigate the higher education system. This could mean that they are able to access financial aid more easily or that they are able to seek out other resources that will help them be successful. The BIF asks respondents about their parents’ highest level of education and if they have any siblings who have attended college to see if individuals with more exposure to higher education do better than those with less exposure.
19b.	What is the highest level of school completed by your father (or guardian #2)?		
20.	Do you have any brothers or sisters who have attended college?	Adapted from Opening Doors	
21.	What grades did you usually get in high school?	ACT, Inc	Grade point average has consistently been shown to be a predictor of future educational performance.
<b>Employment and Income</b>			
22a.	Are you currently working at a job for pay?	SHM Baseline	There is strong evidence showing a stable job history is an important factor in finding future employment. Being able to keep a job is likely as important as being able to find a job because job stability signals to employers that an individual will be a reliable worker. Research has found both job skills and years worked for pay are significant predictors of future employment. <sup>9</sup> However, it is also possible that career pathway programs will be less successful for those with stronger employment histories because they already possess the skills and resources needed to find work. There is evidence that job search activities most benefit those who do not have recent work experience. <sup>10</sup> By asking about their employment history, the ISIS evaluation can examine the extent to which employment history is a factor in determining how individuals fare in career pathway programs.
22b.	How many hours per week on average are you currently working (include all jobs)?		
22c.	When did you last work?		

<sup>8</sup> See Hamilton et al. (1997).

<sup>9</sup> See Riger et al. (2004).

<sup>10</sup> See Hamilton et al. (2001).

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<b>Q #</b>	<b>Question</b>	<b>Source</b>	<b>Justification</b>
23.	About how much do/did you usually earn per hour before taxes in your current or most recent job?	Adapted from Fragile Families	Having the resources to participate in career pathway programs is an important determinant of success. There are many costs associated with participating in career pathway programs, including tuition, the cost of course materials, and most importantly the opportunity cost associated with working fewer hours. It is likely that some individuals will be working while they are in the career pathways program. The time they devote to the program necessarily limits the amount of time they can spend earning money to support themselves through regular employment. By asking them about their income, ISIS will be able to examine if individuals with higher levels of income are more likely to succeed in career pathway programs.
24.	In the last 12 months did you or anyone in your family (your spouse or partner and any other relative who live with you) have income or benefits from any of the following sources:	Adapted from SHM Baseline	
24a.	Job earnings?		
24b.	Public assistance, welfare, or WIC?		
24c.	Food stamps (also known as Supplemental Nutrition Assistance Program – SNAP)?		
24d.	Free or reduced price lunch program?		
24e.	Unemployment insurance, worker’s compensation, disability or social security benefits?		
24f.	Family and friends (outside the household)?		
24g.	Grants or loans for school?		
25.	Last year, what was your household’s total family income?		
<b>Contact Information</b>			
26.	Please provide your contact information.	Adapted from SHM Baseline	In order to achieve high response rates in subsequent follow-up surveys, it is important for the researchers to track all ISIS participants between waves of data collection. The BIF asks respondents both for their contact information and the contact information of three people who could locate them in the future. Extensive experience of Abt’s survey division attests to the great value of multiple points of contact in increasing the chances of contacting the respondents in the future.
27.	Please provide information for three persons not living with you who can help us locate you in case you move.		

**Appendix D:**

**Item-by-Item Justification for the Self-Administered Questionnaire**

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Q #	Question	Source	Justification
<b>Resource Constraints</b>			
1.	Thinking about the near future, do you expect to be going to school part-time or full-time if you are selected for this program?		A substantial body of evidence documents negative associations between resource constraints and low-income adults' enrollment, performance, and persistence in post-secondary education and training. <sup>11</sup> Such adults typically face greater needs to work than traditional-aged students, who are less likely to have children and more likely to have access to some support from their own parents. A number of studies have found post-secondary success to be positively related to access to financial aid and fewer work hours (particularly below the 20-hour/week threshold). <sup>12</sup> Additional constraints arise from limited access to computers and transportation and other personal and family challenges that occur more frequently in low-income populations. <sup>13</sup> Financial hardship can create debilitating stresses and mental health problems, as well as increasing vulnerability to more acute emergencies that can negatively affect performance and persistence in school and at work. <sup>14</sup> Strong social supports can provide instrumental as well as emotional reinforcements to buffer the potentially destabilizing effects of financial and other stresses. <sup>15</sup>
2.	Do you expect to be working for pay in the next few months?		
2a.	If yes, how many hours to you expect to be working in a typical week?		
3.	How difficult do you expect it will be to find enough time to do well in school?		
4.	While you are in school, do you expect to need financial assistance to help with:		
4a.	Tuition and fees?		
4b.	Living expenses?		
5.	How difficult to you expect it to be to obtain enough financial support for school?		
6.	Do you have a computer at home?		
6a.	Does this computer have a working Internet connection?		
7.	Do you own a car?		Some potential ISIS career pathway programs targeting various populations of low-income and low-skilled adults seek to address these and associated issues in a variety of ways. Many include assistance in obtaining financial support from public benefits and financial aid, as well as personal counseling and case management to connect students to additional supportive services. Some foster supportive social environments to create additional sources of help and emotional support.
8.	In the past 12 months has there been a time when you could not pay the full amount of the rent or mortgage that you were supposed to pay?		
9.	Think again over the past 12 months. Generally, at the end of each month do you end up with: more than enough money left over, some money left over, just enough to make ends meet, or not enough to make ends meet?		
10.	The following statements are about help from other people. Please indicate whether you strongly disagree, disagree, agree, or strongly agree with each	Scale of Social Provision	
			Key uses of baseline measures for resources include profiling participants in each site and measuring differences in impacts on

<sup>11</sup> See Goldrick-Rabb & Sorenson (2010), Long (2010), Community College Survey of Student Engagement (2008), Fein & Beecroft (2006), Matus-Grossman & Gooden (2002), Wlodkowski et al. (2002).

<sup>12</sup> See Bound et al. (2010), Scott-Clayton (2010), Long (2010), Deming & Dynarski (2009), Navarro et al. (2007), Berker & Horn (2003), Seftor & Turner (2002).

<sup>13</sup> See Hinckley & Hull (2007), Purnell & Blank (2004), and citations under "Personal and Family Challenges" below.

<sup>14</sup> See citations under "Personal and Family Challenges" below.

<sup>15</sup> See Cooper (2010), Scrivener et al. (2008), Engstrom & Tinto (2008), Conger et al. (1999), Vinokur et al. (1996).

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Q #	Question	Source	Justification
	item.		
10a.	There are people I can depend on to help me if I really need it.		<p>key school and work outcomes for participants with varying initial resource constraints. In general, we hypothesize that training and employment-related impacts will be less positive among participants with fewer than for those with greater initial resources. Where programs effectively address resource constraints, however, it is possible that training and employment-related impacts will be as, or possibly more, positive among initially more disadvantaged subgroups. We will be able to measure impacts on many of the same resource outcomes over time through planned follow-up surveys to see if programs did affect them.</p> <p>Items in this section measure a number of specific resource constraints (In addition, the BIF includes direct measures for income). We designed SAQ items 1-5 (see Appendix C for the SAQ instrument) to assess expected difficulties managing both work and school and concerns about financial support. Items 6-7 tap access to a computer and car, two resources that can be critical to success in school and finding and retaining employment. Items 8-9 are two widely-used measures of financial hardship. Items in Question 10 reproduce the short form of the widely-used Social Provisions Scale.<sup>16</sup></p>
10b.	I feel that I do not have close personal relationships with other people.		
10c.	There is no one I can turn to for guidance in times of stress.		
10d.	There are people who enjoy the same social activities that I do.		
10e.	I do not think other people respect my skills and abilities.		
10f.	If something went wrong, no one would come to my assistance.		
10g.	I have close relationships that provide me with a sense of emotional security and well-being.		
10h.	I have relationships where my competence and skills are recognized.		
10i.	There is no one who shares my interests and concerns.		
10j.	There is a trustworthy person I could turn to for advice if I were having problems.		
<b>Psycho-Social Factors</b>			
11a.	Discipline (10 items)	<p>Each construct is part of a proprietary scale designed, used, and validated by ACT, Inc. as part of their Student Readiness Inventory or Talent Assessment tools.</p>	<p>The last two decades have been marked by growing interest in the psycho-social factors linked to success in post-secondary education and employment. Economists and education researchers have argued for greater attention to these factors.<sup>17</sup> Important governmental and non-governmental initiatives followed in the wake of the 1991 DOL report of the Secretary's Commission on Needed Skills.<sup>18</sup> These initiatives variously have sought to map out the wide range of skills, classify occupations according to skills required, identify skills required for success in occupational training programs, and develop approaches to instilling these skills. Yet as interventions have proliferated, there has been surprisingly little effort to inventory approaches, carefully distinguish their target factors, or rigorously evaluate impacts on these factors.<sup>19</sup> ISIS affords a valuable opportunity to build knowledge in this arena.</p>
11b.	Training Commitment (10 items)		
11c.	Determination/Striving (11 items)		
11d.	Self-confidence (12 items)		
11e.	Steadiness (12 items)		
11f.	Optimism (13 items)		

<sup>16</sup> See Cutrona & Russell (1984, 1987).

<sup>17</sup> For example, see Allen et al. (2010), Conley (2007), Heckman et al. (2006), and Colquitt et al. (2000).

<sup>18</sup> U.S. Department of Labor (1991).



Q #	Question	Source	Justification
			<p>In addition to fitting within our broader theory of change for career pathways, a number of potential ISIS sites incorporate components targeting psycho-social factors and related coping skills. Examples include job readiness training focused on work habits/communication, student success curricula, and intensive mentoring and guidance.</p> <p>Absent components effectively addressing these factors, we generally expect less favorable training and employment impacts for participants with initially weaker psycho-social skills. For interventions that effectively impact these skills, we expect training and employment impacts to be comparable to – and perhaps even more favorable than – those for initially more psycho-socially advantaged participants. Some evidence exists that is consistent with these hypotheses.<sup>20</sup></p> <p>Our proposed measures capitalize on perhaps the most comprehensive effort to date to conceptualize and measure psycho-social factors—a program undertaken by researchers at ACT Inc. The ACT team conducted extensive research to identify and measure psycho-social factors important in college and work settings. Their progress is summarized in a series of peer-reviewed papers, including two meta-analyses<sup>21</sup> and reports on psychometric results on the new measures.<sup>22</sup> The final products are embodied in two instruments: one for college settings (Student Readiness Inventory/SRI) and one for work settings (Talent Assessment).<sup>23</sup> These instruments have been administered to thousands of students and workers, and ACT has extensive data on national norms.</p>

<sup>19</sup> Exceptions include a random assignment test of the Michigan JOBS program (Vinokur et al 2000) and limited investigation of moderating (Leininger & Kalil 2008) and mediating (Gottchalk 2005) effects of psycho-social factors in random assignment evaluations of welfare-to-work programs.

<sup>20</sup> Vinokur et al. (2000) found statistically significant moderating effects for baseline measures of motivation and self-mastery on employment and mental health outcomes, respectively. As expected, impacts were greater for initially less motivated/lower mastery participants for this program, which focused on building self-esteem and motivation. On the other hand, Leininger & Kalil (2008) found positive impacts on GED receipt concentrated among initially more confident welfare recipients for programs that did not target psycho-social factors.

<sup>21</sup> See Robbins et al. (2004, 2009).

<sup>22</sup> See Le et al. (2005), Peterson et al. (2006), Robbins et al. (2006), and ACT Inc. (2007).

<sup>23</sup> See materials at: <http://www.act.org/sri/pdf/UserGuide.pdf>, <http://www.act.org/workkeys/assess/talent/>.

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Q #	Question	Source	Justification
			Based on a series of discussions with ACT staff and published psychometric evidence, the ISIS team has identified a subset of scales with the greatest relevance to adult career pathway programs (see SAQ items 11a-f). We have selected six ACT scales for inclusion: discipline, training commitment, determination/striving, self-confidence, emotional steadiness, and optimism. In each case, scales will sum a series of 10-13 items developed and validated by ACT. Illustrative items for each scale are shown in the ISIS SAQ. The full set of items is proprietary and copyrighted by ACT. <sup>24</sup>
<b>Career Orientation and Knowledge</b>			
12.	When it comes to careers, some people are more certain than others that they know where they are headed and how to get there. Please indicate for each item in the list below whether you strongly disagree, disagree, agree, or strongly agree that it reflects your career situation.	Career Decisions Self-Efficacy Scale Short Form	A key assumption in the career pathways framework is that more effective guidance is needed to foster career knowledge and planning skills and equip students to maximize their access to available supports in pursuing desired training and employment. <sup>25</sup> Low-income adults with little exposure to careers or post-secondary training are particularly likely to lack direction and skills for planning careers, obtaining financial aid, getting extra help at school when needed, and identifying appropriate employment opportunities. <sup>26</sup>  In response, career pathway programs are developing and using improved career exploration and planning instruments, providing more intensive counseling and “career navigation” supports, packaging training and supports in ways that allow students to concentrate on big picture decisions with less need to arrange
12a.	You know how to accurately assess your abilities and challenges.	New Item	
12b.	You know how to make a plan that will help achieve your goals for the next 5 years?	Career Exploration Survey	
12c.	You know how to get help from staff and teachers with any issues that might arise at school?	New Item	
12d.	You know the type of job that is best for you?	Career Exploration Survey	
12e.	You know the type of organization you want to work for?	Career Decisions Self-Efficacy Scale Short Form	

<sup>24</sup> ISIS is developing an agreement with ACT for permission to use these instruments.

<sup>25</sup> See for example Choitz (2010), Cooper (2010), and Conley (2007).

<sup>26</sup> See Long (2010), Roderick et al. (2009), Purnell & Blank (2004), and Matus-Grossman & Gooden (2002).

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Q #	Question	Source	Justification
12f.	You know exactly the occupation you want to enter?	New Item	<p>myriad details, and formally instructing students in skills needed to succeed in college and work. By infusing courses on foundational academic skills (math, reading) with examples from different occupations, some programs are trying to foster awareness and interest in relevant careers while providing more engaging basic skills training.</p> <p>Absent such services, we expect that participants with weaker initial career orientations will not benefit from other career pathways strategies – such as occupational training and material supports – as much as those with stronger career orientations. Given strong career services, however, we might expect commensurate, or even greater, impacts on training and employment outcomes among those with weaker initial career orientations.</p>
12g.	You know the kind of education and training program that is best for you?	Career Exploration Survey	<p>To measure career directedness, SAQ items 12a-g elicit participants' assessments of self-knowledge and skills in several key areas – self-assessment and planning, getting help at school, and having a sense of one's preferred occupation and training. Items a-b are adapted from the Career Decisions Self-Efficacy Scale-Short Form,<sup>27</sup> d-f are from the Career Exploration Survey,<sup>28</sup> and c and g are new items.</p>
<b>Personal and Family Challenges</b>			
13.	The questions below ask you about your feelings and thoughts during the last month. The best approach is to answer each question fairly quickly, giving a reasonable estimate without trying to count up the exact number of times. In the past month, how often have you felt:	Perceived Stress Scale	<p>Poverty and its associated financial hardships are associated with elevated levels of a variety of personal and family challenges that can interfere with success at school and work. Extensive research has documented connections between poverty, psychological stress, mental health and resulting difficulties sustaining levels of concentration and engagement needed to pursue a career and balance doing so with family responsibilities.<sup>29</sup> Additional barriers include access to child care and transportation, substance abuse, other health conditions, family violence, and criminal background.<sup>30</sup></p>
13a.	That you were unable to control the important things in your life?		
13b.	Confident about your ability to handle your personal problems?		

<sup>27</sup> See Chaney et al. (2007).

<sup>28</sup> See Stumpf et al. (1983).

<sup>29</sup> See Cutrona et al. (2005), Turner & Turner (2005), Turner & Avison (2003), Kessler (2002), Price et al. (2002), Vinokur & Schul (2002), Conger et al. (1999), Turner & Lloyd (1999), Vinokur et al. (1996), and Turner et al. (1995).

<sup>30</sup> See review in Lee & Vinokur (2007), also Fein & Becroft (2006), Grossman & Gooden (2002).

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Q #	Question	Source	Justification
13c.	That things were going your way?		Career pathways initiatives have sought to increase access to services addressing these challenges, services that traditionally have been more abundant in social service settings than in community college and other post-secondary education settings. Most of the potential programs ISIS will be testing include some form of needs assessment and case management, with varying connections to local providers and in-house services. Some programs offer workshops and training aiming to strengthen skills for coping with stress, building resilience in the face of reversals, and finding help for oneself.
13d.	That difficulties were piling up so high that you could not overcome them?		
14.	In the past 12 months, please note how often each of the following items interfered with important school, work, job search, or family responsibilities.	Adapted from the Composite International Diagnostic Interview (CIDI) Short Form, the Prime-MD scale, and the Employment, Retention, and Advancement (ERA) baseline study	In addition to providing information essential to developing individual profiles on these dimensions of disadvantage across potential ISIS sites, baseline measures will support subgroup analyses to test important hypothesized moderating effects. Absent intervention provisions addressing them effectively, we expect less favorable training and employment impacts among individuals with higher levels of stress, depressive symptoms, and other personal and family challenges than among those with lower levels. With effective provisions addressing these problems, we expect more favorable impacts for more than for less initially disadvantaged groups. <sup>31</sup>
14a.	Child care arrangements		
14b.	Transportation		
14c.	Alcohol or drug use		
14d.	An illness or health condition		
14e.	Arguments with a family member		
14f.	Physical threats/violence from a family member		
15.	Have you ever been arrested?	ERA baseline study	To capture key challenges, the ISIS SAQ includes three sets of items: one series measuring perceived stress, a second measuring a set of widely-studied barriers, and a third set measuring depressive symptoms. Our stress measure (SAQ Items 13a-d) is a widely used four-item version of the Perceived Stress Scale <sup>32</sup> , SAQ items 14a-f adapt the functional impairments format used to assess mental health and substance abuse problems to several other barriers <sup>33</sup> , and Item 15 is from the baseline survey used in the Employment Retention and
15a.	Have you ever been convicted of a crime?		
15b.	Have you been convicted of a felony?		
16.	Below is a list of the ways you might have felt or behaved in the last week. For each, please indicate how often you felt this way during the past week.	Center for Epidemiologic Studies-Depression Scale (CES-D)	To capture key challenges, the ISIS SAQ includes three sets of items: one series measuring perceived stress, a second measuring a set of widely-studied barriers, and a third set measuring depressive symptoms. Our stress measure (SAQ Items 13a-d) is a widely used four-item version of the Perceived Stress Scale <sup>32</sup> , SAQ items 14a-f adapt the functional impairments format used to assess mental health and substance abuse problems to several other barriers <sup>33</sup> , and Item 15 is from the baseline survey used in the Employment Retention and
16a.	I was bothered by things that usually don't bother me.		
16b.	I felt that I could not shake off the blues even with help from my family or friends.		
16c.	I had trouble keeping my mind on what I was doing.		
16d.	I felt depressed.		
16e.	I felt that everything I did was an effort.		
16f.	My sleep was restless.		
16g.	I was happy.		
16h.	I enjoyed life.		
16i.	I felt sad.		

<sup>31</sup> Some experimental evidence exists supporting these hypotheses. Impacts on earnings and welfare payments in a review of 20 random assignment tests of welfare-to-work programs generally were more favorable for participants with low initial risk of depression compared with those at high initial risk, particularly for programs with an educational focus (Michalopolous & Schwartz 2001). In contrast, a random assignment test of a psycho-educationally focused intervention for recently unemployed job seekers found both reductions in depressive symptoms and somewhat more favorable economic impacts among initially high-risk participants in the short (six months) though not longer (two years) run (Vinokur et al. 2000). There also is some experimental evidence that programs effectively treating substance abuse among low-income adults also produce more favorable employment outcomes. (Morgenstern et al. 2009)

<sup>32</sup> Cohen et al. (1983).

<b>Q #</b>	<b>Question</b>	<b>Source</b>	<b>Justification</b>
			Advancement project. Finally, Items 16a-i are a short form of the Center for Epidemiologic Studies-Depression scale (CES-D), a measure of depressive symptoms that has been widely used in comparable intervention studies. <sup>34</sup>

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<sup>33</sup> E.g., World Health Organization Composite International Diagnostic Interview Short Form (CIDI-SF, see [www3.who.int/cidi](http://www3.who.int/cidi)); Prime-MD, another widely used mental health screening instrument (Spitzer et al. 2000); and the Employment Retention and Advancement baseline form.

<sup>34</sup> SAQ items from Santor & Coyne's (1997) CES-D short form. We opted for this leading depression measure rather than another widely used general measure of psychological distress, the K6, because depression is a more clearly defined condition whose import is well established in the clinical and intervention literatures. Compared with indices developed to measure risk of major depressive episodes, the CES-D provides valid measures of sub-clinical symptoms likely to affect behavior at school, work, and home.

## **Appendix E:**

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## **Appendix F:**

### **60-day notice**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* Innovative Strategies for Increasing Self-Sufficiency: Baseline Data Collection.

*OMB No.:* 0970-0343.

*Billing Accounting Code (BAC):* 418409 (CAN G996121).

*Description:* The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Innovative Strategies for Increasing Self-Sufficiency (ISIS) demonstration and evaluation. The ISIS project will test a range of promising strategies to promote employment, self-sufficiency, and reduce dependence on cash welfare.

The ISIS project will evaluate multiple employment-focused strategies that build on previous approaches and are adapted to the current Federal, State, and local policy environment. The major goals of the project include increasing the empirical knowledge about the effectiveness of a variety of programs for low-income families to sustain employment and advance to positions that enable self-sufficiency, as well as producing useful findings for both policymakers and program administrators.

This proposed information collection activity focuses on collecting baseline data elements. Two data collection instruments will be completed by all participants prior to random assignment, and a third will be an interview guide to collect information from program staff. The first is a short baseline information form (BIF) that will collect basic identification, demographic, and contact information.

The form will include relatively standard items from prior evaluations and national surveys. The second instrument will be a self-administered questionnaire (SAQ), covering information related to the project goals. The third instrument, baseline implementation data collection interviews, will be used to collect information from knowledgeable informants about the service context for each evaluation site using a baseline implementation guide. The purpose of such interviews is to document and assess the service environment in which the evaluation is implemented and the opportunities for control group members to access the same or similar services as the treatment group members.

*Respondents:* Individuals enrolled in ISIS demonstration interventions, control group members, ISIS program operators (BIF and SAQ) and State and local informants (interviews).

**ANNUAL BURDEN ESTIMATES**

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Baseline Information Form .....	4,800	1	0.75	3,600
Self-Administered Questionnaire .....	4800	1	0.75	3,600
Baseline Implementation Data Collection Interviews .....	30	1	1	30

*Estimated Total Annual Burden Hours: 7,230*

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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 21, 2010.

**Steven M. Hanmer,**  
*Reports Clearance Officer.*

[FR Doc. 2010-24122 Filed 9-27-10; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0428]

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." This draft guidance document describes a means by which the herpes simplex virus (HSV) serological assay device type may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to designate this guidance as the class II special control. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 27, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" to the Division of