Study Protocol, Statistical Analysis Plan and Consent Forms for "A Randomized Trial of Letting Go and Staying Connected, an Interactive Parenting Intervention to Reduce Risky Behaviors Among Students"

**Investigators and Environment** 

WSU. Drs. Hill, Bumpus, and Cooper are faculty in the Prevention Science doctoral program at Washington State University (WSU). Collectively, they have extensive research experience in parent-child relationships; young adult risk and protective factors; and evaluation of prevention program implementation and outcomes. Dr. Hill was PI on a NIDA grant to develop econometric methods to improve evaluation of prevention program implementation and effects, is Director of Research for WSU 's Health Promotionunit, with a focus on preventing risk behaviors among first-year students transitioning to university, and will be responsible for management of all aspects of the grant as well as dissemination of scholarship. Dr. Bumpus was PI on an NICHD grant to study parent-child communication and is currently PI on a grant studying parent communication and alcohol use during the transition to college. He will serve as the primary liaison among UW data management and analysis personnel and the WSU team of faculty, and will lead training for graduate students. Dr. Cooper was a fellow on a NIDA methodological training grant and is an expert in parent-child relationships and person-centered analytic techniques. She was previously an investigator on a NIDA grant to develop program implementation and evaluation systems and will supervise 1) collaboration with Drs. Lee and Abar in development of new parent-student communication measures in Year 1, 2) preparation of the Parent Handbook, and 3) the development and implementation of the "Handbook Plus" booster messages. In the Budget Justification and Biosketches (Appendices), individual responsibilities are specified in detail.

**UW**. Drs. Haggerty, Catalano, and Skinner of the Social Development Research Group (SDRG) at University of Washington join this on-site team, bringing widespread experience developing and testing family, school, and community preventive interventions, as well as theory development and testing. Dr. Haggerty is Director of SDRG. He will oversee analysis and contribute to manuscript writing and will participate in the refinement of the intervention, measures, intervention implementation and the evaluation design. Dr. Catalano is former Director of SDRG; he will provide his expertise in research methodology and family substance abuse and prevention. Dr. Skinner is a statistician with expertise in hierarchical linear modeling, structural equation modeling and modeling of non-normal data over time. Her work includes growth trajectories of social and physical development and complex mediation and moderation models. She will participate in measurement refinement, conduct data analyses, and participate in dissemination. Please see the Budget Justification and Biosketches (Appendices), individual responsibilities are specified in detail.

**Consultants**: Dr. Lee is an expert on daily-level data collection and measurement development, in particular for marijuana use and consequences. Dr. Abar is an expert in parental influences on emerging adult substance use and communication. Dr. Borah is an expert on health-related communications using technology. Please see attached biosketches for additional information.

**Environment.** Our environment is well suited to the project. WSU administrators supported the pilot and are enthusiastic about the proposed study, as evidenced by letters of support from the Dean of Students and Executive Director of Health and Wellness Services (Appendix A), and in 2013, the WSU President's Task Force on Alcohol Misuse recommended targeting parents of first-year students. SDRG established a Survey Research Division (SRD) in 1990 that collects all data for SDRG and for many investigators outside of SDRG and will be responsible for collecting, cleaning, and managing data in this study. The SRD has a strong reputation for producing high initial and follow-up response rates for longitudinal studies and high data quality with little missingness. The WSU and UW investigators have worked together for years on state-level prevention committees and collaborated effectively on the development and pilot testing of the intervention.

#### **Approach**

**Institutional Review**. We will submit for approval all procedures and materials to be used during the assignment, recruitment, and consent process, as well as all other communications, measurements, and procedures to the Washington State University (WSU) Institutional Review Board.

**Target Population.** Our target sample size is 900 first-year parent-student dyads, across two cohorts of 450 dyads each, at Washington State University. For each cohort, we will randomly assign 150 dyads to a Handbook-only condition, 150 to a Handbook-plus-boosters condition, and 150 to the control condition. We anticipate that sample demographics will reflect race, ethnicity and SES demographics of the undergraduate student body, which is 65.5% European American; 4.2% African American, 0.7% American Indian, 5% Asian or Pacific Islander, 11.5% Hispanic/Latino; and 9% other race/ethnicities. Students are eligible if they lived in the United States with their parent(s)/caregiver(s) before coming to WSU; will be leaving home for college for the first time; and are aged 18 through 20.

**Recruitment and Assignment.** We will work with WSU's Office of Student Enrollment Management (see letter of support in Appendix A) to identify students who meet inclusion criteria. The 2013-14 WSU student body is 53% male and at least 27% students of color. Based on previous handbook studies with this population and on SDRG uptake rates, we anticipate a 75%-85% rate of agreement to participate (26,53,164a) and will thus draw an initial sample of 1250 (625 per cohort) to achieve our target sample (1250\*.75=900). We will send letters of invitation for the proposed study to the initial sample using an advance letter, to be sent in mid-June, about 2 months before students start school. The letter will inform parents and students about the project's purpose, outline eligibility criteria, and describe assessments and related compensation and ask for their

voluntary consent to be randomly assigned to one of three intervention conditions: Handbook Only, Handbook Plus, or control. WSU's Dean of Students and the Executive Director of Student Health and Wellness Services will sign the letter along with the PI. We will block by gender and race/ethnicity to achieve balance across conditions

**Retention.** SDRG has just completed a followup of a young adult sample (age 25) with 100% location and 87% participation. The sample was last contacted at age 15. Based on our long and well-documented experience (26,53,162) and given that the proposed study population lives on or near campus, we expect a minimum 90% retention rate over 2 years. Retention of participants will be addressed in several ways. First, each student participant will receive incentives for assessment participation-- \$20 for baseline and three follow-up surveys and \$30 for their completion of the fourth and final follow-up survey. Respondents who complete the TLFB daily surveys will receive an extra \$30. Second, we will obtain the names and contact information of three individuals who would be expected to know the whereabouts of families that move during the project. Third, regular mailings and phone calls will provide reminders for participants of surveys. Finally, internet resources will help in locating participants. Procedures such as these have been used successfully at SDRG and will allow us to retain students in the study even if they leave university during the study period.

#### **Procedures and Intervention Content**

**Surveys**. Each cohort will be followed from the web-based baseline survey through spring of their second year or for 21 months if no longer matriculated. The baseline survey will be delivered to parents and students in mid-May, before students' August matriculation. Intervention participants will receive the Handbook after completing surveys. Students and parents will also complete surveys in late fall of their 1<sup>st</sup> year (4m after baseline), and students only will complete 3 further surveys at 9m, 16m, and 21m past baseline. Participants will have a 6-week window in which to answer the baseline survey and 4 weeks to answer the fall/spring surveys, with several prompts via phone, email, and/or postal mail.

Table 2. Timeline of Proposed Grant Activities														
Season/Year of Grant	F1	W1	S1	F2	W2	S2	F3	W3	S3	F4	W4	S4	F5	W5
Design surveys	Χ													
Booster programming/test/revision		Χ												
Edit/redesign pilot handbook & print	Χ	Χ												
Recruitment, consent, baseline survey (S/P)			C1			C2								
Early semester 1, two follow-back surveys (S)				C1			C2							
Parents receive boosters				C1	C1	C1	C1/2	C1/2	C1/2	C2	C2			
Late semester 1 surveys/calls (4mo) (S/P)				C1			C2							
Late semester 2 survey (9mo) (S)					C1			C2						
Late semester 3 survey (16mo) (S)							C1			C2				
Late semester 4 survey (21mo) (S)								C1			C2			
Record academic/demographic data			٧	٧	٧	٧	٧	٧	٧	٧	٧	٧		
Tracking & retention activities						٧	٧	٧	٧	٧	٧	٧		
Clean, merge, compute variables					٧	٧	٧	٧	٧	٧	٧	٧		٧
Data & attrition analysis						٧	٧	٧	٧	٧	٧	٧	٧	٧
Manuscript preparation						٧	٧	٧	٧	٧	٧	٧	٧	٧
Investigator/consultant meetings	٧	٧	٧	٧		٧	٧		٧	٧		٧		٧

NOTE: P = Parent data collection S = Student data collection C1 = Cohort 1 C2 = Cohort 2 F = Fall semester W = Spring semester S = Summer

Graduate student Family Consultants (FCs) will call to orient parents to the survey and research project and to answer questions about the study. During the Year 1 Fall data collection, FCs will also call parents to collect program feedback and implementation data. A Program Coordinator with extensive experience in monitoring participation in parent interventions will provide weekly supervision of the FCs during the month before the Handbook is sent and will train and supervise FCs in refusal prevention strategies, such as asking questions about and addressing participants' concerns regarding participation in the study; in motivational interviewing techniques; and in problem solving to overcome participation obstacles. The Program Coordinator will provide similar coaching and supervision during the collection of implementation data.

To achieve Aim 3 student participants in the normative control condition will also complete 2 one-week timeline follow-back (TLFB) surveys of risk behavior and parent-student communication. The first will take place early in their first semester (during the highest-risk period for first-year students), and the second will occur the week after Halloween, a holiday which has historically been associated with higher rates of risk behavior. TLFB designs, in which people retrospectively report daily behaviors, have been shown to provide reliable and valid assessments of substance use. The test-retest reliability of the TLFB method has been well established for assessment periods of up to 90 days and concordance between prospective dairy methods and TLFB is greater than with retrospective summary reports of drinking, particularly for short time intervals like the 7-day follow-back used in the present study. Students will report on their daily substance use and risk behaviors and their communication with parents, including content, emotional tone, timing, duration, mode, and frequency. This finer-grained look at daily parent-student conversation patterns will provide as many as 4200 data points (14 days X 300 participants). This approach will allow us to use both variable-centered and personcentered analytic methods to identify and describe profiles of parent-student communication, mode, and frequency). We

chose the design to maintain acceptable respondent burden yet still include sufficient days for observing variation in affect, behavior, and social experiences In a similar study with 1<sup>st</sup>-semester college students, 86% of students completed 12 of 14 daily survey.

Intervention Content. The Letting Go and Staying Connected Handbook includes modules adapted from the Raising Healthy Children Navigating Independence (NI) program, developed at SDRG as a booster for students transitioning out of high school as part of a comprehensive school- and family-based program to impact healthy development and reduce drug use. We expanded and adapted NI to include specific guidance for parents of first-year students (Table 3). It has 6 chapters and is designed to be completed in the month before students begin university and then to be referenced as needed throughout the student's college career. The packet includes the Handbook itself, cards for interactive parent-student exercises, worksheets, and checklists to guide completion of the Handbook. There will be a Spanish version of the Handbook so that it is accessible to Spanish-speaking parents. The self-administered Handbook is designed to help parents adapt their parenting behaviors to the new developmental and logistical demands of young adulthood. It describes three parent roles, each corresponding to one of the three parenting constructs in the theoretical model: family management (Safety Monitor), autonomy support (Coach), and emotional support (Cheerleader) and provides activities for parents to practice behaviors that characterize each role. As Safety Monitors, parents learn and practice ways to continue monitoring and guiding student behaviors, by

Table 3. Description of Handbook Contents and How They Relate to Theoretical Constructs

Chapter	Intervention Components and Related Theoretical Constructs
	Parents envision and share their wishes for student during college years.
1) Imagine	Parent constructs: Emotional Support (positive reinforcement for desired behavior; encouragement)
	Student constructs: Bonding to Parents; Healthy Beliefs & Standards
	Information about late adolescent brain development and its effects on behavior. Parents and students discuss
	what "adult" means to them.
2) The Young Adult Brain	<u>Parent constructs</u> : Family Management (guidelines and monitoring); Autonomy Support (self-regulation and decision making skills)
	Student constructs: Perceived Prosocial Rewards; Bonding to Parents; Healthy Beliefs & Standards;
	(-) Bonding to Antisocial Peers
	Parents and students use card-sort activity to identify shared and individual values; practice step-by-step method to
3) From Values to	create action plans for self-regulation, independent decision making, and setting goals aligned with values.
Committed Action	Parent constructs: Autonomy Support (coaching for autonomy, self-regulation, decision-making skills)
	<u>Student constructs</u> : Opportunities; Perceived Prosocial Rewards; Bonding to Parents; Healthy Beliefs & Standards
	Parents learn about 3 parent roles (Safety Monitor, Coach, Cheerleader) and take an inventory to determine their
	readiness to Let Go and Stay Connected; parents and students use a card-sort activity and financial checklist to help
4) How Parents Help	parents clarify and communicate expectations; parents practice celebrating students strengths; parents introduced to state laws and university policies
	••
	Parent constructs: All hypothesized parent-level mediators
	Student constructs: All hypothesized student-level mediators
5) Putting it All Together	Parents practice applying skills to scenarios describing common student problems/situations (e.g. bad grades,
	roommate problems; anticipating a "big party" event) by thinking through how they would respond as Safety Monitors, Coaches, and Cheerleaders
	Parent constructs: All hypothesized parent-level mediators
	Student constructs: All hypothesized student-level mediators
	Listing of university resources available to parents and students
6) Resources	Parent constructs: Family Management; Emotional Support

soliciting information from students and communicating frequently about their expectations of students' behavior and about consequences for violating those expectations. As Cheerleaders, parents learn and practice ways to recognize students' strengths and challenges, celebrate their accomplishments, encourage them, and provide emotional support. And as Coaches, parents learn and practice ways to help students identify their values and visions of who they want to be; to formulate goals consistent with those values; and to identify and commit to short- and long-term actions that will help them achieve those goals. The conceptualization of these roles is based in theory and is empirically supported, as are each role's associated activities. For example, the Values-to-Committed Action exercise is theoretically consistent with our model, as it is designed to promote student autonomy, self-regulation, and decision-making skills; highlight shared healthy beliefs and standards; and increase bonding to parents. It also incorporates motivational interviewing techniques, shown to be highly effective in reducing substance abuse among college students.

Finally, the Handbook includes information that is designed to increase parents' knowledge about developmental issues (e.g. the young adult developing brain) and about WSU-specific norms, student behaviors, policies, and resources. In Table 3 we list the Handbook components and theoretical constructs they address, and in Appendix B we include the pilot Handbook itself.

		ha	SC		
	reporter	scale alpha	items		
Construct	rep	scal	# of	Measure	Assessment
			DI	EMOGRAPHICS (Aims 1-3)	
Race/ethnicity, age, income, education	P,S	NA		Washington State University Registrar's database	BL
		IM	PLEM	ENTATION MEDIATORS (Aim 2)	
Participant Responsiveness as measured by Handbook Uti	lization			, ,	P AT LS1
ranticipant responsiveness as measured by nanubook of	iizatioii	reice		RENT MEDIATORS (Aim 2)	17(1232
F			PA	RENT MEDIATORS (AIIII 2)	
FAMILY MANAGEMENT	1	1	<u> </u>	Communication About Alcohol Scale Wood et al., 2010) (To be adapted for	0 1010164
Clear guidelines	P,S	.96	24	additional substances)	P at BL & LS1 S at all SS
				Parental Monitoring (Capaldi & Patterson 1989, adapted by Arria 2008)	P at BL & LS1
Parental monitoring, consequences	P,S	.76	9	g (	S at all SS
AUTONOMY SUPPORT/SELF-REGULATION		1			0 00 00
·				Secure Base subscale of Network of Relationships Scale (Furman & Buhrmester,	P at BL & LS1
Perceived autonomy support	P,S	.79	3	2009)	S at all SS
Self-regulation skills	S	.85	4	Perceived Competence Scale (Williams, Freedman & Deci, 1998)	All SS
Parents communicate challenges to students	S	.80	18	Parental Challenge Scale (Aldeis & Afifi, 2013)	All SS
Values-Aligned Behavior	S	NA	22	Personal Concerns Inventory (Cox & Klinger 2002)	All SS
EMOTIONAL SUPPORT	1				
Emotional support and comfort	S	.85	30	Parental Bonding Instrument (Patock-Peckham et al. 2007)	BL
			STL	JDENT MEDIATORS (Aim 2)	
PERCEIVED REWARDS FOR PROSOCIAL/RISK BEHAVIOR	1	1	1		
Zero tolerance/Harm Reduction	S	.81	7	Perceived Parental Reactions to Substance Use (adapted from Abar et al., 2013; Martens, 2005)	All SS
Reinforcement of positive behaviors: Parents	S	.80	16	Parental Confirmation Scale (Aldies & Afifi, 2013)	All SS
Reinforcement of positive behaviors: Peers	S	.83	4	Peer Rewards for Antisocial Behavior (Arthur et al. 2002)	All SS
Mastery orientation	S	.81	12	Achievement Goal Orientation (Pastor et al. 2007, adapted from Elliot & McGregor 2001)	All SS
BONDING TO PARENTS AND PEERS					
Conflict	P,S	.88	12	Quality of Relationship Inventory (Parents and Peers) (Pierce, Sarason & Sarason, 1991)	P at BL & LS1 S at all SS
Closeness	P,S	.88	10	Closeness Scale (Aldeis & Afifi, 2013; Buchanan, Maccoby, & Dornbusch 1991)	P at BL & LS1 S at all SS
HEALTHY BELIEFS AND STANDARDS					
Attitudes favorable toward substance use	P,S	.86	4	Attitudes favorable toward substance use (Arthur et al. 2002)	P at BL & LS1 S at all SS
Commitment to academic success	S	.70	6	Commitment subscale of the Personal Views Survey III-R (Sheard & Golby 2007)	All SS
				OUTCOMES (Aims 1-3)	
RISK BEHAVIORS AND HARMS					
Substance use (ever, past year, 30 days, daily) Alcohol,		NI A		Monitoring the Future Survey (Johnson et al. 2002)	All SS
marijuana, nonmedical use of stimulants and opiates,		NA		Washington State Young Adult Survey (Larimer et al., 2014)	All SS
other illegal drugs				Daily Drinking Questionnaire-R (Baer, 2001) (adapted to include other substances)	All
Harms related to substance use		.92	18	Rutgers Alcohol Problem Index (White & LaBouive, 1989)	
	S	NA	8	Washington State Young Adult Survey Marijuana (Larimer et al., 2014)	all
Conduct sanctions  Sovial assault (victim (normatrator)) STIs, Sovially risky	-	NA	NA	WSU Student Standards & Accountability infraction records	All SS
Sexual assault (victim/perpetrator), STIs, Sexually risky behaviors, unwanted pregnancy, protective behaviors related to sexual activity and alcohol		NA		National College Health Assessment (2014)	Ls1
POSITIVE ACADEMIC OUTCOMES					
Academic performance (GPA) and persistence to degree	S	NA	1	Washington State University Registrar's database each semester	
		PARTE	NT-S	TUDENT COMMUNICATION (Aim 3)	
Communication content, emotional tone, timing duration, mode, and frequency	S			To be developed in consultation with Drs. Christine Lee and Caitlin Abar in Year 1 of study	TLFB
Willingness to Reveal	S	.95	3	Aldeis & Afifi (2013)	BL
Note: S = Student, P = Parent, BL = Baseline, LS1 = Late Se	mester	1, SS = S	emes	ster Surveys, TLFB = Timeline Follow Back	

Intervention Delivery. We will send the Handbook packet to parents in both "Handbook Only" and "Handbook Plus" conditions after parents and students have completed the baseline survey and consent.

"Handbook Plus" Booster Delivery. Handbook Plus parents will receive all the above plus a series of booster messages throughout the two years. Strategically-timed and targeted boosters will remind parents that they can continue to make use of the Handbook resources throughout their students' time during college when the resources are most needed; we expect that these reminders will amplify effects of the intervention.

Past research on the efficacy of text messaging-based health behavior interventions suggests that allowing participants to personalize text frequency was most effective. Therefore, at the beginning of the study, parents randomized to the Handbook Plus condition will: 1) receive Handbook-related text messages and/or emails periodically over the course of the study, and 2) will be given a series of options related to the frequency and timing (e.g., day vs. night) of the texts/emails (see Appendix C for examples). In addition, some resarch shows that interactive messaging may be more effects, so parents will have the option of responding to texts with questions or comments. Using a web-based, mass-texting/emailing program used in similar applications by Dr. Porismita Borah (a consultant on this project), we will individualize the frequency and timing of the texts/emails as requested by each parent. Research also suggests that text-based interventions which decrease the frequency of messages over time are most effective. Therefore, we plan to send relatively frequent messages during the month before students move to campus and gradually decrease the frequency (54) across the two years. This type of booster has the potential to enhance parent responsiveness to the intervention, because increased exposure to personally relevant information at strategic times will increase the salience of the material. Parents and their college students report using cell phones/text messages and email as their primary modes of communication with one another, and in our pilot study, 90% of parents reported using texts and phone as their most frequent modes of communication with their students, making texts a logical modality to transmit intervention-relevant content related to parent-student relationships.

#### Measurement

In Table 4 we have listed our proposed covariates, mediators, and outcome measures. In Table 5 we describe our primary measure of implementation, parent responsiveness, adapted from existing implementation measures. In Appendix D we provide brief descriptions of the measures and citations. Some measures will need to be adapted (e.g. to include multiple substances) or developed and piloted.

## **Analysis Plan and Dissemination of Results**

**Data cleaning**. We will conduct tests for out-of-range values, consistency across measurement points, normality, and influential outliers. We will address any issues of bias related to outliers using accepted techniques (e.g. analyses robust to violation of assumptions). Counts of dichotomous substance use variables are frequently skewed; we will use log transformations of variables and appropriate analyses (e.g. survival analysis or Poisson regressions) as needed.

**Selection and Attrition**. Randomized selection of students for invitation into the study should ensure a representative sample of the student population, and numerous studies have demonstrated the ability of the Survey Research Division at the SDRG to retain over 90% of respondents over more than 10 years. However, we will test for differential participation and attrition and for the likelihood of biased outcome estimates; if necessary, we will model those effects and employ correction techniques.

Variability in Implementation and Dosage. Particularly in the case of a self-administered intervention, implementation and dosage are not distributed randomly -- for example, parents in the intervention condition who are particularly motivated or compliant may do all activities, whereas others may pick and choose. The non-random distribution of intervention components across intervention participants confounds our ability to draw causal inferences about program effects and obscures the mechanisms of program effects by treating implementation as a binary event. In addition to intent-to-treat analyses we will employ recent methodological advances that allow for estimation, modeling, and control of selection effects in implementation through use of propensity scoring and inverse probability weighting.

**Missing Data**. When respondents skip items or miss one or more data collection points, missing data may introduce bias and increase the likelihood of Type I errors. Our primary analytic approaches use FIML to manage missing data. In case of excessive missingness, we will use multiple imputation.

**Familywise Error.** We will use summary variables of risk behaviors/harms, but we will also conduct separate analyses for each risk outcome to provide a finer-grained look at individual substances, increasing the likelihood of a Type 1 error. Responses to substance use items are also likely to be highly correlated; in such cases standard Bonferroni corrections tend to be overly conservative with a higher likelihood of Type 2 error. Resampling procedures (e.g. SAS PROC MULTTEST) are more powerful than the Bonferroni test and can be applied to categorical, continuous, and censored data tests, mixed method analyses of between-subjects effects and longitudinal within-subject tests. A global test statistic will be used when appropriate.

#### Aim 1: Test the efficacy of Letting Go and Staying Connected

- H1: There will be a direct effect of the Handbook on student risk behaviors. Students in the two Handbook conditions, relative to those in the control condition, will engage in fewer risk behaviors, including intentions to use, initiation, and use and abuse of substances (alcohol, marijuana, opiates, prescription stimulants, and other illegal drugs) and HIV sex risk behaviors.
- H2: Students in the two Handbook conditions, relative to those in the control condition, will report fewer physical, emotional, social, and academic harms related to risk behaviors.
- H3: Relative to participants in the "Handbook Only" condition, parents and students in the "Handbook Plus" condition will show greater differences from the control condition on risk behaviors and outcomes. The intention of the Handbook (H) and Handbook Plus (H+) interventions is to reduce risk behaviors and their negative consequences and to prevent the expected escalation in risk behaviors and consequences

(164) across the 1st two years of college. As each wave of data collection is completed we will conduct a set of intent to treat ANCOVA. Outcome measures (see table) will be predicted by their baseline level, intervention group assignment, and controls (age, gender, ses, ethnicity). A global test statistic will be computed on groups of outcomes (e.g. substance use frequency for alcohol, tobacco, marijuana, opiates, stimulants, and other illegal drugs) to ascertain overall effects of intervention on families of outcomes. Pairwise comparisons of intervention conditions will address the hypothesis that H and H+ reduce risk compared to controls and that H+ reduces risk more than H alone.

To measure intervention impact on change across time we will model latent growth curves (LGC) for each of the hypothesized outcomes. First, unconditional models will be estimated to confirm the expected escalation across 5 waves of data. We expect a two factor model: an intercept factor set to pre-test levels, and a linear slope factor estimated with factor loadings set to indicate pre-test as intercept and non-equal intervals between surveys [0,1,2.08, 3.25, 4.08]. A non-linear slope will be estimated using quadratic forms for loadings. however we expect primarily linearly increases over all 5 time points. A covariance is typically estimated between the intercept and slope factors to control for pre-test levels of the outcome. Control variables will be added in the next step. Finally, intervention group assignment (in the form of 2 dummy variables) will be added as predictors of the mean and variance of the slope factor (random assignment should preclude group effects on the intercept set at pre-test). We expect these parameters to reflect significant positive slope means and variances in the unconditional model and the minimally conditional model. In the final models, intervention dummy variables are hypothesized to have significant negative effects on slope mean and variance compared to the control condition indicating both intervention conditions reduced the rate of escalation in risk behaviors and consequences and also reduced the variability in these outcomes. By manipulating the coding of dummy variables we can then test the comparison between H and H+ with the expectation that H+ parameters will be significantly more strongly negative than those for H.

Aim 2: Test theoretically specified mediational pathways

Parents in the Handbook conditions, relative to those in control conditions, will report better family management skills, more emotional support, and more autonomy support, and these variables will mediate expected relations between intervention and risk behaviors and consequences.

H5: Students in the Handbook conditions, relative to those in the control conditions, will report higher levels of perceived rewards for prosocial activities with peers and family; and more shared values; and these will mediate expected relations between intervention and risk behaviors and consequences.

Preliminary intent-to-treat analyses (ANCOVA) will be conducted on mediators at each follow up as described for outcomes above. Then LGC analyses described above will be extended to include mediating variables. However, prior to estimating mediation, each mediator will be modeled over time in a LGC model to determine its shape (intercept, linear slope, and quadratic slope) conditioned on control variables as described for outcomes in Aim 1. In the case of mediators the slope factors are less predictable, although in general these positive parenting and parent-student relationship factors are expected to decline over time. Once appropriate models of change have been determined, concurrent/parallel growth processes in mediators and outcomes will be estimated. Parallel process LGM is a technique that has been used to examine interrelationships among various developmental outcomes, including co-occurring drug use and delinquency, in adolescents and young adults and for testing the mechanisms of preventive intervention effects. In the final step the intervention group status dummy variables will be added to the parallel process models. We anticipate H and H+ will positively influence the slope of mediators over the follow up period indicating the intervention slowed the decline in these positive factors or predicting increases over time, which in turn will be associated with slower growth in risk behaviors and their consequences. We note two limitations. The number of mediators and outcomes to be modeled simultaneously is limited by the number of parameters that can be estimated with the available sample size. Additionally, the mediators and outcomes are measured over the same time period, which depicts the natural unfolding over time, but which does not adhere strictly to the logical temporal ordering of predictor, mediator, and outcome variables. This temporal limitation can be partially addressed by setting the intercept of the outcome at the end point rather than at pre-test (done by changing the loadings on the slope factor) and regressing that intercept on intervention condition and the intercept and slope factors of the mediator. This shifts the hypothesis slightly to test whether the intervention or the mediators predict the level of the outcome at the 21 month follow up.

Aim 3: Identify specific attributes of parent-student communication that predict and covary with student substance use risk behaviors, and their consequences (exploratory).

Given the exploratory nature of this aim, there are no hypotheses. Note that changes in communication are not posited to mediate intervention effects. However, if significant relationships are found between intervention status and communication measures, exploratory analyses may be conducted on the control group only to better reflect etiological relationships un-confounded by possible intervention influences. Preliminary analyses will focus on describing levels and variability in content, emotional tone, timing, duration, mode, and frequency and developing appropriate summary scores to best reflect these factors based on reports from the TLFB surveys. Latent class analyses (LCA) with maximum likelihood estimation and robust standard errors will be used to explore parent-student communication patterns using those summary scores. We will derive empirically based classes of participants based on content, emotional tone, timing, duration, mode, and frequency. This will involve estimating a series of models to determine the number of unique classes that best

fit the data by comparing the Bayesian Information Criterion, the Lo-Mendell-Rubin adjusted Likelihood Ratio test and the Parametric Bootstrapped Likelihood Ratio test across models and selecting the most parsimonious model with the best fit. Latent classes will be described based on their mean levels of the component variables and then class membership will be related to demographic and outcome variables. Analyses will include ANCOVA in which class membership and control variables predict risk behaviors and consequences at later time points. This may involve LGC models in which outcome intercept and slope factors are regressed on class membership. If sufficient variability within-person is observed across the two week reporting period, event history analytic strategies<sup>(179)</sup> may be used to estimate the magnitude of relationships between communication style variables (time-varying covariates) and risk behaviors reported over the same time period. This fine-grained analysis may identify particularly salient aspects of parent-student communication which have immediate, short-term impact on student risk behaviors which accumulated over time result in less risk taking overall and fewer negative consequences of risk behaviors.

**Power.** Because LGC models use maximum likelihood estimation procedures, they have greater statistical power in testing for group differences in growth trajectories than does a repeated measures ANOVA and thus do not require as large a sample size. With regard to Aims 1 and 2, Muthén and Curran calculate power to detect main effects of .20 with 5 measurement occasions (baseline plus 4 followups) and a sample size of 900 as  $\beta$  > .90. As clearly illustrated by Zhang and Wang<sup>(149)</sup>, estimates of moderate size (d=.20) can be detected using LGC models with 5 measurement occasions with power greater than .80 with samples as small as 300 cases. The proposed sample sizes of 300 in each condition has more than sufficient power to detect group differences in growth parameters as well as sufficient power to detect effects in etiological analyses in Aim 3 using only families in the control condition. With regard to Aim 3, power to detect Level-2 predictors is affected primarily by the Level-2 sample size. With 14 repeated measures and 300 participants in the control group, this study has power over .80 to detect effect sizes as small as .20 when predictors are correlated approximately .30 using control group families only. Power is increased by lower correlations, higher effect sizes, and lower measurement error. If deemed appropriate the full sample of 900 could be used in these analyses with intervention assignment as a control variable, and power to detect effects even in the presence of higher correlations will be sufficient.

**Dissemination Plan**. We include a productivity plan (Appendix E) with sample abstracts for a series of papers that we expect to write during the grant period. The list is not comprehensive but represents what we believe will be some of the project's primary results. We will also disseminate results to the university administration; study participants; and at conferences, including the Society for Prevention Research, Society for Adolescent Medicine, Society for Study of Emerging Adulthood, and American Public Health Association. **Limitations** 

Our sample consists entirely of incoming 1<sup>st</sup>-year students (and their parents) at Washington State University, a large, public university in which all 1<sup>st</sup>-year students are required to live on campus in residence halls. Handbook material developed for this population may not generalize to families who transition to college in other contexts. However, confining our recruitment to students at a single university will allow us to focus efforts to maximize participation and retention rates. In addition, the handbook format is flexible, and the underlying theoretical model makes it easily adaptable to students in other settings.

A second potential limitation is that we propose to measure student behavior using primarily self-reports. To address this possible problem, we propose a few strategies. First, we will emphasize confidentiality in order to enhance student honesty in responding. Second, we will integrate a TLFB design with more traditional survey measurement of student behavior. Although TLFB involves recall of the previous week and thus may introduce some recall bias, it has been shown to be a promising alternative to daily reports that often involve high participant burden; the TLFB design may be a promising alternative to daily measurement strategies. Third, we will use student conduct sanction data and academic records to supplement self-report.

Recruiting male and minority participants has been problematic for some studies. However, the SDRG Survey Research Division has been highly successful in recruiting male and minority participants, and our Family Consultants will be trained in methods shown to increase study participation among these groups.

#### **WASHINGTON STATE UNIVERSITY**

Department of Human Development

# **Research Study Consent Form [note: for students]**

**Study Title:** First Years Away From Home

Researchers: Dr. Laura Hill; laurahill@wsu.edu; 509-335-8478

Dr. Matthew Bumpus; mbumpus@wsu.edu; 509-335-3816

Dr. Brittany Cooper; brittany.cooper@wsu.edu; 509-335-2896

Danielle Woodward; dgangnes@myuw.net; 206-685-1632

You are being asked to take part in a research study carried out by Dr. Laura Hill, Dr. Matthew Bumpus, Dr. Brittany Cooper, **and Danielle Woodward**. This form explains the research study and your part in it if you decide to join the study. Please read the information carefully, taking as much time as you need. If you have any questions, please contact one of the researchers listed above. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later.

This study has been approved for human subject participation by the Washington State University Institutional Review Board.

## What is this study about?

This research study is being conducted in order to better understand how WSU students and parents experience the transition to college. We are interested in how factors such as communicating regularly with parents might help incoming WSU students better navigate the transition to college. In addition, we are interested in students' ideas and behaviors related to alcohol and marijuana use as they get ready to make the transition to college.

You are being asked to take part because you are a member of the incoming freshman class at WSU.

# What will I be asked to do if I am in this study?

Taking part in the study will involve completing a few surveys over the next two years: one this summer, and then in each of the following 4 semesters. Each will take you

about 25 minutes to complete. Your total time commitment over the next four semesters will be about 2-3 hours if you decide to participate.

The questions on the surveys will ask about a variety of issues, including your relationship with your parents and your expected amount of communication with them while at college, and your overall well-being. Some of the questions will ask you to provide sensitive information, such as sexual behavior, alcohol and marijuana use, and consequences that you may have experienced as a result of alcohol or marijuana use.

Some students will also be asked to complete a brief daily check-in for two 7-day periods during the fall semester of their first year at WSU. The survey will ask about communication and behaviors on that day and will only take a couple of minutes.

# Are there any benefits to me if I am in this study?

There is no direct benefit to you from being in this study, but if you take part in this study, you may help researchers and university personnel better understand what is important for students as they make the transition to college, and may result in programs or policies that are better able to assist students in successfully navigating their time at WSU.

## Are there any risks to me if I am in this study?

The potential risks from taking part in this study are a loss of confidentiality as a result of providing sensitive information. To minimize this risk, your participation and your responses will be kept strictly confidential.

Another potential risk is psychological/emotional discomfort or distress as a result of thinking about potentially sensitive topics. To minimize this risk, please remember that you may choose not to respond to any question that you wish to skip, and you may stop participating at any time with no repercussions.

## Will my information be kept private?

The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. Under certain unlikely circumstances, information that identifies you may be released for internal and external reviews of this project.

Data will be coded so that the only people who will be able to link your identity to your responses are the researchers. Any identifying information will be stored separately from the data. Note also that your parents will not have access to your responses!

Data will be stored on a password-protected server. Only the researchers will have access to the data.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous

The data for this study will be kept for at least 3 years following the conclusion of the study.

Since this is a long-term study, it is extremely important that we are able to get in touch with you for the follow-up surveys. Therefore, we will maintain contact with you even if you move or change schools. To help us keep in touch we will ask you for your contact information such as current address, email addresses, social networking sites, and telephone numbers. If you move or we are unable to reach you, other contacts may be made as needed with your school and/or other names provided by you to confirm or update contact information.

## Are there any costs or payments for being in this study?

There will be no costs to you for taking part in this study.

You will receive up to \$110 **in Amazon gift cards** for participating: a \$20 gift card for each survey you complete, \$30 for completing the last survey (during spring of your second year in college), and up to \$30 if you participate in the daily check-in part of the study. We will email you a link to the gift card within a week after you complete each survey.

# Who can I talk to if I have questions?

If you have questions about this study or the information in this form, please feel free to contact the researchers:

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laurahill@wsu.edu

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Danielle Woodward
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If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-3668, or e-mail irb@wsu.edu, or regular mail at: Albrook 205, PO Box 643005, Pullman, WA 99164-3005.

## What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time.

## By participating in this survey what am I agreeing to?

Your completion of this survey means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.

#### Click here for a PDF of this consent form.

By clicking on the survey link below, you are indicating that you consent to participate in this study.



# I CONSENT AND AGREE TO PARTICIPATE

I DO NOT CONSENT

#### **WASHINGTON STATE UNIVERSITY**

Department of Human Development

# Research Study Permission/Consent Form [note: for parents in control condition]

**Study Title:** First Years Away From Home

Researchers: Dr. Laura Hill; laurahill@wsu.edu; 509-335-8478

Dr. Matthew Bumpus; mbumpus@wsu.edu; 509-335-3816 Dr. Brittany Cooper; brittany.cooper@wsu.edu; 509-335-2896 Danielle Woodward; dgangnes@myuw.net; 206-685-1632

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This study has been approved for human subject participation by the Washington State University Institutional Review Board.

## What is this study about?

This study is being conducted in order to better understand how WSU students and their parents experience the transition to college. We are interested in how factors such as communicating regularly with parents might help incoming WSU students better navigate the transition to college. In addition, we are interested in participants' ideas and behaviors related to alcohol and marijuana use.

You are being asked to take part because you are a parent of a member of the incoming first-year student class at WSU.

## What will I be asked to do if I am in this study?

We will ask you to complete two surveys, one now and one in the fall. **Together, the two surveys will take you between 40 and 60 minutes**. The surveys will ask questions about how you and your student communicate, your expectations for him/her

at college, and some questions about alcohol/marijuana use. Your student will complete similar surveys.

## Are there any benefits to me if I am in this study?

There is no direct benefit to you from being in this study, but if you take part in this study, you may help researchers and university personnel better understand what is important for students and families experiencing the transition to college, and may result in programs or policies that are better able to assist parents and students in successfully navigating their time at WSU.

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The data for this study will be kept for at least 3 years following the conclusion of the study.

Since this is a long-term study, it is extremely important that we are able to get in touch with you for the follow-up surveys. Therefore, we will maintain contact with you even if you move or change schools. To help us keep in touch we will ask you for your contact

information such as current address, email addresses, social networking sites, and telephone numbers. If you move or we are unable to reach you, other contacts may be made as needed with other names provided by you to confirm or update contact information.

## Are there any costs or payments for being in this study?

There will be no costs to you for taking part in this study.

You will receive a \$20 **Amazon gift card** for completing each survey. Your student will receive a total of up to \$110 for completing surveys during the next two years. We will email you a link to the gift card within one week of completing each survey.

## Who can I talk to if I have questions?

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## By participating in this survey what am I agreeing to?

Your completion of this survey means that:

- You understand the information we have provided here
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.

#### Click here for a PDF of this consent form.

By clicking on the survey link below, you are indicating that you consent to participate in this study. By clicking on the survey link, you are also giving permission to have your student participate.

CONSENT AND AGREE TO PARTICIPATE
DO NOT CONSENT

#### **WASHINGTON STATE UNIVERSITY**

Department of Human Development

# Research Study Permission/Consent Form [note: for parents in Parent Handbook condition]

**Study Title:** First Years Away From Home

Researchers: Dr. Laura Hill; laurahill@wsu.edu; 509-335-8478

Dr. Matthew Bumpus; mbumpus@wsu.edu; 509-335-3816 Dr. Brittany Cooper; brittany.cooper@wsu.edu; 509-335-2896 Danielle Woodward; dgangnes@myuw.net; 206-685-1632

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This research study has been approved for human subject participation by the Washington State University Institutional Review Board.

## What is this study about?

This study is being conducted in order to better understand how WSU students and their parents experience the transition to college. We are interested in how factors such as communicating regularly with parents might help incoming WSU students better navigate the transition to college. In addition, we are interested in participants' ideas and behaviors related to alcohol and marijuana use. Finally, we are interested in parents' thoughts and opinions about *Letting Go and Staying Connected*, a handbook for parents that we have developed and will be sending you in the mail.

You are being asked to take part because you are a parent of a member of the incoming first-year student class at WSU.

## What will I be asked to do if I am in this study?

This research study involves two parts:

First, we will ask you to complete two surveys, one now and one in the fall. The surveys will ask questions about how you and your student communicate, your expectations for him/her at college, and some questions about alcohol/marijuana use. **Together, the two surveys will take 40-60 minutes to complete.** Your student will complete similar surveys.

Second, we will be mailing you a handbook titled *Letting Go and Staying Connected* which will provide information about a variety of topics related to how to navigate parent-student relationships across the transition to college, as well as some information on student alcohol and marijuana use. Members of our research team may check in with you periodically over the next few weeks to see how you are using the handbook material and to see if you have any questions. **Each check-in will likely take 15-30 minutes, depending on questions you may have.** 

## Are there any benefits to me if I am in this study?

You may find that the material in our Parent Handbook is useful as you navigate your student's transition to college. In addition, information you provide as a participant in the study may help researchers and university personnel better understand what is important for students and families experiencing the transition to college, and may result in programs or policies that are better able to assist parents and students in successfully navigating their time at WSU.

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I CONSENT AND AGREE TO PARTICIPATE
I DO NOT CONSENT

#### **WASHINGTON STATE UNIVERSITY**

Department of Human Development

# Research Study Permission/Consent Form [note: for parents in Parent Handbook Plus Boosters condition]

Study Title: First Years Away From Home

**Researchers:** Dr. Laura Hill; laurahill@wsu.edu; 509-335-8478

Dr. Matthew Bumpus; mbumpus@wsu.edu; 509-335-3816 Dr. Brittany Cooper; brittany.cooper@wsu.edu; 509-335-2896 Danielle Woodward; dgangnes@myuw.net; 206-685-1632

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You are being asked to take part because you are a parent of a member of the incoming first-year student class at WSU.

## What will I be asked to do if I am in this study?

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First, we will ask you to complete two surveys, one now and one in the fall. The surveys will ask questions about how you and your student communicate, your expectations for him/her at college, and some questions about alcohol/marijuana use. **Together, the two surveys will take 40-60 minutes to complete.** Your student will complete similar surveys.

Second, we will be mailing you a handbook titled *Letting Go and Staying Connected* which will provide information about a variety of topics related to how to navigate parent-student relationships across the transition to college, as well as some information on student alcohol and marijuana use. Members of our research team may check in with you periodically over the next few weeks to see how you are using the handbook material and to see if you have any questions. **Each check-in will take about 15-30 minutes, depending on questions you might have.** 

Third, we will provide you with occasional messages that will help you think about ideas and topics from the Parent Handbook and how you might incorporate material from the handbook into conversations with your WSU student.

## Are there any benefits to me if I am in this study?

You may find that the material in our Parent Handbook is useful as you navigate your student's transition to college. In addition, information you provide as a participant in the study may help researchers and university personnel better understand what is important for students and families experiencing the transition to college, and may result in programs or policies that are better able to assist parents and students in successfully navigating their time at WSU.

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- You believe you understand the research study and the potential benefits and risks that are involved.

#### Click here for a PDF of this consent form.

By clicking on the survey link below, you are indicating that you consent to participate in this study. By clicking on the survey link, you are also giving permission to have your student participate.

I CONSENT AND AGREE TO PARTICIPATE
I DO NOT CONSENT