

INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH

The Ohio State University Institutional Review Boards

Office of Responsible Research Practices (ORRP)
300 Research Foundation Building, 1960 Kenny Road, Columbus, OH 43210
Phone: (614) 688-8457 Fax: (614) 688-0366 www.orrp.osu.edu

OFFICE USE	DATE RECEIVED:	DATE VERIFIED COMPLETE:	OSU PROTOCOL NUMBER:
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1. PROJECT TITLE

Ohio Youth in Transition - Alumni Support & Assistance Project (ASAP)

2. INSTITUTIONAL REVIEW BOARD

Select the Board to review this research:

Final Board assignment is determined by ORRP.

- Behavioral and Social Sciences
 Biomedical Sciences
 Cancer

3. PRINCIPAL INVESTIGATOR (or Advisor) - see [Qualifications for service as a PI](#)

Name (Last, First, MI):	Mares, Alvin, S.	Degree(s):	PhD, MSW
University Academic Title:	Assistant Professor	College (TIU):	Social Work
Department Name (TIU):		Department # (TIU):	
Campus Mailing Address:	325-Q Stillman Hall	OSU ID Number:	07172143
E-mail:	mares.2@osu.edu	Fax:	
Phone:	(614) 292-0425	Emergency phone:	

4. CO-INVESTIGATOR(S)

Are there any OSU Co-Investigators on this protocol?

- Yes → Complete [Appendix A1](#)
 No

Signatures of Co-Investigator(s) are required on Appendix A1.

5. KEY PERSONNEL

Are there any OSU key personnel on this protocol?

- Yes → Complete [Appendix A1](#) [S. Satchell]
 No

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit or consent participants or who collect study data.

6. EXTERNAL CO-INVESTIGATOR(S) & KEY PERSONNEL

Are any external (non-OSU) Investigators or key personnel *engaged* in the OSU research?

- Yes
 No → Go to Question #7

“Engaged” individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by OSU. See <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm> or contact ORRP for more information.

If Yes → Who will provide approval for these external personnel?

- OSU IRB → Complete [Appendix A2](#)
 Non-OSU IRB → *Provide a copy of the approval(s)*

7. ADDITIONAL CONTACT(S)

N/A

If further information about this application is needed, specify the contact person(s) if other than the PI (e.g., study or regulatory coordinator, research assistant, etc.).

Name (Last, First, MI): N/A Phone: _____

E-mail: _____ Fax: _____

Name (Last, First, MI): _____ Phone: _____

E-mail: _____ Fax: _____

All OSU individuals listed on this protocol will have access to information about IRB actions and the completion status of each individual's administrative and training requirements (CITI, COI disclosure). Note: Personal financial information provided in COI disclosures is not included.

8. EDUCATION

Have all OSU investigators and key personnel completed the required web-based course (CITI) in the protection of human research subjects? Yes No

Educational requirements (initial and continuing) must be satisfied prior to submitting the application for IRB review. See <http://orrrp.osu.edu/irb/training/citi.cfm> or contact ORRP for more information.

9. CONFLICT OF INTEREST

Does any **OSU investigator** (including principal or co-investigator), **key personnel**, or their immediate family members have a significant financial interest (e.g., speaking and consultation fees, travel expenses, proprietary interest in the tested product, stock ownership or other equity or membership in the sponsor over \$10,000 per year or representing greater than 5% ownership in the sponsor) with the entity supporting the research or any company that may benefit from the research? Yes No

All OSU investigators and key personnel must have a current COI disclosure form filed before IRB review. See <http://orc.osu.edu/coi/index.cfm> for more information.

10. FUNDING OR OTHER SUPPORT

a. Is the research funded or has funding been requested? Yes No

If Yes → Specify sponsor: _____ and provide OSU RF project number: _____

b. Is there any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study? Yes No

If Yes → Specify: _____

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORRP for more information.

11. OTHER INSTITUTIONAL APPROVALS

Check all that apply and provide applicable documentation. *See websites listed below for information on obtaining approvals.*

None

Clinical Research Center (CRC) Scientific Advisory Committee (SAC) – Approval required for research sponsored by the CRC. Final IRB approval will be held pending receipt of SAC approval. See www.gcrc.osu.edu.

Institutional Biosafety Committee (IBC) – Approval required for research involving biohazards (recombinant DNA, infectious or select agents, toxins), gene transfer, or xenotransplantation. See <http://orrrp.osu.edu/ibc/> or contact ORRP.

Comprehensive Cancer Center (CCC) Clinical Scientific Review Committee (CSRC) – Approval or exemption required for cancer-related research. See www.osuccc.osu.edu/cscc or contact the CCC Clinical Trials Office.

Maternal-Fetal Welfare Committee – Approval required for some research involving pregnant women and fetuses. See <http://orrrp.osu.edu/irb/osupolicies/MFWreview.cfm> or contact ORRP.

- Human Subject Radiation Committee (HSRC)** – Approval required for research involving radiologic procedures for research purposes (e.g., non-clinical care X-rays, DEXA or CT scans, nuclear medicine procedures, etc.). See <http://orrr.osu.edu/irb/osupolicies/Radiation.cfm> or contact ORRP.

For the research described above, IRB review cannot be conducted until required institutional approvals or exemptions are obtained, except as noted.

12. LOCATION OF THE RESEARCH

- a. List the specific site(s) at which the OSU research will be conducted (include both domestic and international locations).

Location Name (or description)	Address (street, city and state, or country)
OSU College of Social Work	Stillman Hall / 1947 College Rd. Columbus, OH 43210

- b. Are all the sites named above on the OSU list of approved research performance sites? See <http://orrr.osu.edu/irb/osupolicies/researchsites.cfm>. Yes → Go to Question #13
 No

If No → Domestic sites → Provide a letter of support, as applicable

International sites → Complete **Appendix U**

Research to be conducted at locations other than approved performance sites will minimally require a letter of support and may require another IRB’s approval if personnel are engaged. See <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm> or contact ORRP for more information.

13. EXPEDITED REVIEW

- Are you requesting **Expedited Review**? Yes → Complete **Appendix B**
 No

14. SUMMARY OF THE RESEARCH

Summarize the proposed research using *non-technical* language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. *Use complete sentences (limit 300 words).*

Survey of young adults participating in the Alumni Support & Assistance Project (ASAP) pilot study. Data on the implementation of the intervention, participant life goals, contact with case manager/research assistant, participation in support groups, and participant outcomes will be collected during the 12-month study period (i.e., 1/1/2010-12/31/2010). Anticipated risks are minimal, in contrast to potentially important benefits informing the continued development of an innovative, low-cost, solution-focused, agency-based, education and employment-focused, replicable “aftercare” model for young adults “aging-out” of foster care, homelessness, and human trafficking into self-sufficiency.

15. SCIENTIFIC BACKGROUND & LITERATURE REVIEW

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. *Use complete sentences (limit 300 words).*

Solution-focused brief therapy (SFBT) is widely used, evidence-based therapeutic approach for both individuals and groups. Strengths-based case management is also a common therapeutic approach often utilized with adults with mental health problems. And within the field of education, “success coaching” is being used increasingly as an alternative means of assisting first generation and other at-risk and under-represented youth (versus the more traditional “deficits-based” approach) to succeed in college. The ASAP intervention integrates SFBT, strengths-based case management, and success coaching for (largely) parentless youth transitioning to adulthood, and is believed to be among the first of its kind “aftercare” intervention developed specifically for this underserved population.

16. RESEARCH OBJECTIVES

List the specific scientific or scholarly aims of the research study.

1. To implement an “aftercare” intervention for youth in Columbus who are transitioning to/through early adulthood (defined here as ages 18-26) with minimal support from their birth parents.
2. To identify life goals among youth participants, particularly concerning education and employment.
3. To determine the best means of maintaining contact with youth participants following discharge from respective “emancipation” treatment programs.
4. To assess participants’ satisfaction with the intervention and functional outcomes periodically throughout the study period.

17. RESEARCH METHODS & ACTIVITIES

- a. Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities.

The same methods and activities will be used for those ASAP intervention participants volunteering to participate in the “research” component of the project; namely, those who agree to have their information (along with their fellow ASAP participants) shared publicly. Research participants and non-participants will be surveyed/interviewed by the BSSW student case manager/research assistant, and by Dr. Mares, Dr. Conrad, and Ms. Dickson. Those data collected from research participants will be shared publicly, in aggregated form, whereas those data collected from non-research participants will not be disclosed. Data will be collected during individual weekly contacts with the case manager, and during monthly and quarterly solution-focused support group meetings.

- b. Check all research activities that apply:

- | | |
|---|---|
| <input type="checkbox"/> Anesthesia (general or local) or sedation | <input type="checkbox"/> Magnetic Resonance Imaging (MRI) |
| <input type="checkbox"/> Audio, video, digital, or image recordings | <input type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading |
| <input type="checkbox"/> Biohazards (e.g., rDNA, infectious agents, select agents, toxins) | <input type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler) |
| <input type="checkbox"/> Biological sampling (other than blood) | <input type="checkbox"/> Observation of participants (including field notes) |
| <input type="checkbox"/> Blood drawing | <input type="checkbox"/> Oral history (does not include medical history) |
| <input type="checkbox"/> Coordinating Center | <input type="checkbox"/> Placebo |
| X Data, not publicly available | <input type="checkbox"/> Pregnancy testing |
| <input type="checkbox"/> Data, publicly available | <input type="checkbox"/> Program Protocol (Umbrella Protocol) |
| <input type="checkbox"/> Data repositories → Complete Appendix C
(future unspecified use, including research databases) | <input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) → Complete Appendix V |
| <input type="checkbox"/> Deception → Complete Appendix D & Appendix M1 | <input type="checkbox"/> Randomization |
| <input type="checkbox"/> Devices → Complete Appendix E | <input type="checkbox"/> Record review (which may include PHI) |
| <input type="checkbox"/> Diet, exercise, or sleep modifications | <input type="checkbox"/> Specimen research |
| <input type="checkbox"/> Drugs or biologics → Complete Appendix F | <input type="checkbox"/> Stem cell research |
| <input type="checkbox"/> Emergency research | <input type="checkbox"/> Storage of biological materials → Complete Appendix H
(future unspecified use, including repositories) |
| <input type="checkbox"/> Focus groups | <input type="checkbox"/> Surgical procedures (including biopsies) |
| <input type="checkbox"/> Food supplements | X Surveys, questionnaires, or interviews (one-on-one) |
| <input type="checkbox"/> Gene transfer | X Surveys, questionnaires, or interviews (group) |
| <input type="checkbox"/> Genetic testing → Complete Appendix G | <input type="checkbox"/> Other |
| <input type="checkbox"/> Internet or e-mail data collection | Specify: _____ |

18. DURATION

Estimate the time required from each participant, including long-term follow-up, if any. Describe the time commitment in detail. No additional time will be required for "research data collection". ASAP intervention participants are expected to spend an average of 15 minutes per week communicating with the BSSW student case manager/research assistant, 60 minutes per month participating in small group discussions, and 60 minutes per month (on average) participating in large group discussions (i.e., 3 hours each quarter). Thus, the total estimated intervention/research time per week per participant is 45 minutes per week, on average, for 40 weeks (i.e., 52 weeks less 12 weeks break during OSU's Christmas/New Years, Spring Break, and Summer Recess).

19. NUMBER OF PARTICIPANTS

a. Provide the maximum number of participants (or number of participant records, specimens, etc.) for whom you are seeking OSU IRB approval. **20**

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not complete the study. The proposed maximum should include the number of participants who are required (considering participation criteria, withdrawals, etc.) to obtain the desired outcome of the study.

b. Explain how this number was derived.

An average of 5 young adults from each of the four youth-serving agencies/programs participating in the pilot study are expected to participate in the research component of the project.

c. Is this a multi-center study? Yes → Indicate the total number of participants to be enrolled across all sites: _____
 No [4 referral sources feeding into a single intervention coordination site]

The total number of research participants may be increased only with prior IRB approval.

20. PARTICIPANT POPULATION

a. Specify the age(s) of the individuals who may participate in the research:

Age(s): 18-26

b. Specify the participant population(s) to be included (check all that apply):

- | | |
|--|---|
| <input checked="" type="checkbox"/> Adults | <input checked="" type="checkbox"/> Pregnant Women/Fetuses → Complete Appendix K |
| <input type="checkbox"/> Adults unable to consent for themselves | <input type="checkbox"/> Prisoners → Complete Appendix L |
| <input type="checkbox"/> Children (< 18 years) → Complete Appendix I | <input type="checkbox"/> Students from participant pools (e.g., REP) |
| <input type="checkbox"/> Healthy volunteers | Specify: |
| <input type="checkbox"/> Neonates (uncertain viability/nonviable) → Complete Appendix K | <input type="checkbox"/> Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols) |
| <input type="checkbox"/> Non-English speaking → Complete Appendix J | |

c. Describe the characteristics of the population(s) and explain how the nature of the research requires/justifies inclusion of the proposed population(s).

Youth in transition, ages 18-26, preparing for discharge from independent living or related self-sufficiency preparation programs at four youth-serving agencies serving the greater Columbus area.

d. Will pregnant women be excluded from participation in the research? Yes
 No

If Yes → Explain how the nature of the research requires/justifies their exclusion. Address means of pregnancy screening.

21. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

- a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how the method(s) for identifying potential participants respects their privacy.

Potential participants will be referred by the staff of those youth-serving agencies participating in ASAP.

- b. State who (investigators and/or key personnel) will recruit participants and what process will be used to determine participant eligibility.

Dr. Mares, the P.I., in consultation with agency staff, will determine participant eligibility; namely, a high level of interest in participating in ASAP and a sufficiently high level of functioning to assist oneself and his/her ASAP peers by doing so.

- c. Describe the recruitment process; including how and where recruitment will take place. *Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).*

A written script (see attached) will be used to recruit potential participants referred to the ASAP intervention by program staff. This script will be read either in-person during a small or large group meeting or by phone.

22. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? Yes No

If Yes → Describe the incentive. *Compensation should be pro-rated (e.g., per visit) and not contingent upon study completion.* Participants will receive food and beverages during small and group meetings (e.g., pizza and soda).

23. INFORMED CONSENT PROCESS

- a. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply.

- | | |
|---|--|
| <input type="checkbox"/> Assent – Form | <input type="checkbox"/> Parental Permission – Form |
| <input type="checkbox"/> Assent – Verbal Script | <input type="checkbox"/> Parental Permission – Verbal Script → Complete Appendix M2 |
| <input checked="" type="checkbox"/> Informed Consent – Form | <input type="checkbox"/> Translated Consent/Assent – Form(s) → Complete Appendix J |
| <input type="checkbox"/> Informed Consent – Verbal Script → Complete Appendix M2 | <input type="checkbox"/> Waiver or Alteration of Consent Process → Complete Appendix M1 |
| <input type="checkbox"/> Informed Consent – Addendum | <input type="checkbox"/> Waiver of Consent Documentation → Complete Appendix M2 |

Provide copies of documents (using OSU templates) and/or complete relevant appendices, as needed. See <http://orrrp.osu.edu/irb/consent/index.cfm> or contact ORRP for more information. ^

- b. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. N/A

After potential participants are referred by agency staff to ASAP, Dr. Mares will meet with them to verbally review both the aspects of the ASAP intervention (i.e., weekly contacts by case manager/life coach, monthly and quarterly support group meetings), and the research component of the pilot project (i.e., sharing of aggregated information collected during the 12-month pilot study period). After doing so, including a verbal “walk-through” of the written consent form, potential participants will be asked if they wish to participate in (a) the ASAP intervention, and (b) the research component of the pilot project. Those wishing to participate in either (or both) will be asked to sign and date the written consent form, and will thus be enrolled into the intervention (and possibly into the research component of the project, if applicable).

- c. List the investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives. N/A

Dr. Mares will be the sole person obtaining written consent from participants.

- d. Explain how the possibility of coercion or undue influence will be minimized in the consent process. N/A
 Participants' right to "opt-out" of the public sharing of their information routinely collected throughout the ASAP intervention at the end of the pilot project/study will be emphasized by Dr. Mares during the recruitment process. This is reflected in the attached recruitment script.
- e. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? Yes → *Provide copies of these tools*
 No
- f. Will any other consent forms be used (e.g., for clinical procedures such as MRI, surgery, etc. and/or consent forms from other institutions)? Yes → *Provide copies of these forms*
 No

24. CAPACITY TO CONSENT

Will adult participants with limited decision-making capacity or who lack the ability to consent be recruited in this research study? Yes
 No

If Yes → Describe the likely range of participant impairment and explain how, and by whom, the capacity to consent/assent will be determined. For adults unable to provide legally effective informed consent, indicate whether assent will be obtained; or if not, explain why not.

25. PRIVACY & CONFIDENTIALITY

a. Does the research require access to personally identifiable private information? Yes
 No

If Yes → Describe the steps you will take to ensure protection of the participants' privacy.

Only two pieces of personally identifiable private information will be collected: name and date of birth. To safeguard this information, the case manager/life coach and group co-facilitators will record participant names as first name plus the initial of the last name (e.g., Alvin M.) on all data collection instruments/forms. Note that the collection of participant date of birth is deemed necessary in order to celebrate birthdays during monthly and quarterly support group meetings.

b. Will personal or sensitive information (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) be accessed or collected from participants? Yes
 No

If Yes → Describe information.

c. Could disclosure of information be potentially damaging to participants' financial standing, employability or reputation, or place the participants at risk of criminal or civil liability? Yes
 No

If Yes → Explain.

d. Explain how you will protect the confidentiality of identifiable data, including where data will be stored, what security measures will be applied, and who will have access to the data.

Completed forms will be stored in a locked filing cabinet in Dr. Mares' office on-campus (i.e., Stillman Hall, Rm. 325-Q). Moreover, electronic data will be secured on Dr. Mares' password-protected computer located within his office on-campus.

e. Will you be obtaining a NIH Certificate of Confidentiality? Yes → *Provide a copy before you begin the research*
 No

See <http://grants2.nih.gov/grants/policy/coc/index.htm> for more information.

f. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. X N/A

g. Indicate what will happen to the identifiable data at the end of the study. Check all that apply:

- Identifiers separated or permanently removed from the data
- Identifiable/coded data is retained
- X Other, specify: Excel file and SPSS data file containing participants' first name and last name initial will be retained.
- N/A

h. Indicate how study results might be disseminated. Check all that apply:

- X Conference/Presentation
- X Dissertation/Thesis
- X Publication/Journal article
- Other, specify: _____

26. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the [HIPAA Privacy Rule](#) requirements be accessed, used, or disclosed in the research study? Yes
 No → Go to Question #27

If Yes → Will a written authorization be used?

- Yes → **Provide a copy of the Authorization Form**
 - a. Describe the PHI involved in the research (e.g., demographic information, health history, diagnosis, test results). Be as specific as possible. **Provide a copy of the data collection form(s) to be used.**

- b. List the source(s) of the PHI (e.g., OSUMC Information Warehouse, physician's own records, etc.), including whether any information will be obtained from sources external to OSU.

- No → Indicate the type of waiver or alteration requested (check all that apply) and complete **Appendix N**.
 - Partial Waiver (recruitment purposes only)
 - Full Waiver (entire research study)
 - Alteration (written documentation)

27. REASONABLY ANTICIPATED BENEFITS

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. **Compensation is not to be considered a benefit.**

Participants will be assisted and supported in attaining their life goals, including educational and employment-related goals, that they establish for themselves at the beginning of the ASAP intervention.

b. List the potential benefits that society and/or others may expect as a result of this research study.

Other youth in transition in Columbus may benefit from the results of this study through the on-going development and refinement and expansion of the ASAP intervention. Moreover, society may benefit as the well-being of youth in transition is enhanced and their life goals are realized, making them more productive and contributing members of the local community.

28. RISKS, HARMS, & DISCOMFORTS

a. Indicate all reasonably expected risks/harms/discomforts that may apply to the research study:

- | | |
|---|---|
| <input type="checkbox"/> Breach of confidentiality | <input type="checkbox"/> Psychological stress |
| <input type="checkbox"/> Discovery of previously unknown condition | <input type="checkbox"/> Risk to reputation |
| <input type="checkbox"/> Economic risk | <input type="checkbox"/> Social or legal risk |
| <input checked="" type="checkbox"/> Invasion of privacy (participants or other individuals) | <input type="checkbox"/> Other |
| <input type="checkbox"/> Physical injury or discomfort | Specify: _____ |

b. For each category of risk checked above, describe the specific risk. For physical injury or discomfort include the following:

- Frequency/likelihood of occurrence
- Potential severity of the harm/discomfort
- Possible consequences (including long-term effects)

Reference the section of this application (e.g., Appendix F for drugs) if the risks are described elsewhere.

By participating in small and large support groups, participants' privacy may be compromised by their peers.

c. Describe the specific protections that will be used to minimize the identified risks and harms.

Confidentiality will be stressed as an important rule of all groups; namely, what's shared within the group "stays within the group" and will not be gossiped-about outside of the group.

29. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Question #28 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? Yes No

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

30. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

The anticipated benefits are believed to far exceed/outweigh the minimal risks, especially in light of the serious risks of homelessness, dropping-out of school, becoming incarcerated, birthing or fathering a child out-of-wedlock, etc. routinely experienced by youth aging-out of foster care in particular and at-risk youth in transition in general. We believe that having someone check-in with these young adults weekly and meeting with them in small groups monthly and in a larger quarterly may help them to make important, life-altering decisions and to access existing services/resources needed to attain their life goals. To this investigator's knowledge, there is no such existing "aftercare" intervention for youth in transition in Columbus or elsewhere in Ohio. Thus, this pilot project may generate particularly useful information for both knowledge and program development purposes.

31. ALTERNATIVES TO STUDY PARTICIPATION

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject.

Since ASAP is an adjunctive intervention, potential participants who decide to not participate in the intervention may access usually available services. Those referred but not enrolled into ASAP will be referred to FirstLink to identify such usually available services.

32. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs subjects (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

N/A.

b. List any costs to participants that will be covered by the research study.

OSU parking vouchers will be offered to all participants attending quarterly meetings on-campus in Stillman Hall.

33. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes.

- Initial Review of Human Subjects Research Application**
- Appendix A1: OSU Co-Investigators & Key Personnel (questions 4 & 5)
- Appendix A2: External (non-OSU) Co-Investigators & Key Personnel (question 6)
- Appendix B: Expedited Review – Initial Review (question 13)
- Appendix C: Data Repositories (question 17b)
- Appendix D: Deception (question 17b)
- Appendix E: Devices (question 17b)
- Appendix F: Drugs or Biologics (question 17b)
- Appendix G: Genetic Testing (question 17b)
- Appendix H: Storage of Biological Materials (question 17b)
- Appendix I: Children (question 20b)
- Appendix J: Non-English Speaking Participants (questions 20b and 23a)
- Appendix K: Pregnant Women/Fetuses/Neonates (question 20b)
- Appendix L: Prisoners (question 20b)
- Appendix M1: Waiver or Alteration of Consent Process (questions 17b & 23a)
- Appendix M2: Waiver of Consent Documentation (question 23a)
- Appendix N: Waiver of HIPAA Research Authorization (question 26)
- Appendix U: Research in International Settings (question 12)
- Appendix V: Radiation (question 17b)
- Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question 23a)
- HIPAA Research Authorization Form(s) (question 26)
- Data Collection Form(s) involving protected health information (question 26a)
- Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 21c)
- Script(s) or Information Sheet(s), including Debriefing Materials (question 23a)
- Instruments (e.g., questionnaires or surveys to be completed by participants) (question 17b)
- Other Committee Approvals/Letters of Support (questions 11 & 12)
- Research Protocol
- Complete Grant Application
- Drug Manufacturer’s Approved Labeling/Investigator’s Drug Brochure (Appendix F)
- Device Manufacturer’s Approved Labeling (Appendix E)
- Other supporting documentation and/or materials

For Multi-Center Clinical Trials supported by DHHS, the submission will also include:

- DHHS-approved Sample Informed Consent Document (if one exists)
- DHHS-approved Protocol (if one exists)

34. ASSURANCE

PRINCIPAL INVESTIGATOR (or Advisor)

I agree to follow all applicable policies and procedures of The Ohio State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- The research will be performed as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- The research will not be initiated until written notification of IRB approval has been received;
- Informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) will be obtained and documented (unless waived) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others;
- Significant new findings that develop during the course of the study that may affect the risks or benefits of participation will be reported;
- The IRB will be informed of any proposed changes in the research or informed consent process before changes are implemented, and no changes will be made until approved by the OSU IRB (except where necessary to eliminate apparent immediate hazards to participants);
- A Continuing Review of Human Subjects Research application will be completed and submitted before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Research-related records (and source documents) will be maintained in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Research-related records will be retained and available for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- The Office of Responsible Research Practices will be contacted for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave);
- A Final Study Report will be provided to the IRB when all research activities have ended (including data analysis with individually identifiable or coded private information); and
- All Co-Investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this Initial Review of Human Subjects Research application is accurate and complete.

Signature of Principal Investigator (or Advisor)

Date

Printed name of Principal Investigator (or Advisor)

DEPARTMENT CHAIR (or Signatory Official)

As Department Chair (or Signatory Official) for the Principal Investigator, I acknowledge that this research is in keeping with the standards set by our unit and that it has met all Departmental/College requirements for review.

If the PI or any Co-Investigator is also the Department Chair, the signature of the Dean or other appropriate Signatory Official, such as the Associate Dean for Research, must be obtained.

Signature of Department Chair

Date

Printed name of Department Chair

APPENDIX A1

OSU Co-Investigators & Key Personnel

Complete this form to list OSU Co-Investigators and key personnel on the research study. Signatures are required of all OSU Co-Investigators. Use [Appendix A2](#) to list external (non-OSU) Co-Investigators and key personnel.

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit or consent participants or who collect study data.

All OSU individuals listed on this protocol will have access to information about IRB actions and the completion status of each individual's administrative and training requirements (CITI, COI disclosure). Note: Personal financial information provided in COI disclosures is not included.

PI Name: Alvin S. Mares, PhD

OSU CO-INVESTIGATORS

As Co-Investigator, I agree to comply with all policies and procedures of The Ohio State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators.

Name (Last, First, MI):	N/A	Degree(s):
University Academic Title:		College (TIU):
Department Name (TIU):		Phone:
Department # (TIU):		E-mail:
OSU ID Number:		

Signature of Co-Investigator

Date

Printed name of Co-Investigator

OSU KEY PERSONNEL

Name (Last, First, MI):	Satchell, Samantha	University Title:	BSSW Student (Research Assistant)
Department Name:	Social Work	OSU ID Number:	
E-mail:	satchell.9@buckeyemail.osu.edu	Phone:	(414) 322-6339

Name (Last, First, MI):		University Title:	
Department Name:		OSU ID Number:	
E-mail:		Phone:	

Name (Last, First, MI):		University Title:	
Department Name:		OSU ID Number:	
E-mail:		Phone:	

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PI Name: Alvin S. Mares, PhD

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As Co-Investigator, I agree to comply with all policies and procedures of The Ohio State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators.

Name (Last, First, MI):	N/A	Degree(s):
University Academic Title:		College (TIU):
Department Name (TIU):		Phone:
Department # (TIU):		E-mail:
OSU ID Number:		

Signature of Co-Investigator

Date

Printed name of Co-Investigator

OSU KEY PERSONNEL

Name (Last, First, MI):	Satchell, Samantha	University Title:	BSSW Student (Research Assistant)
Department Name:	Social Work	OSU ID Number:	
E-mail:	satchell.9@buckeyemail.osu.edu	Phone:	(414) 322-6339

Name (Last, First, MI):		University Title:	
Department Name:		OSU ID Number:	
E-mail:		Phone:	

Name (Last, First, MI):		University Title:	
Department Name:		OSU ID Number:	
E-mail:		Phone:	

Name (Last, First, MI):		University Title:	
Department Name:		OSU ID Number:	
E-mail:		Phone:	

APPENDIX A2

External (non-OSU) Co-Investigators & Key Personnel

Complete this form to list external (non-OSU) Co-Investigators and key personnel if they are engaged in the research and you are requesting that an OSU IRB provide approval for their research activities on the study. Use [Appendix A1](#) to list OSU Co-Investigators and key personnel.

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit or consent participants or who collect study data.

“Engaged” individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by OSU. See <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm> or contact ORRP for more information.

PI Name: Alvin S. Mares, PhD

EXTERNAL CO-INVESTIGATOR(S) & KEY PERSONNEL

Name (Last, First, MI):	Conrad, Tim	Title:		
Organization:		Degree:	PhD, LPC	
E-mail:	timlconrad@gmail.com	Phone:	(614) 314-7690	
Research role/activities performed in study:	ASAP Group Co-Facilitator			<input type="checkbox"/> Co-Investigator <input checked="" type="checkbox"/> Key Personnel

Name (Last, First, MI):	Dickson, Lisa	Title:		
Organization:		Degree:	MLS	
E-mail:	lisa@miss-lisa.com	Phone:	(614) 787-5257	
Research role/activities performed in study:	ASAP Group Co-Facilitator			<input type="checkbox"/> Co-Investigator <input checked="" type="checkbox"/> Key Personnel

Name (Last, First, MI):		Title:		
Organization:		Degree:		
E-mail:		Phone:		
Research role/activities performed in study:				<input type="checkbox"/> Co-Investigator <input type="checkbox"/> Key Personnel

Name (Last, First, MI):		Title:		
Organization:		Degree:		
E-mail:		Phone:		
Research role/activities performed in study:				<input type="checkbox"/> Co-Investigator <input type="checkbox"/> Key Personnel

Name (Last, First, MI):		Title:		
Organization:		Degree:		
E-mail:		Phone:		
Research role/activities performed in study:				<input type="checkbox"/> Co-Investigator <input type="checkbox"/> Key Personnel

APPENDIX K

Pregnant Women/Fetuses/Neonates

Complete this form to request inclusion of participants who are pregnant, fetuses, or neonates (of uncertain viability and nonviable) in the proposed research. The inclusion of these groups as participants in research requires that the investigator comply with the additional protections provided in [45 CFR 46 Subpart B](#).

Research involving pregnant women and fetuses may require approval by the Maternal-Fetal Welfare Committee. See <http://orrrp.osu.edu/irb/osupolicies/MFWreview.cfm> or contact ORRP for more information.

Research involving “viable” neonates must comply with the additional regulatory protections for children → Complete [Appendix I](#). For children who are pregnant, assent and parental permission are required.

Indicate the applicable section(s) and provide the corresponding information below.

- A. Pregnant Women and Fetuses
 B. Neonates (of uncertain viability and nonviable)

PI Name: Alvin S. Mares, PhD

A. Pregnant Women and Fetuses

1. Describe preclinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women), where scientifically appropriate, that provide data for assessing potential risks to pregnant women and fetuses.

There are no such studies known to this P.I.

2. Indicate for whom the prospect of **direct benefit** exists:

- Pregnant woman
 Fetus
 Both
 Neither

The father's consent must be obtained for research that holds the prospect of direct benefit solely to the fetus, unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

3. The risk to the fetus is (check one):

- Caused solely by procedures that hold the prospect of direct benefit for the woman or fetus
 Not greater than minimal and the purpose of the research is development of important knowledge that cannot be obtained by any other means, but there is no prospect of direct benefit

4. Explain how the risks are the least possible for achieving the objectives of the research.

None of the ASAP intervention/research procedures involve either the fetus or minor child(ren) of female or male participants. Only adults will be surveyed/interviewed, some of whom may be or become pregnant or father a child over the 12-month study period.

B. Neonates - Only neonates of uncertain viability and nonviable neonates

1. State who (other than investigators and key personnel) will determine the viability of a neonate and what procedures will be used to determine viability.

N/A

2. Describe preclinical studies and clinical studies, where scientifically appropriate, that provide data for assessing potential risks to neonates.

3. The viability of neonates to be involved in the research is:

- Uncertain Viability
- Nonviable
- Both

4. For neonates of uncertain viability, the risk to the neonate is (check one):

- The least possible and the research holds the prospect of enhancing the probability of survival to the point of viability
- No added risk will result from the research and the purpose of the research is development of important knowledge that cannot be obtained by other means
- N/A

The consent of either parent or either parent’s legally authorized representative (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity) is required, except that the consent of the father (or his legally authorized representative) need not be obtained if the pregnancy resulted from rape or incest.

5. For neonates of uncertain viability, explain how the research meets one of the two conditions above. N/A

6. For nonviable neonates, explain how each of the following conditions for inclusion are met: N/A

- a. There will be no added risk to the neonate resulting from the research.

- b. The purpose of the research is the development of important knowledge that cannot be obtained by other means.

The consent of both parents is required. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

1
2 **The Ohio State University Consent to Participate in Research**
3
4

Study Title: **Ohio Youth in Transition – Alumni Support and Assistance Project (ASAP)**

Researcher: **Alvin S. Mares, PhD**

Sponsor:

5
6
7 **This is a consent form for research participation.** It contains important information about
8 this study and what to expect if you decide to participate.

9 **Your participation is voluntary.**

10 Please consider the information carefully. Feel free to ask questions before making your
11 decision whether or not to participate. If you decide to participate, you will be asked to sign
12 this form and will receive a copy of the form.

13
14 **Purpose:**

- 15 1. To implement an “aftercare” intervention for youth in Columbus who are transitioning
16 to/through early adulthood (defined here as ages 18-26) with minimal support from their birth
17 parents.
18 2. To identify life goals among youth participants, particularly concerning education and
19 employment.
20 3. To determine the best means of maintaining contact with youth participants following
21 discharge from respective “emancipation” treatment programs.
22 4. To assess participants’ satisfaction with the intervention and functional outcomes
23 periodically throughout the study period.
24
25

26 **Procedures/Tasks:**

27
28 ASAP Intervention

- 29 - Weekly "well-being" contacts with case manager/life coach
30 - Monthly small group meetings with youth from each pilot site/program
31 - Quarterly larger group, "all-sites" psycho-educational meetings at OSU
32

33 Research Component (Optional)

34 Sharing of information about yourself, your life goals, contact with your case manager and
35 participation in groups, your satisfaction with ASAP, and your accomplishments in school, at
36 work, and in other basic aspects of life.
37

38 **Duration:**

39
40 The ASAP intervention/pilot research study will last one year, from January 1, 2010, through
41 December 31, 2010.

42
43 You may leave the study at any time. If you decide to stop participating in the study, there
44 will be no penalty to you, and you will not lose any benefits to which you are otherwise
45 entitled. Your decision will not affect your future relationship with The Ohio State
46 University.

47
48 **Risks and Benefits:**

49
50 The major anticipated risk of participating is an invasion of privacy, primarily due to
51 participating in monthly and quarterly support group meetings with other young adults in
52 transition.

53
54 The major anticipated benefit of participating is assistance and support in achieving life goals
55 (including educational and employment) that you identify for yourself.

56
57 **Confidentiality:**

58
59 Efforts will be made to keep your study-related information confidential. However, there may
60 be circumstances where this information must be released. For example, personal information
61 regarding your participation in this study may be disclosed if required by state law. Also,
62 your records may be reviewed by the following groups (as applicable to the research):

- 63 • Office for Human Research Protections or other federal, state, or international
64 regulatory agencies;
- 65 • The Ohio State University Institutional Review Board or Office of Responsible
66 Research Practices;
- 67 • The sponsor, if any, or agency (including the Food and Drug Administration for FDA-
68 regulated research) supporting the study.

69
70 **Incentives:**

71
72 You will receive food and beverages at monthly and quarterly support group meetings.

73
74 **Participant Rights:**

75
76 You may refuse to participate in this study without penalty or loss of benefits to which you
77 are otherwise entitled. If you are a student or employee at Ohio State, your decision will not
78 affect your grades or employment status.

79
80 If you choose to participate in the study, you may discontinue participation at any time
81 without penalty or loss of benefits. By signing this form, you do not give up any personal
82 legal rights you may have as a participant in this study.

83

84 An Institutional Review Board responsible for human subjects research at The Ohio State
85 University reviewed this research project and found it to be acceptable, according to
86 applicable state and federal regulations and University policies designed to protect the rights
87 and welfare of participants in research.

88

89 **Contacts and Questions:**

90 For questions, concerns, or complaints about the study you may contact: **Alvin Mares, PhD,**
91 **Assistant Professor, College of Social Work, OSU, at (614) 292-0425.**

92

93 For questions about your rights as a participant in this study or to discuss other study-related
94 concerns or complaints with someone who is not part of the research team, you may contact
95 Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

96

97 If you are injured as a result of participating in this study or for questions about a study-
98 related injury, you may contact: **Alvin Mares, PhD, Assistant Professor, College of Social**
99 **Work, OSU, at (614) 292-0425.**

100

101

102 **Signing the consent form**

103
104 I have read (or someone has read to me) this form and I am aware that I am being asked to
105 participate in a research study. I have had the opportunity to ask questions and have had them
106 answered to my satisfaction. I voluntarily agree to participate in this study.

107
108 I am not giving up any legal rights by signing this form. I will be given a copy of this form.

109
110 **ASAP Intervention (i.e., weekly case manager contacts, monthly and quarterly groups)**

111

_____	_____
Printed name of subject	Signature of subject
	_____ AM/PM
	Date and time
_____	_____
Printed name of person authorized to consent for subject (when applicable)	Signature of person authorized to consent for subject (when applicable)
	_____ AM/PM
_____	_____
Relationship to the subject	Date and time

112

113 **Research Component (i.e., sharing of aggregated, anonymous participant information)**

114

_____	_____
Printed name of subject	Signature of subject
	_____ AM/PM
	Date and time
_____	_____
Printed name of person authorized to consent for subject (when applicable)	Signature of person authorized to consent for subject (when applicable)
	_____ AM/PM
_____	_____
Relationship to the subject	Date and time

115

116 **Investigator/Research Staff**

117

118 I have explained the research to the participant or his/her representative before requesting the
119 signature(s) above. There are no blanks in this document. A copy of this form has been given
120 to the participant or his/her representative.

121

_____	_____
Printed name of person obtaining consent	Signature of person obtaining consent
	_____ AM/PM
	Date and time

122

Ohio Youth in Transition
Alumni Support and Assistance Project (ASAP)

Written Script for Recruiting Potential Participants referred to ASAP by Agency Staff

9-22-09

Hello. My name is Alvin Mares. I am a professor in the College of Social Work at Ohio State University. We are excited about working with you through the Ohio Youth in Transition Alumni Support & Assistance Project (ASAP) in the weeks and months ahead to help you reach the life goals that you identify for yourself. Do you have any questions about ASAP? [Answer any questions.]

As you meet regularly with your case manager/life coach and as we meet regularly in small and large groups for support and assistance, basic information will be gathered and updated over time about yourself, your life goals, contact with your case manager and participation in groups, your satisfaction with ASAP, and your accomplishments in school, at work, and in other basic aspects of life. Do you have any questions about the types of information that will be routinely collected as part of the ASAP program? [Answer any questions.]

After working together for a year or so, we would like to share some of what we have learned from our experience working together and from the information gathered with other researchers and service providers interested in assisting youth transitioning to adulthood, such as yourself. In sharing with others, we would NOT share information about you individually and by name, rather we would share information on the experiences of everyone participating in ASAP, with possible “case-specific” illustrations in which individual youth names are changed to safeguard your confidentiality. Do you have any questions about how participant information may be shared after this 1-year pilot project is completed in December of 2010? [Answer any questions.]

You may, however, request at any time that your information be excluded from such reporting of ASAP pilot study results. Regardless of whether (or not) you request for your information to be excluded from the reporting of pilot study results, you will receive the same level of assistance and support through ASAP in the coming weeks or months. Do you have any questions about your right to request, at any time, that your information not be shared with others after the pilot study is completed? [Answer any questions.]

Okay. So it's now time to review the “Consent to Participate” form, which is intended to provide you with a little more detailed information about the ASAP intervention and the research component of the pilot study (i.e., the sharing of information for participants as a group after the pilot study is completed). After we review it together, I'll ask you to decide whether or not you would like to participate in ASAP and the research component of the project. Shall we review the form together now? [If YES, continue to verbally review the consent form. IF NO, ask why not and exclude from participation in ASAP or in the research component of the project, as applicable.]