Information Collection Request

New

Supporting Statement Part A

The Girl Power Project Efficacy Trial

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Goal of the study: Evaluate the efficacy of a mobile phone app intervention in promoting healthy sexual behaviors.

Intended use of results: Disseminate mobile phone app intervention to girls in the United States.

Methods to be used to collect: Two-arm randomized controlled trial with repeated measures at baseline, 3-month and 6-month. Surveys will be self-administered to control and intervention groups.

Subpopulation to be studied: Girls 14 to 18 years of age in the United States. The study is open to girls of any racial or ethnic background. However, we will more heavily recruit black and Latina girls by focusing recruitment efforts in cities with high black and Latina adolescent populations. In addition, we will target our banner ads to these aforementioned populations. We will also continuously track the age and race/ethnicity of enrolled participants and refocus our recruitment strategies to achieve a balanced sample.

How data will be analyzed: General linear model.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This is a new information collection request, and approval is requested for 1 year. The information proposed for collection will be used to evaluate Crush, a smartphone application designed to reduce teen pregnancy among black and Hispanic girls ages 15-17 years. Crush was developed through a Small Business Innovation Research (SBIR) contract awarded by the Centers for Disease Control and Prevention (CDC).

Despite drastic reductions in teen births across all racial and ethnic groups, black and Latino girls continue to have disproportionately high rates of teen births, 39.0 and 41.7 per 1,000 girls respectively compared to 18.6 per 1,000 non-Hispanic white girls in 2013 (Martin, Hamilton, Osterman, Curtin, & Mathews, 2015). According to the Youth Risk Behavior Survey (YRBS) 46% of high school girls have had sex but 70% did not use an effective birth control method to prevent a pregnancy (YRBS, 2013). Increasing girls' access to medically accurate and comprehensive sexual health information is the first step in sustaining momentum in teen pregnancy reduction among all racial and ethnic groups, and in promoting healthy sexual behaviors, especially among minority girls. The information and features of Crush are grounded in the Theory of Planned Behavior (TPB). TPB is a health behavior change theory that focuses on promoting positive attitudes, norms, behavioral control, self-efficacy and behavioral intentions in order to achieve the desired behavior. This study will also advance our understanding on the efficacy of mobile health (mHealth) interventions. There is no consistent definition of mHealth. For the purpose of this project we define mHealth as the use of mobile communication technology in public health.

The main goal of the Girl Power Project Efficacy Trial is to evaluate Crush on the following outcomes: delay sexual debut among non-sexually active girls, increase the use of effective birth control among sexually active girls, specifically long-active reversible contraception (LARCS), and increase the utilization of clinics for sexual and reproductive health services among all girls.

The behavioral goals targeted through Crush are congruent with CDC's Winnable Battles which identifies the priorities for teen pregnancy prevention: promotion of delaying sexual onset through evidence-based programs and social norm changes, expansion of Medicaid family planning services and the promotion of effective contraceptive methods, including LARCS, by sexually active teens (CDC, April 2015).

Crush's goals are also aligned with multiple Healthy People 2020 goals and objectives:

- FP-7.1 Increase the proportion of sexually active females aged 15-44 years who received reproductive health services in the past 12 months
- FP- 8.1 Reduce pregnancies among adolescent females aged 15 to17 years
- FP 9.1 Increase the proportion of female adolescents aged 15 to 17 years who have never had sexual intercourse
- HIV-2 Reduce the number of new HIV infections among adolescents and adults

- HIV-14.4 Increase the proportion of adolescents and young adults who have been tested for HIV in the past 12 months
- HIV-17.1 Increase the proportion of sexually active unmarried females aged 15 to 44 years who use condoms

Crush also supports the Healthy People 2020 overall Health Communication and Health Information Technology goal "Using health communication strategies and health information technology to improve population health outcomes and health care quality, and to achieve health equity". These evaluation results will enhance understanding on the effects of mHealth interventions on youth.

In this project we will evaluate Crush in a two-arm randomized-controlled trial (RCT) to establish its efficacy in promoting effective birth control use and utilization of clinical services among 768 girls ages 14-18 years living in the United States. Participants will be randomized to either the Crush app (intervention) or a general health app (control). Additionally, the findings will help determine the potential mobile applications have in promoting long lasting healthy behaviors among youth. Participants will not be denied any regular service or support.

The authorizing law for this data collection is Section 301 of the Public Health Service Act (42 U.S.C.241) (See **Attachment 1: Authorizing Legislation**).

A.2. Purpose and Use of Information Collection1

A research team at Healthy Teen Network, and senior research consultants, will conduct the proposed evaluation research. This study will collect data electronically directly from participants through three mechanisms: (1) electronic enrollment database, (2) self-administered online surveys, and (3) web usage analytics.

Subjects will be screened electronically (See **Attachment 3a**). Eligible teens who enroll will be placed in an electronic database. The electronic enrollment database will contain enrollment relevant data such as name and demographic information, and contact information such as telephone number, email, and address. Enrollment information will be used for sample analysis. Demographic data will be used to describe the diversity of the population and ensure study arms are balanced (See **Attachment 3: Enrollment Questions**). All contact information will be used to communicate directly with participants throughout the study period, to send surveys via text message to their phones, and send study incentives by mail. The electronic enrollment database will unobtrusively track participants' navigation of the mobile application. This will allow us to study participants' exposure and dosage on the intervention, and assess dosage response based on behavioral outcomes. The navigation and utilization data will also be used to identify the mobile application content most popular with participants.

The self-administered surveys (**Attachments 4-9**) will be administered through the enrollment database as well. Participants will complete a total of three online surveys: at baseline, a three-month follow up, and an exit survey at six months post-baseline. The survey questions will directly respond to the theoretical construct of the TPB. These data will allow us to test changes in behavior, behavioral intentions, attitudes, social norms,

behavioral control and self- efficacy. The data collection instrument was designed for the purpose of this study. Some of the survey questions have been used in the National Longitudinal Study of Adolescent and Adult Health (Add Health), and thus have been tested and validated extensively in the past. Many questions are new questions specifically to address the study constructs. The questions were developed through extensive consultation with experts in the field and members of the target population who provided feedback.

The Baseline Surveys (**Attachments 4-5**) will be used to establish sexual health knowledge, attitudes, intentions, and behaviors at baseline and prior to exposure to the intervention. Additionally the Baseline surveys will assess self-efficacy of effective contraception utilization of sexual reproductive health services at baseline among the study participants.

The 3-Month and 6-Month surveys (**Attachments 6-9**) will collect data similar to the baseline survey in order to measure changes over the study period in the 2 study arms. For the intervention group, these surveys will also assess participants' use of and attitudes towards Crush.

The primary outcomes of this RCT are increased consistent contraceptive use and increased clinic utilization among the participants. Therefore it is necessary to collect these data at baseline and during follow-up. Secondary outcomes of this RCT include changes in behavioral intentions on birth control use, especially LARCS, pregnancy events, and the use of dual protection for pregnancy and STI prevention. While the main analysis is designed to detect differences in birth control use and clinic utilization between the treatment and control groups, it is not sufficiently powered to statistically distinguish differences in the secondary outcomes observed in this study (i.e., pregnancy outcomes). In order to advance the body of evidence of mHealth interventions, we will also assess how Crush is utilized by the target audience.

We will use usage analytics to collect participants' Crush navigation information, such as pages viewed, and duration of visit. This information will be collected unobtrusively and automatically every time the participant visits the app and will not impact participants' response burden. Only navigation within the Crush mobile app will be tracked. Participants' general web browsing will not be monitored. These data will be used to determine level of exposure and dosage of the intervention. Users do not need to download any additional application for tracking purposes. WordPress can only collect information generated by the app. We cannot collect any information of other activities on the user's phone external to the application. Also, Crush is not integrated into any other phone feature (such as phone, camera, or social media), so we can't collect information on these features either. The usage analytic capability consists of web analytics automatically collected by the WordPress platform that tracks how each users navigates the application. The data consists of pages viewed, when the page was visited and number of times each user has logged into the mobile app. Therefore, mobile app usage tracking can only occur when participants' logged into Crush app.

The data collected will allow a thorough evaluation of Crush. The short-term efficacy of Crush will be evaluated by determining whether exposure to Crush results in increased self-reported used of effective birth control and increased self-reported utilization of clinical services for sexual and reproductive health. Main behavioral outcomes of interest include use of effective birth control, in particular LARCs, and visiting a health care provider for any sexual and reproductive health service. The specific behavioral determinants that we will examine are congruent with the TPB and include participants' past behavior, attitudes, subjective norms, perceived behavioral control, self-efficacy and behavioral intentions regarding the use of effective birth control and clinic utilization. We will assess participants' satisfaction with and level of use of Crush content and features through the self-administered surveys. Dosage will be measured via web analytics and its effect on behavioral determinants will be assessed. If these data are not collected, there will be no way to evaluate the effectiveness of this mobile app. Not collecting this data may result in the dissemination of a program with no evidence of its potential impact for teen girls.

The goal of Crush is to reduce teen pregnancy and improve health by delaying sexual debut among non-sexually active girls, increasing the use of effective birth control among sexually active girls, specifically LARCS, and increasing clinic utilization for sexual and reproductive health services among all girls.

A.3. Use of Improved Information Technology and Burden Reduction

All data will be collected electronically to reduce respondent burden. Participants can complete the electronic enrollment form from a smartphone, tablet or their computers. Participants will receive a text message with a link to each self-administered survey published through the enrollment database which they can complete on a smartphone. Surveys are responsive to a mobile device for easy viewing and completion. Surveys should not take more than 15 minutes to complete. Crush utilization data will be automatically collected and logged via web analytics and does not require any response burden from the participants. Web analytics will only be collected from participants navigating Crush and only when they are logged in as users. Data will not be collected from any other web activity participants engage in.

A.4. Efforts to Identify Duplication and Use of Similar Information

There is very limited data on the efficacy of similar health education programs. A recent study explored a contraceptive support website on young women's sexual health. This study recruited women 18-29 years old and the educational focus of the program was limited to contraception use (Antonishak, 2015). Our program has a holistic approach including a wider variety of health topics and is targeted for a younger audience.

A.5. Impact on Small Business or Other Small Entities

This data collection will not involve small business.

A.6. Consequences of Collecting the Information Less Frequently

This is a single-time research study in which participants will complete questionnaires three times over a six month period. Participants in the study will be randomized into two groups: Crush intervention or a general health app specifically designed for girls. For the duration of the RCT, participants will be asked to complete surveys at baseline, at three months and at six months. This study was designed to reduce participant attrition often found in studies testing at longer intervals.

If this data collection is not conducted or is conducted less frequently, we will not comply with the CDC contract agreement requiring the rigorous testing of Crush to assess its efficacy for modifying behavior. The collection would not be beneficial to the public if it were conducted less frequently given that the program activities (participants' completion of three online surveys over the course of six months) are necessary for measuring behavior change.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The proposed data collection is a single-time research study in which 768 black and Latino girls age 14-18 will complete 3 survey questionnaires during a six-month period. The data collection protocol is consistent with OMB guidelines. The statistical data collected is intended to produce valid and reliable results that can be generalized to the universe of the intended audience.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A 60-day Federal Register Notice was published in the Federal Register on August 13, 2015, vol. 80, No. 156, pp. 48534-48536 with the title "Efficacy Study of a Mobile Application to Provide Comprehensive and Medically Accurate Sexual Health Information for Adolescent Girls" (see **Attachment 2a**). CDC received one non-substantive comment (see **Attachment 2b**) related to this notice from SisterLove, Inc. (SLI), an Atlanta-based organization working on reproductive justice and sexual health. SLI commented on two of the five issues the public has been invited to comment on: (a) whether the proposed information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility, and (c) ways to enhance the quality, utility and clarity of the information to be collected. A point by point response to the issues brought up by SLI is provided in **Attachment 2c**.

A.9. Explanation of Any Payment of Gifts to Respondents

The target population of Crush, black and Latina teenage girls, is in need of effective interventions for preventing teen pregnancy, but they may be difficult to reach and/or motivate. Additionally, the longitudinal study design requires high retention of recruited

participants in order to have meaningful results. Therefore, we will need to use incentives to both recruit and retain girls in the study.

We will incentivize survey completion by sending a study branded wristband ($1.00 value) and a $10 store gift card to participants upon completing the baseline survey. Participants will receive a $10 store gift card after completing the 3 month follow-up survey and a $15 store gift card after completing the 6 month follow-up survey. The role of incentives to increase participation in surveys has been widely used in online and face to face surveys (Singer, 2002). A recent study in United Kingdom which examined the effects of a sexual health website on youth's behavior offered the equivalent of $16 for final survey completion and $32 if they had to provide a urine test (Carswell, McCarthy, Murray & Bailey, 2012). A focus group study in the United States increased their incentives from $10 to $25 in order improve recruitment rates.

A.10. Protection of the Privacy and Confidentiality of Information Provided to Respondents

Data will be collected as information in identifiable form (IIF) therefore the Privacy Act does apply. The applicable Privacy Act System of Records Notice (SORN) for this data collection is 09-20-0164. The compilation of individual research results and responses into a study database will be used only for research purposes. The steps below describe the protections in place to preserve privacy of respondents.

The proposed data collection will include identifiable and non-identifiable information. The data in the electronic enrollment database will contain all identifiable data such as name, phone numbers, email addresses and physical address of all participants. All baseline, 3 month and 6 month follow-up surveys will only use unique identifiers to allow researchers to match their surveys and link them with the electronic enrollment database. All data will be kept in password protected files in the locked offices of the computer programmer and of the principal investigator. No one other than project staff will have access to the data. Upon the conclusion of the study, all data collected will be de-identified by removing full names and all contact information making the database anonymous.

When participants register into the study they will use their email as a username and will create a password of their choosing. They will use this information to log into the Crush app as well. However, the database will automatically assign each user a unique identifying number. This number will be used to match participants' surveys and Crush navigation activity. Database reports will only show data associated to the unique identifying case number and not with personal username, email or any personal identifying information

Personal privacy will be protected as follow:

1. Enrollment, survey and navigation data will be identified only by the participant's unique identifying number.

2. Password generated by the participants will be encrypted preventing anyone other than the participant to alter their personal information.

3. Once data collection concludes, all study data will be extracted from the database without any identifying information (name, email, address or phone numbers).

4. Once all participants receive final incentives all personal information (phone, mailing address) will be deleted and destroyed from the database.

5. Only the principal investigator, Genevieve Martínez-García, and data manager will have access to the database hosting personal data. Both have had human subjects training and are well aware of the ethical considerations involving data privacy.

6. Data will be stored in a password protected file in secured server. The server is protected by a firewall, daily virus scan software, anti-hacking protection software. Moreover, all data will be backed-up daily in three different secured servers: one secondary internal server, one solid SSD hard drive, and one server in a remote location.

Personally Identifiable Information

Use of unique identification numbers will be used to protect participants' identity. For all the data collected and analyzed as part of the RCT, unique identification will be used in place of names and email addresses to protect respondents' privacy. Contact information such as telephone numbers, home addresses, and email addresses, will be collected because: (1) the study is a mobile app intervention, (2) email addresses are needed for participants to be able to reset their passwords if needed and also for study staff to get in contact with the participants if their phone is off, (3) home addresses are needed to mail incentives to the participants, and (Healthy Teen Network staff and the data manager from MetaMedia Training International will have access to participants' personal information. Unique identification numbers instead of actual participants' names will be available to the statistician for analysis.

Consent Process and Privacy of Data

All participants will be provided the consent form prior to accessing the app content. To ensure that participants read the consent form, there will be multiple questions at the end of the consent form to assess participants' understanding of the study. There will be a pop-up correct answer to reiterate the importance of the specific section. For the purpose of this study, we will allow participants under the age of 18 to self-assent. A waiver of parental consent is consistent with federal regulations, is necessary to make this study possible, and is a common practice for research involving services youth already have access to without parental consent. A full description of our rationale to waive parental consent can be found in **Attachment 10**: Informed Consent and Assent forms and **Attachment 11**: Parental Consent Waiver.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study was approved by Solutions IRB on October 8, 2015, Approval No. 1510060. (**Attachment 12: IRB Approval Letter**)

Sensitive Questions

The main goal of Crush is to deliver comprehensive and medically accurate sexual health information. In order to measure Crush's efficacy it is necessary to ask sensitive questions (See **Attachments 4-9** Surveys). More specifically we will ask questions about: knowledge, past behavior, intended behavior, attitudes, social norms, perceived behavioral control and self-efficacy of effective contraception and use and clinic utilization. Information about sexual partners, birth control use, frequency of sexual behavior, and use of alcohol and marijuana prior to sexual intercourse will be asked. Participants will be made aware that some of the questions might be uncomfortable or seem intrusive but should be answered as honestly as possible.

The primary outcomes of this RCT are increased consistent contraceptive use (self-reported) and increased clinic utilization among the participants (self-reported). Additionally, we are interested in learning about changes in behavioral intentions on birth control use, especially LARCS, pregnancy events, and the self-reported use of dual protection for pregnancy and STI prevention. In order to advance the body of evidence of mHealth interventions, we will also assess how Crush is utilized by the target audience. The data collected from this study will prove useful to the application of disseminating sexual and reproductive health services among girls for teen pregnancy and STI reduction and increase use of birth control.

A.12. Estimates of Annualized Burden Hours and Costs

The analysis plan assumes 768 girls will complete all phases of data collection. We estimate that we will lose 20% of respondents between enrollment and the 3-month time point, and another 20% between the 3-month time and the 6-month time point. Therefore, taking into account participant attrition we will need to recruit 1,200 participants to yield a final sample size of 768 girls. To recruit 1,200 participants, it is estimated we will need to screen 3,000 individuals who follow the link from the recruitment website. The estimated response burden is 802 hours. Each participant who completes follow-up will spend approximately 46 minutes total. For both the intervention and control groups, this includes the completion of the screener, enrollment form, baseline survey, 3 month follow-up and 6 month exit survey. The total estimated annualized burden hours are 812.

Table 1: A.12-1 Estimates of Hour Burden

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Annual Hour Total Burden Hours
Interested Individuals	Screener Questions	3,000	1	1/60	50
Girls 14-18 years old	Enrollment Questions	1,200	1	5/60	100

Intervention Group	Baseline Survey	600	1	15/60	150
	3-Month Survey	480	1	10/60	80
	6-Month Survey	384	1	15/60	96
Control Group	Baseline Survey	600	1	15/60	150
	3-Month Survey	480	1	10/60	80
	6-Month Survey	384	1	15/60	96
Total					**802**

Table 2: A.12-2 Annualized Cost to Respondents

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Interested Individuals	Screener Questions	50	7.25	$363
Girls 14-18 years old	Enrollment Questions	100	$7.25	$725
Intervention Group	Baseline Survey	150	$7.25	$1,088
	3-Month Survey	80	$7.25	$580
	6-Month Survey	96	$7.25	$696
Control Group	Baseline Survey	150	$7.25	$1,088
	3-Month Survey	80	$7.25	$580
	6-Month Survey	96	$7.25	$696
Total				**$5,816**

*Calculated as the Federal minimum wage ($7.25).

The total estimated annualized cost to respondents is $5,816.

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

This information collection does not require respondents to purchase new or additional equipment or services. Participants must have regular access to a smartphone in order to participate in the study. Therefore, all data collection devices (smartphones in this case) would have already been purchased. There is no cost associated with this research for the participant.

A.14. Annualized Cost to the Government

The annual cost to the Federal Government is $500,000.00 through an SBIR Phase II contract between CDC and MetaMedia Training International, part of a two-year SBIR contract- September 6, 2014 to September 5, 2016. The budget includes $40,000 for participant incentives (see section A.9, Explanation of Any Payment of Gifts to Respondents).

Table 3: A.14-1 Annualized Cost to the Government

Type of Cost	Amount
CDC Staff Costs:	
5% GP-14	$7,622
10% GS-13	$9,594
10% GS-13	$8,721
Annualized Total for CDC Staff	$25,937
Contract Cost	$500,000
Total	$525,937

A.15. Explanation for Program Changes and Adjustments

There are neither program changes nor adjustments. This is a new collection of information

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data Collection and Publication:

Data collection will take place during an 11 month period. Participants will be enrolled on a rolling basis. Enrollment will take place for 3 months, until our target sample size (n=1,200) is reached. If the desired sample size is reached at month 3, the enrollment period will close. If we have not reached the desired sample size, we will continue to recruit for one more month. Each participant will be followed for 6 months. On Month 9 (or month 10 if recruitment period is extended) all participants will complete the 6-month exit survey. Participants in the control group will then gain access to the intervention and be followed for an extra month to acquire navigation and utilization data. This will not require any additional response burden from participants as data is automatically collected through web analytics. On month 11 all data collection will stop. Data analysis will take

place months 11-12 A technical report will be submitted to the CDC between September and November 2016. Manuscripts and abstracts for peer review journals and conferences will be prepared and disseminated up to 5 years after the conclusion of the study.

Statistical Analyses:

Preliminary Analyses: The first stage of data analysis is to create a codebook for data processing of all measures. After the first baseline survey, we will develop a coding system to clean, recode, create and transform variables as needed to make them suitable for analysis according to the statistical analysis plan. Second, we will conduct baseline equivalency test of the control and intervention group to assess whether randomization resulted in equivalent and comparable groups. We will test for missing data at each wave of data collection, and will continuously monitor attrition for both groups throughout the data collection process.

Main Analyses: All data collected for this study will be analyzed using statistical methods. Analysis methods will directly respond to the main research questions and will include descriptive statistics, linear and logistic regressions, analysis of variance and chi-square. Results from this study will be published through multiple channels including technical reports to the Federal contracting agency (the CDC), peer review journals, and national and international conferences. All data tabulations will correspond to the reporting standards appropriate for each statistical analysis method used.

We will conduct descriptive analyses (percentage, mean, median, and cross tabulations) to obtain central tendency of the variables of interest: outcome variables, theoretical constructs, demographic, sexual behavior, clinic utilization, and Crush utilization and satisfaction variables. Additional descriptive analysis will consist of t-tests for continuous variables and chi-square for categorical variables between predictors and the outcome variable. Bivariate tables will show the number of effective episodes of contraceptive use or clinic visitation by covariates expected to influence these outcomes.

In the Crush efficacy analyses, the unit of analysis will be the subject. Weights consisting of the number of sexual encounters will be used to account for differing numbers of encounters among subjects. Data analysis will consist of calculating statistics and tables describing the use of effective contraception and clinic visitation, plus employing multivariate linear and logistic models for assessing differences in effective contraception use and clinic utilization between the intervention and control groups.

A multivariate statistical model will be used to assess differences between intervention and control groups. The model will be based on generalized linear model theory. The use of generalized linear models will allow us to specify the mean of a population as a function of a number of predictor variables through a nonlinear link function. The link function most suited for analyzing the number of effective contraceptive episodes is the log link, assuming a Poisson distribution for the number of contraceptive episodes. Using this link, the number of sexual encounters is specified as the offset variable.

The link function most suited for analyzing clinic visitation when measured as yes/no variable is the logit link, assuming a binomial distribution. Model diagnostics will include goodness of fit tests, influence statistics, and residual plots. Analyses will be carried out

using the SAS 9.4 statistical software package.

We will explore Crush's usability mainly through descriptive statistics (percentage, mean, median). Data tables will disaggregate content dosage, uptake, exposure, dosage and participation data rate by age and racial groups, and intervention and control groups. Bar charts will display the frequency of visitation of each page by thematic and media content.

Table 4: A.16.1

Project Time Schedule

Activity	Time Schedule
Start participant recruitment	1 months after OMB approval
Enroll study participants	1-3 months after OMB approval
Start data Collection	1-11 months after OMB approval
Complete data collection	8-10 months after OMB approval
Conduct data analysis	4-13 months after OMB approval
Prepare primary publications	12-24 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for PRA Submissions

There are no exceptions to the certification.

References

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