EmpowerU: Promoting Health-Related
SEL Skills Development in High-Needs Populations

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*Empowerment /ɪmˈpaʊ.ɚ.mənt/ (noun): the process of gaining freedom and power
to do what you want or to control what happens to you.*

A.1 Potential Contribution to Increase Knowledge and Address Educational Problems

The interdependence between health, social, emotional, and educational outcomes has never been more evident (McCann et al., 2023; National Public Radio, 2023; Prothero, 2021; U.S. Department of Education, 2021). The COVID-19 pandemic not only transformed how, when, and where students learn, but it also exposed disparities between student populations and critical gaps in existing educational programming (Cheng et al., 2020; Hoofman & Secord, 2021; Kappler Hewitt et al., 2020). One such gap is the urgent need to elevate the nation's mental and physical health literacy (Abdel-Latif, 2020; Farrell, 2021; McCann et al., 2023). Defined as the ability to locate, understand, and use health related information and services to navigate, manage, and advocate for ones' health and well-being (USHHS ODP, 2010), health literacy has been directly linked to a myriad of short and long-term social, emotional, physical, financial, and educational outcomes (Berry, 2000; Liu et al., 2020; Nutbeam & Lloyd, 2021; Stormacq et al., 2019).

National surveys reveal that nearly 9 out of 10 U.S. adults (Fleary & Ettienne, 2019; Logan, 2017; Polster, 2018) and about two-thirds of adolescents (Trout, Lambert et al., 2014; Trout, Hoffman et al., 2014) lack health literacy. Poor health literacy limits one's ability to develop a healthy identity, achieve goals, and make responsible decisions related to one's health and well-being. These elements, embedded in social-emotional learning (SEL) and its aligned core competencies (i.e., self-awareness, self-management, social awareness, relationship skills, responsible decision-making; CASEL, 2023) receive little attention in U.S. schools (Hess & Straub, 2010; Huscroft-D'Angelo & Trout, 2018; Trout et al., 2017; see Table 1). We propose to address this shortcoming by developing *EmpowerU*, a timely comprehensive web-based curriculum to explicitly teach health literacy concepts incorporating SEL competencies. Our overarching goal is to improve health-related social, emotional, and educational outcomes of

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high-needs secondary students in rural, urban, and suburban economically disadvantaged, underrepresented, and underperforming settings.

EmpowerU aligns with EIR Absolute Priorities 1 and 4 (<u>Demonstrates a Rationale</u> and <u>Meeting Student Social, Emotional, and Academic Needs</u>), and Competitive Preference Priority 1 (<u>Promoting Partnerships with Underrepresented Entities</u>). It builds on over a decade of work funded by the U.S. Department of Education (grant #R324A160170) to develop and evaluate *HealthyU,* an evidence-supported, web-based health literacy program for underperforming adolescents. We propose this EIR Early-Phase project to: (a) iteratively develop, modify, and evaluate the effects of *EmpowerU* on the social, emotional, and educational outcomes of rural, urban, and suburban high-needs secondary students who are economically disadvantaged, underrepresented, or underperforming and (b) develop the infrastructure (e.g., hosting platform, distribution approach) to enable long-term program sustainability and future replication efforts to meet *What Works Clearinghouse* standards for national dissemination.

> *"The foundation of success in life is good health: that is the substratum fortune; it is also the basis of happiness." – P. T. Barnum*

Good health and wellness (i.e., physical, social, emotional) are related to positive educational outcomes and facilitate successful living (McCann et al., 2023; U.S. Department of Education, 2023). Poor health and well-being are linked to limited health literacy and have serious consequences in terms of medical care quality, costs, and disparities nationwide (Mantwill et al., 2015; Parker & Ratzan, 2010), as shown in studies evaluating the economic impact of low health literacy. For example, a 2020 evaluation by the United Health Group indicated that an increase in health literacy across the U.S. could prevent over $25 billion in unnecessary healthcare costs each year. Almander-Douglas (2013) argued that, considering the future costs of low health literacy and the lack of education to address these key skills, the real costs are more likely <u>1.6 trillion</u> to <u>3.6 trillion</u> dollars annually.

These economic costs illustrate considerable societal impact of poor health literacy, but personal costs on individual well-being are equally concerning. In his call to action to prioritize

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health literacy, a former U.S. Surgeon General stated, *"The poor state of health literacy in America is a crisis. It is an underlying cause of disparities. It is also a source of extensive disempowerment and perpetuates preventable disease"* (p. 803; Carmona, 2006). Decades of extensive health, education, and economic research support this conclusion, now further exacerbated by the pandemic. Poor health literacy has detrimental effects on all aspects of a person's s health, education, employment, and social-emotional outcomes (see Table 1).

Table 1: *Impact of Low Health Literacy in Targeted Domains*

Social Outcomes Related to Low Health Literacy	*Supporting Literature*
➢ Negative psychological and social consequences, including increased feelings of stigma and shame	Chen et al., 2018; Hurley et al., 2019; Mackert et al., 2014; Palumbo, 2017
➢ Decreased communication, miscommunication, limited trust and self-advocacy with providers on health-related matters	Damm et al., 2015; Hess et al., 2011; Hurley et al., 2019
➢ Social, economic, and environmental disadvantages as a mediator of health disparities and as a determinant of health	Mantwill et al., 2015; Nutbeam & Lloyd, 2021; Schillinger, 2021
Emotional Outcomes Related to Low Health Literacy	*Supporting Literature*
➢ Decreased use of mental health services, missed appointments, understanding of treatments and provider types	Connor & Casey, 2015; Hurley et al., 2019; Mendenhall & Frauenholtz, 2013, Tambling et al., 2021
➢ Misuse of medications treating mental health disorders	McCay, 2023; Mafruhah et al., 2021
➢ Decreased self-determination and efficacy to navigate physical and mental healthcare systems	Damm et al., 2015; Hess et al.,
Transition Outcomes Related to Low Health Literacy	*Supporting Literature*
➢ Poorer short- and long-term achievement, negative impact on lifelong learning and school transition readiness skills	Bonell et al., 2014; Chisolm et al., 2021; Frauenholz et al., 2017; St. Leger, 2001; Trout et al., 2018
➢ Poorer self-ratings of health and health outcomes during the transition to young adulthood, higher unemployment and economic instability	Berkman et al., 2011; Sentell, 2012; Stormacq et al., 2020; Trout et al., 2018; Xin et al., 2022
Health Outcomes Related to Low Health Literacy	*Supporting Literature*
➢ Higher rates of preventable hospital visits, use of emergency services, and hospital admissions	Berkman et al., 2011; Chen et al., 2018; Morrison et al., 2019
➢ Higher annual healthcare costs (estimated at four times that of health literate peers), less likely to be insured	Berkman et al., 2011; Haun et al., 2015; Palumbo, 2017; Sentell, 2012

➢ Decreased use of preventative services such as mammograms, pap smears, and immunizations	Ratzan, 2020; Ratzan, 2011; Stormacq et al., 2019
➢ Entry into the healthcare system sicker than literate peers	Levy & Janke, 2016
➢ Higher rates of chronic conditions, such as high blood pressure, diabetes, and asthma, less knowledge about chronic illness management	Liu et al., 2020; Williams et al., 1998a; Williams et al., 1998b; Schillinger et al., 2002; Schillinger et al., 2003

Addressing the problem. Given the broad negative effects of low health literacy across multiple key life domains, and the current attention to health literacy due to the COVID-19 pandemic, national calls to improve health literacy at all levels of the U.S. population have been made by multiple agencies, including the U.S. Department of Health and Human Services, Center for Disease Control and Prevention, American Academy of Pediatrics, World Health Organization, American School Health Association, and the Society for Public Health Education. For example, the Center for Disease Control and Prevention released a *Health Literacy Action Plan* and the U.S. Department of Health and Human Services released *Healthy People 2030* providing a national approach to improve health literacy. The framework, designed as action items, includes *developing* and sharing accurate, accessible, and actionable health and safety information; *integrating* health literacy and clear communication into public health planning, policy, funding, research, and evaluation; and *incorporating* standards-based accurate and developmentally appropriate school-based curricula. Specific health literacy SEL aligned goals include improving communication, increasing self-efficacy and self-management, and navigating social systems and outlets (CDC, 2010; DHHS, 2023). Some aspects of this framework focus on medical practitioners and public health departments, but the Center for Disease Control and Prevention, in line with National Health Education Standards, identifies schools as a key agent of change and calls on the educational system to begin to select, develop, implement, and evaluate programs to improve health literacy and associated outcomes in our nation's youth (CDC, 2022).

EmpowerU is designed to answer the call to action and change the national trajectory of inadequate health literacy in adolescents. It will help all students, including high-needs students, develop critical health literacy-related skills, including social and emotional skills related to

communication, self-determination, stigma awareness, and transition preparedness. The proposed project will develop, refine, and preliminarily evaluate *EmpowerU,* and establish the hosting platform, assets, dissemination approach, and infrastructure needed for further evaluation and broad scale-up.

A.2 Development and Demonstration of Promising New Strategies

EmpowerU offers a promising new strategy that will extend an existing evidence-supported health literacy curriculum, *HealthyU*, which was developed over the past decade through research conducted by our investigative team, curriculum specialists, expert consultants, IT professionals, and web developers. *HealthyU* is an online, self-paced curriculum that builds comprehensive health literacy skills in secondary underperforming students. The prototype was developed and tested for efficacy with U.S. Department of Education funding (grant # #R324A160170) which ended in 2023.

The *HealthyU* curriculum consists of seven content modules and two evaluation modules hosted on the TalentLMS cloud-learning platform. *HealthyU* students watch instructional videos, read presented material, apply skills through real-life scenarios, and complete interactive activities to reinforce key concepts. Each session takes about 45 minutes and <u>requires minimal teacher training and teacher support</u>. Curriculum objectives include: (a) developing skills necessary for personal management of individual health across the five SEL core competencies (i.e., self-awareness, self-management, social awareness, relationship skills, and responsible decision-making); (b) improving health-related quality of life; (c) improving health-related knowledge and skills that influence employment and economic stability; and (d) identifying health-related services, resources, and supports. Objectives are met through the scope and sequence, and content is broken down into skills and applied activities to develop health literacy strategies that generalize to real-world situations. Appendix J presents the *HealthyU* scope and sequence and examples of content and activities.

Preliminary evidence. *HealthyU* was iteratively developed and evaluated with a series of pilot studies to examine feasibility, functionality, social validity, and efficacy with

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underperforming students (i.e., students with or at risk of disabilities) across suburban classrooms in the Midwest. The first study was conducted with a sample of 8 secondary students served in a behavior-based alternative education setting. Results demonstrated an average of 30% improvement in health literacy knowledge per module and an overall *HealthyU* curriculum satisfaction rating of 3.9 (1 = *not at all satisfied* to 5 = *very satisfied*). The second study was conducted with 12 students in a self-contained high-school classroom. At program completion, all participants reported that they would recommend *HealthyU* to a peer, providing an average overall satisfaction score of 4.04 (i.e., very good satisfaction). Students averaged 17% gain in knowledge across the eight modules. The third study was conducted with 67 students in a credit-recovery health-education summer school course. Students' scores on the Health Literacy Knowledge Test increased 10.8% from pretest to posttest, representing a medium effect size (Hedges's $g = 0.69$). A fourth study was conducted with 36 students across two alternative school settings in spring 2022. Using an unconditional model, students had significant gains on the Health Literacy Knowledge Test (a medium effect size of $g = 0.62$, or a 12.9 percentage point gain from pretest to posttest), the Health Literacy Self-Determination questionnaire (representing a large effect, $g = 0.84$), and the health-related Transition Preparedness scale (representing a medium effect, $g = 0.58$). In these studies, student satisfaction scores ranged from 2.50 to 5.00 with a mean of 3.77 (*SD* = 0.77). These studies provide evidence that <u>students receiving explicit instruction improve health literacy-related educational outcomes, self-determination, and transition preparedness</u>.

These findings suggest that the core content of *HealthyU* holds promise for high-needs secondary students in rural, urban, and suburban economically disadvantaged, underrepresented, and underperforming settings. *HealthyU* offers a good starting place to improve student health literacy but has several limitations: it was developed to address the needs of students prior to the global pandemic; it was designed primarily for underperforming students; and it was built on a LMS platform with narrow capabilities for customization, dissemination, and widespread school integration. The modifications proposed to create *EmpowerU* are necessary to (a) improve the

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hosting platform; (b) enhance curriculum concepts based on findings from our existing studies and feedback from key stakeholders (i.e., students, educators, curriculum specialists) and our multidisciplinary *HealthyU* Advisory Board (mental health, infectious disease, pediatrics, obstetrician, education, nursing, and research experts); and (c) develop mechanisms for scaling. The proposed *EmpowerU* platform, content enhancements, and added curriculum concepts (i.e., stigma, mental health literacy, rural health literacy) will better address health literacy and health-related SEL development for today's high-needs students across diverse educational settings and geographic regions.

      EmpowerU **program description.** *EmpowerU* will be a web-based, self-paced curriculum encompassing health literacy skills, knowledge, behaviors, self-management, and communication for secondary students, including those in targeted high-needs populations (defined as identified with disabilities; living in low-income households; educated in traditionally underserved rural settings or alternative education settings; or members of racial, ethnic, or gender groups who have been traditionally underrepresented). *EmpowerU* will consist of 11 (12 for rural populations), 45-minute modules, including 10 content modules and two evaluation modules (pretest and posttest). Each module will present content on a key concept in health literacy with animated instructional videos, reading materials, and engaging interactive games and activities. The program will be delivered on a customized training, technically supported, and evidence-based platform (i.e., Technology-based Behavioral Intervention Delivery System [T-BIDS]; https://influentsin.com/products/), designed for the management of multimedia curricula in education, healthcare, and social service markets (see Appendix J; Conroy et al., 2022; Feil et al., 2014; Sawyer et al., 2022; Self-Brown et al., 2017; Snow-Hill et al., 2021). Each *EmpowerU* module will end with a review activity, knowledge check, and brief satisfaction survey, and student progress will be easily accessible to teachers via the T-BIDS *EmpowerU* dashboard (see Appendix J). *EmpowerU* will take about 9 instructional hours, assuming 11-12, 45-minute lessons.

      Table 2 summarizes *EmpowerU* key features, as well as features and content to be

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retained from *HealthyU*. Revisions and additions reflect extensive feedback gathered during the *HealthyU* development project, and address three primary areas: instructional assets, support and sustainability, and curriculum content. More details about the development and refinement of *EmpowerU*, and a timeline, are presented in Section B.

Table 2. *EmpowerU Program Description and Additions*

		HealthyU	EmpowerU
	Instructional Assets		
New	T-BIDS integrated learning games and review activities[a]		✓
Revised	Universal Design for Learning tools	✓	✓
Revised	Media (e.g., audio, images, animated videos, slides)	✓	✓
- Revised	Glossary	✓	✓
Revised	Quizzes	✓	✓
New	Feedback/encouragement (e.g., rewards, reminders)[a]		✓
	Support & Sustainability		
New	Adaptable enrollment structure[a]		✓
New	T-BIDS technical support[a]		✓
New	Integrated single sign on capabilities[a]		✓
New	*EmpowerU* marketing video[a]		✓
New	Instructor/proctor dashboard and analytic reports[a]		✓
	Curriculum Content[b]		
New	Instructor video: *EmpowerU* overview[a]		✓
Revised	Module 1: Introduction to health literacy	✓	✓
Revised	Module 2: Health-related decisions and self-advocacy	✓	✓
Revised	Module 3: Health-related rights and responsibilities	✓	✓
Revised	Module 4: Health insurance and government programs	✓	✓
Revised	Module 5: Medical providers, settings, and appointments	✓	✓
Revised	Module 6: Communication and medical paperwork	✓	✓
Revised	Module 7: Medication self-management	✓	✓
Revised	Module 8: Prevention, immunizations, and ethics	✓	✓
New	Module 9: Mental health literacy[a]		✓
New	Module 10: Health-care stigma[a]		✓
New	Module 11: Health literacy in rural settings*[a]		✓
Revised	Module 12: Wrap-up, summary, and evaluation	✓	✓

Note. *Module 11 will be only for rural students. [a]Modifications and additions reflect student, teacher, administrator, and district feedback obtained during the development and evaluation of *HealthyU* during the COVID-19 pandemic. [b]The proposed content areas align to K-12 National Health Education Standards (https://www.cdc.gov/healthyschools/sher/standards/index.htm).

Section B: Project Design

B.1. Conceptual Framework

Grounded in the How People Learn framework (Bransford et al., 2000), universal design

for learning (CAST, 2022) principles, and digital pedagogy (Howell, 2012), *EmpowerU* will incorporate individual and contextual factors that influence student learning. This framework will be used to promote a health literacy foundation for learners that will foster positive short- and long-term social, emotional, and health behaviors (see Logic Model, Appendix G). This framework is not static, but represents key instructional, learning, engagement, and support mechanisms integrated in the *EmpowerU* program to maintain a student-centered focus and enhance engagement. Each program feature supports the curriculum content, reinforces conceptual understanding, and encourages learning, thus promoting students' health literacy, SEL, enhanced health, and academic achievement (Bonell et al., 2014; Chisolm et al., 2021; Frauenholz et al., 2017; McCann et al., 2023; Trout et al., 2018).

The How People Learn framework ensures that learning environments are centered on the learner, knowledge, assessment, and community (Bransford et al., 2000; Gentry, 2015; Yalvac et al., 2006). This framework supports the notion of sense-making, development, insight, and metacognition. It accounts for how individual students learn and identifies SEL skills or supports needed to reinforce content (Bransford et al., 2000; Gentry, 2015; Yalvac et al., 2006).

Universal design for learning principles acknowledge that learning environments must appeal to all learners and promote equity of access to content for curriculum engagement (CAST, 2022). These principles encompass the why, what, and how aspects of student learning through engagement (e.g., purposeful content to stimulate learning and motivation), representation (e.g., varied presentation of content to promote learning for all students), and action or expression (e.g., integration of differentiated methods so that learners can express what they know and comprehend). Although especially important for underperforming students, these principles demonstrate practical aspects to equalize learning opportunities for all high-needs learners.

Because the T-BIDS platform will be the instructional delivery mechanism for *EmpowerU,* digital pedagogy (Howell, 2012) is reflected in the system's functionality, and is key for establishing efficient and fluent online learning. Digital pedagogy encourages responsiveness to fast-changing and evolving technologies, incorporates electronic support tools and web-based

instructional practices, and allows students to control the pace of learning (Howell, 2012; Teaching and Learning in the Digital World, 2017). This approach focuses on helping learners understand how to access and use system assets and promote critical thinking in the digital learning environment (Howell, 2012; Zedgod, 2016).

B.2. Goals, Objectives, and Outcomes

The *EmpowerU* team will address eight primary goals in the 5-year project (see Table 3). Goals will be accomplished in four phases to allow for iterative development and refinement.

Phase A. Goal 1 will be achieved through collaboration with the research, technology, and expert content reviewer teams. This collaboration will secure the assets transfer, revise practice activities, build system analytics, develop the teacher dashboard, and revise curriculum outcome measures. Upon completion of Goal 1, *HealthyU* will be transferred into the enhanced *EmpowerU* learning platform to provide the foundation for expansion, scale-up, and replication. Goal 2 will be achieved through collaborative efforts between school professionals, high-needs students, the original *HealthyU* developers, and the external evaluators. First, we will conduct nine focus groups (i.e., three high-needs student, three school professional, and three provider groups) using the nominal group technique (Delbecq et al., 1986) method to establish content objectives for three new *EmpowerU* content modules. This method was selected because it is effective for use in intervention design (Krueger, 1988), provides participants with a safe environment in which to build on others' ideas (Madriz, 2000), gathers information about a specified topic in a timely manner (Johnson & Turner, 2003), allows for a one-time discussion that may be replicated with similar participants (Krueger & Casey, 2000), and is an effective way to gather information in areas with little prior research (Fontana & Frey, 2005). We have used this approach with high-needs students, school professionals, and providers in our previous studies, including the original *HealthyU* project and our existing Early-Phase EIR project (CFDA# 324A160170; U411C190009; Trout & Epstein, 2010; Tyler et al., 2014). Further, as this method is effective for triangulating results across groups, it will allow our evaluators to quickly identify key content objectives and engagement features needed for Phase B.

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Recruitment method. The research team will work with school districts, agencies (i.e., Latino Center of the Midlands – [LCM; see support letter]), and team members (see support letters in Appendix C) to implement recruitment procedures that have been successful in our prior projects with high-needs students, school personnel, and community providers (CFDA #R324A160170; U411C190009). Specifically, we will work with ▆▆▆▆▆▆ to secure the participation of students (i.e., those attending school in rural settings; $n = 10$) and school personnel (e.g., health educators, physical education teachers, transition focused educators; $n = 10$) engaged in rural school settings, along with healthcare professionals (e.g., pediatricians, family providers, nurse practitioners; $n = 10$) practicing in rural communities. This will provide the foundation for content objectives for the proposed module on rural health literacy. Second, we will work with ▆▆▆▆▆▆ and LCM to secure the participation of students (i.e., underperforming, underrepresented, economically disadvantaged, identified with mental health disorders; $n = 10$), school personnel (e.g., counselors, social workers, transition focused educators, behavior specialists; $n = 10$), and providers (e.g., mental health practitioners, psychologists; $n = 10$) from alternative education settings to help identify key concepts for the proposed mental health literacy module. Finally, we will work with ▆▆▆▆▆ and LCM to secure the participation of students (i.e., underperforming, economically disadvantaged, underrepresented; $n = 10$), school personnel (e.g., health educators, health education administrators, special educators, transition specialists; $n = 10$), and community providers (e.g., health, mental health, nurses, and vocation rehabilitation specialists; $n = 10$) to help identify key concepts for the proposed health stigma module. With this approach, the target population will be involved in the *EmpowerU* development process from inception to evaluation.

Phase B. Goal 3 will be addressed through collaboration between the research, content expert, and technology teams. Research and content team members will write content for the each of the proposed modules. Drafts will be reviewed by an Advisory Board (see Table 6), and the technology team will build related curriculum assets. This work will result in the prototype *EmpowerU* program that will be evaluated in Goal 4. To achieve Goal 4, we will conduct a

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feasibility study of the prototype *EmpowerU* program with at least 36 high-needs students and their teachers spanning rural, urban, and suburban settings. High-needs students in rural settings will complete the core *EmpowerU* curriculum (Modules 1-8; see Table 2), all three newly added modules (mental health, health stigma, and rural settings), and the wrap-up and assessment module. High-needs students in suburban and urban school settings will complete the core *EmpowerU* curriculum, the newly added mental health and health stigma modules, and the wrap-up and assessment module. All participants will complete the refined outcome measures (to test feasibility and identify necessary changes prior to Phase C pilot testing) and the satisfaction survey (to determine social validity; see Table 4). Participants will be offered the opportunity to engage in structured interviews to gather additional social validity and consumer feedback. Upon completion, the team will analyze the implementation, outcomes, social validity, and structured interview data to develop a plan for content and measure refinement in Phase C.

  Recruitment method. The research team will use methods that have been successful in prior feasibility study projects (CFDA #R324A160170; U411C190009), and collaborate with Drs. Adkins, Gordon, and Avey to recruit participants. The first 36 assenting high-needs students and their teachers attending a rural, urban, or suburban school enrolled in health- or transition-focused courses will be invited to join the study (see Appendix C for support letters). Teachers also will complete informed consent procedures to provide social validity and interview data.

  Phase C. <u>Goal 5</u> will focus on iterative refinements to *EmpowerU* based on results from Goal 4. Team members will revise *EmpowerU* content, assets, and measures to achieve Goal 6. To achieve <u>Goal 6</u>, we will conduct a pilot study with at least 36 high-needs students and their teachers using recruitment methods described in Phase B to test the refined *EmpowerU* prototype, including implementation, outcome, and social validity measures (see Table 4). The purpose of Phase C is to (a) test the implementation of the revised *EmpowerU* curriculum based on feedback and input from Phase B, (b) refine the teacher dashboard, (c) evaluate user buy-in, (d) test measure quality and implementation fidelity, (e) determine *EmpowerU* acceptability, and (f) evaluate dosage. We will conduct follow-up interviews and meetings with the Advisory

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Board to finalize the *EmpowerU* program and training, evaluation, and fidelity procedures for the Phase D wait-list randomized controlled trial.

Phase D. Goal 7 will involve members of the research, technology, and content review teams for final revisions to *EmpowerU*. Goal 8 will use a wait-list randomized controlled trial to evaluate effects of the revised curriculum on the health-related outcomes of high-needs students. As one objective of this EIR grant is to develop programs and identify practices that demonstrate a significant impact on high-needs student outcomes, we will assess outcomes related to health literacy (e.g., self-awareness, decision-making, self-management, communication/relationships, social awareness), health-related transition preparedness, health self-determination, stigma, fidelity, and social validity (see Table 4 and Appendix J for details on measures).

Method. Using recruitment methods described above, in project years 4-5 we will recruit, consent/assent, and randomly assign at least 480 students to *EmpowerU* or a "business-as-usual" wait-list control condition (see pilot study for recruitment and eligibility criteria; see Section E for additional evaluation study information).

Table 3. *Project Goals Objectives, and Anticipated Outcomes*

Project Goal 1 (Y1): Transfer, adapt, and enhance the existing HealthyU curriculum to a sustainable platform (T-BIDS) to enable expansion, scale-up, and replication of EmpowerU.	
Objectives	(1) Transfer existing *HealthyU* curriculum assets and integrated practice activities to the T-BIDS platform to build the foundation of *EmpowerU*; (2) Develop system analytics to capture fidelity, feasibility, dosage, and user engagement; (3) Develop a teacher dashboard to capture student progress and outcomes*;* (4) Refine outcome measures (Health Literacy Knowledge Test; Health Literacy Self-Determination; Transition Readiness Adolescent Questionnaire; Health Stigma); (5) Obtain input from expert content reviewers on refined outcome measures.
Outcomes	(1) Prototype of the *EmpowerU* platform (i.e., modules, formative assessments, activities, universal design for learning features, videos) that can be feasibility tested with students in rural, urban, and suburban school settings; (2) Prototypes of the implementation and outcomes measures; (3) Prototype teacher dashboard; (4) Completed teacher tutorial video; (5) Completed student tutorial video.
Project Goal 2 (Y1): Begin initial curriculum development through engagement with stakeholders.	
Objectives	(1) Recruit/consent/assent 30 high-needs students, 30 school personnel, and 30 providers to participate in focus groups; (2) Conduct nine nominal group technique focus groups with key stakeholders (students, educators, providers); (3) Hold one meeting with the Advisory Board to solicit feedback on *EmpowerU* and focus group

findings; (4) Identify key concepts for integration into the three new *EmpowerU* modules developed in Phase B (i.e., rural health literacy, mental health literacy, and health stigma).

Outcome	(1) Identification of content objectives for three new *EmpowerU* modules.

Project Goal 3 (Y2): Develop three new EmpowerU modules.

Objectives	(1) Develop curriculum for three new *EmpowerU* modules (i.e., content and assessments); (2) Develop assets for new modules (i.e., videos, activities, dashboards); (3) Obtain expert input on curriculum content for new modules; (4) Finalize changes to newly developed modules based on expert input (i.e., content, activities, assessments).
Outcome	(1) Three fully developed additional modules ready for feasibility testing.

Project Goal 4 (Y2): Test EmpowerU feasibility with high-needs students to determine necessary changes to impact health literacy-, implementation-, and social validity-related outcomes.

Objectives	(1) Recruit/consent/assent 36 high-needs students and their educators (*n*=3); (2) Obtain 90% district participation rate; (3) Implement *EmpowerU* at 90% fidelity; (4) Conduct follow-up interviews with 13 high-needs students and 3 educators; (5) Hold one meeting with the expert Advisory Board; (6) Identify curriculum refinements; (7) Identify measurement refinements; (8) Identify teacher dashboard refinements.
Outcomes	(1) Fully established curriculum refinements; (2) Fully established measure modifications; (3) Fully established teacher dashboard refinements.

Project Goal 5 (Y3): Refine the three new EmpowerU modules, assets, and outcome measures.

Objectives	(1) Refine curriculum content and measures for the three proposed *EmpowerU* modules; (2) Refine assets for new modules; (3) Obtain expert input on refined curriculum content for new modules; (4) Finalize changes to the refined modules based on expert input (i.e., content, activities, assessments).
Outcome	(1) Three fully refined modules for *EmpowerU* ready for pilot testing.

Project Goal 6 (Y3): Conduct a preliminary pilot study of EmpowerU and further refine components.

Objectives	(1) Recruit/consent/assent 36 students and their educators (*n*=3); (2) Obtain 90% district participation rate; (3) Implement *EmpowerU* at 90% fidelity; (4) Conduct 13 individual student and 3 teacher follow-up interviews; (5) Hold one meeting with content experts; (6) Determine final content, measure, and asset refinements.
Outcome	(1) Finalized set of *EmpowerU* curriculum, measurement, and asset refinements.

Project Goal 7 (Y4): Final modifications to EmpowerU modules, assets, and outcome measures.

Objectives	(1) Modify curriculum content and measures for existing and new *EmpowerU* modules; (2) Modify assets for new modules (i.e., videos, dashboards, activities); (3) Obtain expert input on refined curriculum content for existing and new modules; (4) Finalize changes to the refined core content and new modules based on expert input (i.e., content, activities, dashboard, assessments).
Outcome	(1) Finalized *EmpowerU* modules and core content ready for efficacy testing.

Project Goal 8 (Y5): Examine the effects of EmpowerU on student health literacy, self-

	determination, transition preparedness, and stigma.
Objectives	(1) Recruit/consent/assent at least 480 high school students (240 treatment, 240 control); (2) Recruit/consent a minimum of 8 teachers; (3) Obtain 90% district participation rate; (4) Implement *Empower*U at 90% fidelity; (5) Complete all data analyses for primary and secondary research questions; (6) Determine student costs; (7) Disseminate locally, regionally, and nationally for expansion and replication; (8) Meet with 80% of participating districts to discuss continued implementation of *EmpowerU* following study completion.
Outcomes	(1) Increased access to supplemental curriculum addressing health literacy, rural health, health stigma, and mental health care literacy; (2) Increased health and mental health literacy and self-determination; (3) Increased awareness of health-related stigma; (4) Improved health preparation for the transition to adulthood; (5) Determination of program costs; (6) Completed *EmpowerU* curriculum and content management system for scale-up and dissemination.

Table 4. *EmpowerU Measures for the Feasibility, Pilot, and RCT (Goals 4, 6, and 8)*

Construct	Measure(s)	Respondent	Occasion
Health Literacy Knowledge[1,2]	Health Literacy Knowledge Test Module Formative Assessments	Student Student	Pre/Post Post each module
Transition Preparedness[2]	Transition Readiness Assessment Questionnaire	Student	Pre/Post
Self-Determination[3]	*EmpowerU* Self-Determination Scale	Student	Pre/Post
Stigma[3,4]	Mental Health Stigma Measure *EmpowerU* Health Stigma Scale	Student Student	Pre/Post Pre/Post
Demographics	Questionnaire	Student Teacher	Intake Intake
Implementation/ Adherence	Content Accessed/Time	System Analytics	Post each module
Social Validity	*EmpowerU* Satisfaction Survey Interviews	Student Teacher	Post Post

Note. [1]Aligns with What Works Clearinghouse eligible outcome domain Life Sciences. [2]Aligns with What Works Clearinghouse eligible outcome domain Civic, Social, and Economic Participation. [3]Aligns with What Works Clearinghouse eligible outcome domain Intrapersonal Competencies. [4]Aligns with What Works Clearinghouse eligible outcome domain Student Behavior.

B.3. Addressing the Needs of the Target Population

The development and evaluation design for the proposed *EmpowerU* project was based

on our previous U.S. Department of Education-funded project (CFDA #R324A160170) to

support underperforming students, a high-needs population. Given preliminary evidence of

success (see Section A), we anticipate that a similar approach will also produce positive outcomes in an underrepresented, economically disadvantaged, and rural adolescent population. Evidence for this hypothesis stems from the underrepresented empirical literature on the health literacy status of our proposed target populations (see Table 5) and the evidence base for the *EmpowerU* instructional practices that have proven effective for these subgroups of students. Moreover, to ensure *EmpowerU* meets the diverse needs of high-needs students across geographic and educational settings, participants will be drawn from high schools in two states, including traditionally underserved educational service units in rural Nebraska, alternative high school settings (McAdams Academy in Wichita, Kansas, and Hanny Arram Center for Success in Kearney, Nebraska), and public schools in Lincoln, Nebraska (see Appendix C for details).

Table 5. *Health Literacy Status in High-Needs Student Populations*

Empirical Literature Evaluating Health Literacy in High-Needs Student Populations[a]
Students who are identified with disabilities or educated in alternative academic settings:
– Half reported concerns over their current health status, a prevalence rate nearly 68.7% higher than their peers (31.6%; $\chi^2_1 = 5.74$, $p < .05$; Trout et al., 2018).
– On direct measures of health literacy, the proportion of youths scoring in the "possible limited health literacy" range was 128% higher for underperforming students (68.6% vs 30.1%, $\chi^2_1 = 20.74$, $p < .001$) than for their peers (Trout et al., 2018).
Students who live in low-income households:
– Report poorer health behaviors, including less sleep, higher rates of substance use, and unhealthy diets (Buck & Frosini, 2012; Hall et al., 2011; Hiscock et al., 2010; Smith et al., 2021).
Students who are educated in traditionally underserved rural settings:
– Demonstrate elevated physical and mental health problems, lower health literacy, and increased health inequities (Fleary et al., 2018; Paakari et al., 2019; Smith et al., 2021).
Students who are members of racial, ethnic, or gender groups who are traditionally underrepresented:
– Black and Hispanic youth scored significantly lower on direct measures of health literacy compared to White or multiracial peers (Trout et al., 2014).
– One out of three youth demonstrated some level of risk on applied measures of health literacy (i.e., 50% were unaware of how to access health insurance, knew how to make medical or dental appointments, or were aware of family medical history; Trout 2015; Trout et al., 2015).

The extant literature demonstrates a clear need to promote health literacy as a mechanism for addressing inequities for rural, underrepresented, and economically disadvantaged youths.

High-quality education is a fundamental and necessary first step.

Instructional approach supporting literature. Both the Centers for Disease Control and Prevention (2022) and the World Health Organization have identified the provision of health literacy information as critical for the advancement of student health, social-emotional well-being, academic performance, and transition preparedness (Smith et al., 2021; Langford et al., 2014). How the content is presented is equally important (Borzekowski, 2009; Langford et al., 2014; Smith et al, 2021). Our conceptual framework (Section B.1) has been tested in prior development studies (see Section A). Each of the three theoretical approaches (the How People Learn framework, universal design for learning principles, and digital pedagogy) has been empirically studied with economically disadvantaged, underrepresented, underperforming, and rural learners (Bransford, 2000; Borzekowski, 2009; Conroy et al., 2022; Feil et al., 2014; Gentry, 2015; Sawyer et al., 2022; Self-Brown et al., 2017; Snow-Hill et al., 2021; Yalvac et al., 2006). Considering the moderate to large program effects obtained in *HealthyU* pilot studies with underperforming students, we expect that the proposed *EmpowerU* content, iterative design approach, and transfer to the T-BIDS platform will serve the needs of the target population.

Section C: Personnel

The *EmpowerU* project will be a diverse, multidisciplinary collaboration between professionals in curriculum development, health education, mental health, technology, research, and evaluation. The team will consist of a cadre of experts representing different geographic regions (e.g., rural, urban, suburban), content expertise (e.g., education, mental health, physical health, technology), and underrepresented backgrounds (e.g., multilingual, multiracial) to develop, refine, and evaluate *EmpowerU*. Personnel resumes are presented in Appendix B.

Recruitment of members from traditionally underrepresented groups. The Project Director and Co-Project Director are scientists at Oregon Research Institute, an independent behavioral sciences research center dedicated to understanding human behavior and improving the quality of human life through the prevention and treatment of health, educational, and social problems. To foster physical and mental health and well-being, and a society based on equity and

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justice, the institute values collaboration with diverse, vulnerable populations to identify and address their needs through research. The institute promotes diversity, equity, inclusion, and anti-racism within the organization and in the broader community through community partnerships. The institute's Racial Equity Working Group (REWork), comprised of administrators, scientists, and science support employees, makes recommendations to the Board of Directors for continuously improving diversity, equity, inclusion, and sense of belonging among employees, research partners, and community groups. To recruit project employees, the institute will actively seek individuals from diverse communities, backgrounds, and abilities that have been traditionally underrepresented based on race, color, national origin, gender, age or disability, and will offer a collaborative, flexible, and supportive working environment where contributions are rewarded and recognized, and employee well-being is prioritized.

Partnerships with underrepresented entities (Competitive Preference Priority 1). To ensure materials are culturally competent and representative of the diverse population of high-needs students, we have partnered with a minority-led company, Influents Innovations (the CEO is African American, the COO is Latina) for content and platform (T-BIDS) development and with the Latino Center for the Midlands for assistance with participant recruitment (see recruitment above).

Influents Innovations has built successful, culturally relevant research and commercial products across a range of areas from professional development to education and public health. Influents uses five levers to drive change towards a more diverse, equitable, and inclusive community, and support anti-racism: *products, research, staffing, procurement,* and *charitable giving*. *Products* include diverse representation, convey inclusion, and are informed by and address the needs of Black, Indigenous, and people of color. *Research* focuses on problems, participants, Advisory Boards, and engagement with diverse communities. A *diverse workforce* enables the inclusion of more perspectives in the work products, communicates the brand, and makes the commitment to inclusion explicit. *Procurement* activities support a diverse ecosystem of businesses. With *charitable giving,* Influents leverages other organizations for greater impact

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on diversity, equity, and inclusion.

The Latino Center for the Midlands is a community center established in 1971 to cultivate generations of engaged, thriving bilingual and Latino community members through educational support, workforce development, and leadership opportunities. Through its three main programs: workforce education and innovation, pathways to success, and family and community well-being, the Latino Center for the Midlands seeks to provide clients with the tools necessary to live a healthy, self-sufficient, and fulfilling life through directly interacting with the community, partnering with other organizations, and advocating on the community's behalf.

Table 6. *EmpowerU Key Personnel, Training, and Experience*

Research and Development Team – Oregon Research Institute
████████████████ **(PD),** *Senior Scientist.* ████████ (formerly ███) has over 20 years of experience developing, evaluating, and disseminating interventions in secondary educational settings, and has secured over $16 million in federal funding and evaluation contracts. She is the lead developer of *HealthyU* and was the PI for the original development work funded through the DOE (CFDA#R324A160170). ██████████ is currently the Co-PD of an EIR Early-Phase project (CFDA #U411C190009).
████████████████ **(Co-PD),** *Research Scientist.* ████████████ has 14 years of intervention research, development, and dissemination experience across middle and secondary settings. She has served as key personnel on several federally funded projects, including *HealthyU*. ██████████ is currently the PD of an EIR Early-Phase project focused on improving educational outcomes of secondary child-welfare involved students (CFDA# U411C190009).
Technology Team – Influents Innovations
████████████, *CEO.* ████████ has over 25 years of experience translating research into commercially viable products. He has served as PI or Co-I on over 20 Phase I and Phase II NIH-funded SBIR/STTR grants addressing challenges and opportunities in digital health and education. He has held senior corporate leadership positions in Research and Development, Information Technology, Marketing, and Design, and holds several U.S. patents.
████████████, *T-BIDs Platform Director and Senior Research Scientist.* ██████ has 25 years of experience developing and evaluating internet-based educational programs and is the developer of the T-BIDS learning management system. He has led over 15 federally funded research studies on computer-based interventions and over 30 research studies funded by NIH, DOE, CDC, and ACYF.
████████████, *Technology Program Manager.* ████████ has 11 years of experience developing digital health interventions and working with software engineers to ensure that platforms meet content and design requirements. She is expert in integrating media into technology-based interventions.

██████████████, *Senior Program Developer.* █████████ has over 17 years of experience in cross-cultural media and instructional design, translating evidence-based content into award-winning multimedia and technology programs for broad audiences.

████████████████, *Principal Graphic Designer and Strategist.* ██████████ is an award-winning designer with over 13 years of experience. She uses her advanced degrees in Cognitive Psychology and Graphic Design to integrate conceptual depth with visual appeal.

███████████, *Visual Designer.* ██████████ is a trained photographer and web designer with extensive expertise in branding and graphic design.

████████████, *Media Producer/Director.* █████████ is an award-winning bilingual media producer/director with over 10 years of experience. He specializes in developing culturally resonant educational videos, visual effects, and animation.

███████████, *Animator/Motion Graphic Specialist.* █████████ has an extensive background in 2D/3D Animation and Cinematography and will develop video animations.

████████████████████████████████████, *Software Engineers.* ███ ███████ is the lead software engineer for T-BIDS, defining the overall technical architecture, back end, and database capabilities. ██████████ leads T-BIDS front-end, gamification, and mobile app development.

████████████, *Data Manager.* █████████ will have primary responsibility for the tracking, cleaning, and entry of questionnaire data, including preparation of data entry formats and codebooks for all study measures. She will ensure data are ready for analysis.

Curriculum Content Team

████████████, *Associate Dean of Graduate Studies and Academic Outreach, University of Nebraska-Kearney.* █████████ has 20 years of experience creating and implementing health and technology-based interventions for rural PK-12+ settings. She served on the *HealthyU* Advisory Board and collaborates with the PDs on evaluations of rural adolescent health literacy.

████████████, *Health Curriculum Specialist, Curriculum and Instruction K-12 Health and Physical Education, Lincoln Public Schools.* █████████ has 25 years of experience in curriculum and instruction and the development of skills-based health education programs in K-12 and higher-education settings. He collaborated on the *HealthyU* project.

████████████, *Research Scientist, Child and Family Translational Research Center, Boys Town.* █████████ is a trained clinical psychologist with expertise in interventions for high-needs populations and transition preparation. █████████ was a member of the *HealthyU* Advisory Board and collaborates with the PDs on youth health literacy in residential care.

Advisory Board Members – ████████████, *Distinguished Professor of Psychology, UC – Berkeley;* █████████████, *MSN, RN, NCSN, FNASN;* █████████████, *Administrator ESU 6;* █████████████, *Director, Center for Health Communication, UT – Austin.*

External Evaluation Team

████████████, *Abt Associates.* ████████ is a policy analyst and program evaluator with expertise in designing and implementing statistical analyses and the design and implementation of randomized controlled trials. ████████ has served in project management roles on evaluations of education, training, and health interventions.

███████████████, **Abt Associates.** ████████ has 11 years of experience providing qualitative and quantitative support with expertise on implementation and descriptive data evaluation plans. She is deputy project director for two large-scale impact studies and task lead for the DOL RESEA evaluation.

Section D: Management Plan

ORI researchers will oversee all aspects of the project management, including IRB, budget, measure development and refinement, participant/district recruitment, implementation fidelity, *EmpowerU* refinement, data collection, dissemination, and sustainability planning. Staff from Influents Innovations will be involved in *EmpowerU* asset refinement, transferring of content to T-BIDS, consenting/assenting of research participants, *EmpowerU* implementation, data collection, dissemination, and sustainability efforts. Statisticians at Abt will be external evaluators, and assist with the randomization schema, outcome measure development and refinement, data analysis, cost analysis, and dissemination (see Table 7).

Table 7. *Project Timeline, Milestones, and Responsible Person(s)*

EmpowerU Project Activity	Timeline	Responsible Person(s)
Phase A: Initial Development (Jan 2024-Dec 2024)		
Prepare and submit IRB for focus groups	1/24-2/24	PD, Co-PD, KP (1-2), EE
T-BIDs platform enhancements	2/24-12/24	PD, Co-PD, KP (4-6;10-11;13)
T-BIDS transfer, activity, dashboard integration	2/24-12/24	PD, Co-PD, KP (6;10-11), RA
Measure development	3/24-5/24	PD, Co-PD, KP (1-3), RA
Prepare required design documents	4/24-9/24	PD, Co-PD, EE
Expert review of *EmpowerU* outcome measures	6/24-7/24	PD, Co-PD, AB
Focus group participant recruitment (*N*=90)	8/24-9/24	CO-PD, KP (1-3;12), AG
Train for nominal group technique focus groups	8/24	PD, Co-PD, EE
Conduct nominal group technique focus groups	10/24-11/24	PD, Co-PD, KP (1-3), RA
Prepare and analyze data	12/24	KP (12), EE
Expert Advisory Board meeting	12/24	PD, Co-PD
Weekly planning meetings	1/24-12/24	PD, Co-PD, KP (1;4-6), RA
Prepare and submit IRB for feasibility study	11/24-12/24	PD, Co-PD, EE
Begin new module content development	12/24	PD, Co-PD, KP (1-3), RA
EIR post-award meeting	TBD	PD, Co-PD, EE
Phase B: Feasibility Study Milestones (Jan 2025-Dec 2025)		
New module content development/refinement	1/25-8/25	PD, Co-PD, KP (1-3;6-9;13;14), AB
Integrate new modules into T-BIDs	1/25-8/25	KP (6-9, 14)
Participant identification/consent/assent (*N*=36)	8/25	PD, Co-PD, KP (1-3;12), AG
EmpowerU implementation	9/25-11/25	PD, Co-PD, KP (1;6), RA
Data collection	9/25-11/25	PD, Co-PD, DC, KP (12), RA

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Individual interviews (*N*=13)	10/25-11/25	PD, Co-PD, KP (1-3;7), RA
Prepare data files/clean data	12/25	KP (12), EE
Analyze all data	12/25	EE
Weekly planning meetings	1/25-12/25	PD, Co-PD, KP (1;4-6), RA
Expert Advisory Board meeting	12/25	PD, Co-PD, RA
Prepare and submit IRB for pilot study	12/25	PD, Co-PD, EE
Annual PD meeting	TBD	PD, Co-PD, EE
EIR annual report (APR1)	TBD	PD, Co-PD, EE, RA

Phase C: Pilot Study Milestones (Jan 2026-Dec 2026)		
EmpowerU content refinement	1/26-7/26	PD, Co-PD, KP (1-3), AB, RA
EmpowerU measure refinement	1/26-7/26	PD, Co-PD, KP (1-3), AB, EE
Revised content and measure TBIDs integration	1/26-7/26	KP (6-9;11-14)
Participant identification/consent/assent (*N*=36)	8/26	PD, Co-PD, KP (1-3;12), AG
EmpowerU implementation	9/26-11/26	PD, Co-PD, KP (1;6), RA
Data collection	9/26-11/26	PD, Co-PD, DC, KP (12), RA
Individual interviews (*N*=13)	10/26-11/26	PD, Co-PD, KP (1-3;7), RA
Prepare data files/clean data	12/26	KP (12), EE
Analyze all data	12/26	EE
Weekly planning meetings	1/26-12/26	PD, Co-PD, KP (1;4-6), RA
Expert Advisory Board meeting	12/26	PD, Co-PD, AB, RA
RCT school district recruitment /district IRBs	8/26-10/26	PD, Co-PD, KP (1-3), RA
Prepare and submit IRB for RCT study	10/26-12/26	PD, Co-PD, EE
Annual PD meeting	TBD	PD, Co-PD, EE
EIR annual report (APR2)	TBD	PD, Co-PD, EE, RA

Phase D: RCT Study Milestones (Jan 2027-Dec 2028)		
Final *EmpowerU* content refinement	1/27-5/27	PD, Co-PD, KP (1-3), AB, RA
Final *EmpowerU* measure refinement	1/27-5/27	PD, Co-PD, KP (1-3), AB, EE
Final content and measure T-BIDs integration	1/27-6/27	KP (6-9;12;14)
Participant consent/assent (*N*=480)	6/27-1/27	PD, Co-PD, KP (1-3;12), RA
EmpowerU RCT study	6/27-7/28	PD, Co-PD, KP (4-6)
Data collection (outcomes/fidelity/validity)	6/27-7/28	PD, Co-PD, DC, KP (5;12), RA
Prepare data files/clean data	7/28-8/28	KP (12), EE
Analyze all data	9/28-10/28	EE
Determine program costs	10/28	EE
Bimonthly team meetings	1/27-12/28	PD, Co-PD, KP (1;4-6), RA
Dissemination efforts	12/24-12/28	PD, Co-PD, KP (1;4;6), EE, RA
District meetings for sustainability	8/28-11/28	PD, Co-PD, KP (4;6), RA
EIR annual/final reports (APR3, APR4, Final)	TBD	PD, Co-PD, EE, RA
Annual PD meeting	TBD	PD, Co-PD, EE

Note. PD = Project Director; Co-PD = Co-Project Director; KP = Key Personnel; AG = Agency; EE = External Evaluator; DC = Data Collectors; AB = Advisory Board; RA = Research Assistant(s); ORI project personnel include ██████████, PD; ██████████, Co-PD; RA (TBD). UNK personnel include ███████ (KP1), curriculum; RA (TBD). BT Personnel include ██████████ (KP2), curriculum; RA (TBD). Lincoln Public Schools personnel include ██████████ (KP3), curriculum. Agency includes the Latino Center of the Midlands (AG). Influents Innovations project personnel include ████████ (KP4), CEO; ████████ (KP5), technology

integration; ████████ (KP6), program manager; ██████████, (KP7), assets developer; ████████ (KP8), graphic designer; ████████, media producer (KP9); ████████████, software engineer (KP10); Mr. Leong, software engineer (KP11); ████████, data manager (KP12); ████████, animator (KP13); ████████, graphic designer (KP14); RA (TBD). Abt Associates personnel include ██████, statistician (EE); ████████ (EE), statistician. AB members listed in Section C.

Section E. Evaluation Plan

E.1. What Works Clearinghouse Standards

In years 4 and 5, Abt Associates will conduct a randomized controlled trial to evaluate the effects of *EmpowerU* on student outcomes. The study is designed to meet What Works Clearinghouse standards without reservations. The trial will address the following research questions using posttest outcomes: (1) What is the impact of *EmpowerU* on students' health literacy knowledge and health preparation for the transition to adulthood compared to a "business-as-usual" control group? (2) What is the impact of *EmpowerU* on students' health self-determination compared to business as usual? (3) What is the impact of *EmpowerU* on students' awareness of health-related stigma compared to business as usual?

Random assignment. A stratified or blocked individual-level randomized controlled trial will be used. High school students within schools in each semester will be assigned either to the treatment or the wait-list control condition. All participating students will receive *EmpowerU,* but the condition will determine the timing of completion. Participating schools will participate across four different semesters during the study period: summer 2027, fall 2027, spring 2028, and summer 2028. In collaboration with our team, schools will decide when the curriculum best fits into their existing class offerings. As in previous *HealthyU* studies, schools have successfully implemented the curriculum in classroom settings during the traditional school year and in summer school. We expect schools will opt to use the curriculum for at least two semesters; they will be permitted to use it for more than two semesters if desired.

For each semester, all consenting students that enrolled in an *EmpowerU* participating course within a school (e.g., Health, Life Skills) will be randomly assigned to the treatment or control condition. Students in the treatment condition will be assigned to a classroom where they

will complete the *EmpowerU* curriculum at the beginning of the semester, while students in the wait-list control condition will be assigned to a business as-usual classroom. After all posttest data are collected, delayed-treatment students will be able to complete *EmpowerU*.

Sample size and minimum detectable effect size. With the assistance of collaborating sites, we expect to recruit at least 8 schools across urban, suburban, and rural settings, with 60 students per school, for a total of 480 students (240 treatment, 240 control). An average of 30 students within each school will be assigned each semester (15 treatment, 15 control) over 2 semesters during the study period. We expect student attrition to be low due to: (a) random assignment occurring after students enroll in the course and (b) a short-duration intervention contained within one semester. Statistical power was calculated assuming a two-tailed test and an alpha threshold of .05. With the target sample of 480 students across 16 schools by semester blocks, we will have 80% power to detect a minimum detectable effect size of 0.199, or 9.9 percentage points, in line with previous *HealthyU* research results (see Section A).

Analysis plan. To estimate the average impacts on student outcomes for the sample overall, a two-level linear regression model will be estimated for each outcome. With students nested within school-semester block, level 1 will estimate student-level outcomes, including treatment effects and effects of individual-level student covariates, including pretest scores. Level 2 will estimate school-by-semester-level outcomes, including mean and random intercepts, mean and random treatment effects, and mean effect of student covariates. We will use Hedges's *g* (for continuous outcomes) or Cox (for binary outcomes) to calculate effect sizes.

Baseline equivalence. Random assignment should lead to balanced groups prior to the intervention. We will collect pretest measures and student characteristics to check for baseline equivalence, and to provide more precise measures of the impact of *EmpowerU* on outcomes.

E.2. Performance Feedback and Assessment of Progress Monitoring

The evaluation will consist of three phases: (1) a feasibility study and refinement of the *EmpowerU* curriculum modules; (2) a pilot study to test implementation, outcome, and social validity measures of *EmpowerU*; and (3) a randomized controlled trial to study the impact of

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EmpowerU. The evaluation plan combines qualitative and quantitative data across phases to assess program feasibility, fidelity, social validity, and efficacy. Qualitative data related to program refinement, implementation feasibility and fidelity, and social validity will include individual interviews and focus groups with key stakeholders. Quantitative data includes measures of implementation fidelity and outcome variables for the randomized controlled trial. Quantitative data on implementation will come directly from the web-based application of *EmpowerU.* Outcome measures will exhibit face validity and reliability as required by What Works Clearinghouse standards. We will pilot test these measures and estimate internal consistency (Cronbach's alpha) and will refine and retest the measures until internal consistency reaches or exceeds 0.7, which is well above the What Works Clearinghouse threshold of 0.5.

E.3. Components, Mediators, Outcomes, and Measurable Threshold

The evaluation will be guided by the *EmpowerU* Logic Model (see Appendix G). Implementation fidelity of *EmpowerU* will be measured using methods built directly into the web-based application. Fidelity of implementation will be measured based on student completion rates, with a goal of 90% fidelity. The Logic Model specifies short-term outcomes (i.e., students' ability to locate, understand, and use health related information and services to make informed decisions); intermediate outcomes (i.e., students' perceptions of health-related stigma, student self-determination, and students' perception of preparedness for transition); and long-term outcomes (i.e., student social/emotional, physical, and mental health well-being) that build from the skills and knowledge students obtain from the *EmpowerU* curriculum. The impact of *EmpowerU* on intermediate outcomes is expected to be mediated by the short-term outcomes (i.e., students with greater ability to locate, understand, and use health related information and services to make informed decisions will demonstrate better readiness for transition); the impact on long-term outcomes is expected to be mediated by intermediate outcomes (i.e., students with enhanced self-determination skills will demonstrate better independence in management of personal health needs). We will explore these potential mediator effects by adding terms to the regression models described above.

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