A. SIGNIFICANCE

A.1. Pediatric behavioral health problems are prevalent and costly, but access to quality care is poor. Behavioral health concerns are prevalent across the lifespan, first emerging in childhood and accelerating through adolescence and into early adulthood. Approximately 54% of youth will experience a clinically significant behavioral health problem before age 18, with the most common diagnoses of disruptive behavior disorders (e.g., ADHD), mood disorders, anxiety disorders, and substance use disorder. Left untreated, behavioral health problems levy tremendous costs ranging from academic and occupational underperformance to medical comorbidities to death. Behavioral health problems are also associated with a staggering economic burden. In 2013, spending for behavioral health care problems topped $201 billion, making it the most costly category of health conditions in the U.S. Careful assessment and quality, evidence-based intervention during childhood and adolescence can prevent negative outcomes, yet fewer than 2 in 5 youth who need treatment ever receive it. Indiana’s behavioral health system ranks 37th out of 50 in access to care nationwide. Data from the 2015 National Surveys on Drug Use and Health indicate that only 37.6% of Indiana teens aged 12-17 with depression received treatment for depression. This amounts to approximately 45,000 depressed youth in Indiana never receiving treatment. Bolstering access to evidence based behavioral health care services for children and adolescents would likely have a marked impact on long-term population health and wellbeing.

A.2. Pediatric primary care clinics can help bolster access to care, but PCPs often need additional support to address complex behavioral health concerns. A major barrier keeping these vulnerable youth from receiving behavioral health services is the severe lack of behavioral health specialists – including psychiatrists, psychologists, social workers – nationwide. This workforce shortage is especially prominent in rural communities, resulting in expansive behavioral health care deserts where many low-resource families are faced with months-long waits to access behavioral health care clinics, sometimes hundreds of miles away. Families in rural, underserved communities typically can access local primary care clinics, where they often seek treatment for their children’s behavioral health problems. Recent data from a nationally representative sample of medical expenditures revealed that 35% of youth with behavioral health conditions see primary care providers (PCPs) only for diagnosis and management of behavioral health concerns—compared to 26% who saw psychiatrists only, 15% who saw psychologists or social workers only, or 24% who saw multiple providers. Moreover, millions of youth are seen annually by PCPs for routine care. Each encounter is an opportunity for previously unrecognized or untreated behavioral health concerns to be identified, but PCPs are often unable to address these concerns due to a variety of barriers such as limited behavioral health training; time constraints; unfamiliarity with psychotropic treatment recommendations; reimbursement challenges; and practice-level policies regarding scope of practice. Still, some estimates show that prescription rates of psychotropic medications (stimulants, SSRIs, antipsychotics etc.) in pediatric primary care have soared in recent years, including relative to psychiatry clinics. The status quo model, characterized by poor access to specialists, therefore yields both under- and over-treatment of pediatric behavioral health problems.

A.3. Child Psychiatry Access Programs (CPAPs) can extend the reach of behavioral health specialists into primary care through technology-facilitated consultation and targeted clinical services. One option for solving this problem is to integrate and co-locate behavioral health specialists in primary care practices. While appealing, this approach requires substantial buy-in and system- or practice-level reorganization to accommodate new personnel and procedures. In-person integrated care models may be difficult to scale statewide, especially in remote areas or small clinics. Another approach that extends the reach of the existing behavioral health workforce is to link specialists to PCPs in underserved communities via telemedicine (telephone, videoconference, etc.). One such model, known as Child Psychiatry Access Programs (CPAPs), has been launched in various forms in 28 states—including Michigan, Illinois, and Ohio—with notable success in bolstering access to pediatric behavioral health services in the communities served. No such program currently exists in Indiana. CPAPs typically involve multiple centers or “nodes” that house behavioral health teams that serve PCPs within defined geographic catchment areas. Program characteristics vary, but core features typically include 1) on-demand telephone-based behavioral health consultations between PCPs and child and adolescent psychiatrists; 2) care coordination by a social worker or case manager who can link PCPs to local behavioral health resources; and 3) timely in-person or tele-video evaluations by psychiatrists or psychologists to clarify diagnoses and guide treatment planning. Figure 1 illustrates states with current CPAPs. Table 1 summarizes features of existing CPAPs.
Although evidence emerging in the past 5-6 years supports the feasibility and value of CPAPs in improving access to care,10-15 most of the published research to date has focused on just 3 existing programs in Massachusetts, New York, and Washington. Critical questions remain about their implementation,16 such as which components of CPAPs are most effective, which strategies for disseminating and implementing CPAPs result in maximal uptake and impact, and which CPAP elements could be automated, scaled, or otherwise enhanced via online tools and mobile technologies (e.g., web-based treatment modules, telehealth delivery of brief psychotherapies, PCP behavioral health education modules, app-based decision-support tools). Moreover, there is virtually no research comparing CPAPs to other approaches to increasing access to services, such as in-person integrated care models. Establishing the IN-BeHAPY CPAP program would not only increase access to quality pediatric behavioral health care for Indiana families, but successful completion of the current objectives would also generate crucial preliminary data and create a platform for the current multidisciplinary investigative team to pursue a systematic program of research to address key clinical and implementation science questions.

Consistent with this proposal, virtually all CPAPs started as pilots with a small number of enrolled primary care practices followed by expansion following initial feasibility demonstration and identification and addressing barriers. This grant would allow our team to develop and implement the first CPAP in Indiana while simultaneously engaging in best practice implementation science research and laying the foundation for expansion geographically and with regard to program features and offerings with an emphasis on telepsychiatry services. Our consultant, Dr. Barry Sarvet (see Letter), is the Medical Director for the Massachusetts CPAP (MCPAP), which is a national model for CPAP design and implementation. MCPAP enrolled PCPs serve over 95% of Massachusetts youth. Our long-term goal is similar coverage in Indiana.

A.4. The Indiana Behavioral Health Access Program for Youth (IN-BeHAPY) will leverage partnerships between behavioral health specialists and IUH PCPs to increase families’ access to high quality care.

A.4.1. Proposed Program. Figure 2 depicts a "baseline model" for how IN-BeHAPY may be structured. This workflow is based on the structure of existing CPAPs. Once practices have enrolled in the CPAP and are oriented to the scope of services, they can access consultations and other services as needed, typically via phone call. As shown, a sequence of events is initiated by a telephone call from a PCP to IN-BeHAPY during weekday business hours. From there, the care coordinator will triage each call to determine the required next steps, which may involve rapid-access consultation with the on-call psychiatrist (typically within 30-60 minutes) or assistance identifying local behavioral health resources. Consultations may involve advice regarding patients’ diagnosis (screening, assessment, differential diagnosis), comorbidities, psychopharmacology, behavioral interventions, or assistance with referrals to behavioral health specialists. Other clinical or consultative services may include tele-video evaluations of the child by the IN-BeHAPY psychiatrist, telemedicine based brief psychotherapy sessions delivered by an IN-BeHAPY therapist, or referral to online tools and resources to promote evidence based pediatric behavioral health care practices. Integrating tele-video assessments and tele-therapy into a CPAP is innovative (see Table 1) and complements current IU Health (IUH) priorities in the evolving telemedicine arena. Incorporating telepsychiatry services will also help reduce geographic barriers to receiving behavioral health treatment. Future program modifications may include online trainings and resources, web- and mobile-based assessment and treatment tools, and other resources for improving population-level behavioral health in youth & families. Importantly, these services can be applied in response to PCP questions regarding ADHD, anxiety disorders, depression and other mood disorders, disruptive behavior disorder, substance use disorders, autism spectrum disorders, and a wide range of other behavioral health conditions.

### Table 1. Features of existing CPAPs

<table>
<thead>
<tr>
<th>CPAP Feature</th>
<th>% of Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone consultation</td>
<td>100</td>
</tr>
<tr>
<td>Online provider resources</td>
<td>100</td>
</tr>
<tr>
<td>Online provider training modules</td>
<td>65</td>
</tr>
<tr>
<td>Online patient resources</td>
<td>65</td>
</tr>
<tr>
<td>In-person provider trainings</td>
<td>50</td>
</tr>
<tr>
<td>In-person assessments</td>
<td>42</td>
</tr>
<tr>
<td>Tele-video assessments</td>
<td>38</td>
</tr>
<tr>
<td>Tele-therapy</td>
<td>8</td>
</tr>
</tbody>
</table>

*Note. Based on N=26 programs with data available online.*
A.4.2. The Timing is Right for a CPAP in Indiana, led by IUH. An anticipated benefit of this project is that it will fuel enthusiasm around adoption of best practice behavioral health intervention practices within the IUH system and across the state. Successful implementation, evaluation, and expansion of IN-BeHAPY in this and subsequent projects will yield several anticipated benefits to IUH: 1) improved population health among lives served, particularly in pediatric behavioral health; 2) reduced costs associated with untreated or poorly managed pediatric behavioral health problems (e.g., ED visits, etc.); 3) heightened patient and provider satisfaction; 4) increased opportunities to involve multidisciplinary learners in cutting edge models of pediatric behavioral health service delivery; 5) strengthened connections and relationships across multiple IUH sites and specialties (e.g., psychiatry, pediatrics, family medicine, telemedicine); 6) expanded research portfolio to include pediatric behavioral health services; and 7) development of a platform on which future child mental health research can be based. By sponsoring the launch, initial evaluation, and eventual expansion of the first and only CPAP in Indiana, IUH will further cement its role as preeminent leader in promoting health and wellness, especially among underserved Indiana communities.

Funding through the IUHV Grand Challenges Program would accelerate progress at a key time in the development of a coordinated, state-of-the-art, behavioral health services infrastructure across the IUH network and the state of Indiana. This project will dramatically amplify the impact of existing investments in integrative collaborative care for youth experiencing behavioral health concerns in primary care clinics around the state. This project would be carried out in parallel with the recently launched in-person Integrated Care pilot initiative, led by faculty in the departments of Psychiatry, Family Medicine, Internal Medicine, and Pediatrics. The Integrated Care pilot embeds psychiatrists and psychologists to provide in-person behavioral health care support within three primary care practices located within 5 miles of the IU academic medical center in Indianapolis. This proposal differs from the IC program in its capacity to extend the geographic reach of behavioral health specialists to outlying communities served by IUH. The project also coincides with the increasing capacity of the IUH Video Visits program, which targets common primary care health problems through statewide access to affordable, on-demand, high quality healthcare. Funding will help establish initial capacity for future test of hypotheses regarding the efficiency, quality, satisfaction, and costs associated with different modalities of delivering behavioral health services to youth in high-need, low-resource communities.

This approach also comes at a time when there is substantial interest from the IN Division of Mental Health and Addiction to fund projects targeting improvements to child and adolescent behavioral health care. One major barrier to investment by the state is a lack of evidence demonstrating the feasibility, efficacy, cost, and sustainability of models for delivering outstanding behavioral health care to youth across Indiana, particularly in communities devoid of an in-person, local or resident behavioral specialist workforce. Evidence from this project would surely be valuable to state officials tasks with allocating resources to programs designed to improve behavioral health while also managing costs.

A.5. Impact on the Field: Scientific Knowledge, Technical Capacity, Clinical Practice, and Education

A.5.1. Impact on Scientific Knowledge. In addition to expanding access to high quality pediatric behavioral health services, this project would facilitate the development of a model of care that can be used to systematically test research questions about behavioral health consultation and telemedicine in pediatric

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**IN-BeHAPY CPAP program workflow.**

- **PCP has behavioral health question**
- **PCP calls IN-BeHAPY (weekdays, 8a-5p)**
- **IN-BeHAPY Care Coordinator triages call**
  - **IN-BeHAPY Care Coordinator offers resource assistance or phone consult (by request)**
  - **IN-BeHAPY rapid televideo evaluation scheduled if desired by PCP and family**
  - **IN-BeHAPY televideo brief therapy delivered by therapist, if rec’d**
  - **IN-BeHAPY rapid televideo evaluation scheduled if desired by PCP and family**
  - **PCP implements behavioral health recommendations**
  - **Child/Adolescent Psychiatrist paged, provides rapid-access phone consult (within 30 min) Audiorecorded**
  - **Dr/Treatment Consultation Request**
  - **Resource Linkage Request**
primary care on a large scale. We have assembled a team of experts across pertinent domains (child and adolescent psychiatry, addiction medicine, clinical psychology, implementation science, telemedicine and mobile health, data analysis) that bring the content knowledge and technical capability to execute this project and set up a series of subsequent research and clinical service initiatives that would grow naturally out of this project. Successful completion of the current aims and objectives will yield several products, such as a novel system for expanding access to pediatric behavioral health care in Indiana, a tested battery of assessment instruments, vetted data collection methods and accompanying data analysis scripts that can be applied in future studies. The study will also yield operating procedures for carrying out a telemedicine-enhanced CPAP in Indiana, including work-flow algorithms and educational materials PCPs, patients, and other stakeholders. Having a CPAP in place in Indiana will allow this team to study critical questions regarding implementation strategy, efficacy of key program elements delivered in varying modalities, and cost and impact of CPAPs relative to other care access models – areas sorely lacking evidence currently – in collaboration with other IU/IUH investigators and with the broader network of CPAP and integrated care programs nationwide.

A.5.2. Impact on Technical Capacity. Currently, there is no established system for obtaining or providing specialty consultation and treatment services to pediatric primary care practices in Indiana. Despite a small telemedicine service offered through the IU/Riley Adolescent Dual Diagnosis program (see Preliminary Studies), there is not currently a coordinated system for delivering direct-to-patient behavioral health care remotely via telemedicine or web-based intervention tools. Completion of this project would result in a novel CPAP in Indiana that could be used as a platform for future projects aimed at increasing the technical capacity of IUH to offer remote telepsychiatry services to youth and families in primary care settings statewide.

A.5.3. Impact on Clinical Practice. Establishing the IN-BeHAPY network – starting with the formative work detailed here – ultimately will transform clinical practice for pediatric behavioral health care in Indiana beyond the Indianapolis core and into underserved outlying rural communities. The current project will expand the capacity of IUH to deliver cutting edge behavioral health clinical services to patients anywhere in the state. It remains unknown exactly how such a system should be designed, developed, and implemented to meet local needs; the current project will begin to address these questions. After a thorough development phase, we will pilot the program at two IUH sites to develop standard operating procedures and implementation strategies driven by patient and provider input. The long-term goal is to scale the program into a robust pediatric behavioral health service platform open to PCPs within and, eventually, beyond the IUH system. Specifically, we predict long-term outcomes of IN-BeHAPY will include outcomes such as increased number of children screened for behavioral health problems in primary care, greater PCP knowledge and confidence regarding assessment and treatment of behavioral health problems, and decreased instances of over- and under-prescription for pediatric behavioral health problems. Measurement of these outcomes are beyond the scope of the current project, but completion of the aims described here is a necessary first step toward achieving those impacts. This initial development work and open pilot trial will yield important information regarding the acceptability and feasibility of selected procedures, as well as initial evidence regarding evaluation measures. These data will inform the design of future research studies, such as randomized controlled trials testing the impact, relative efficacy, and cost-effectiveness of different variants of behavioral health consultation and telemedicine delivery. Such data will be essential for future extramural funding applications, as well as for sustainability planning with payers (Medicaid, etc.) and other key stakeholders. If funded, we will engage university officials involved in government affairs and negotiations with external payers to promote long-term improvements in pediatric behavioral health access in Indiana.

A.5.4. Impact on Education. Impact of this specific project on education will be limited to new knowledge gained by participating PCPs who receive consultation as part of the CPAP to be developed here. Over time, as with other CPAPs, IN-BeHAPY will serve a professional education capacity and broaden the workforce of PCPs who are knowledgeable and confident about evidence-based pediatric behavioral health practices as more PCPs take advantage of consultations. Learners who train at participating IUH sites will gain valuable exposure to this service model and, in turn, learn how to engage in psychiatric consultation for pediatric patients in their own practices. Eventually, we plan to expand the offerings of IN-BeHAPY to include web-based training modules for asynchronous, self-directed continuing education purposes, as has been done in other states. During this award period, we will consult with Dr. Sarvet (see Letter) and gather data from Indiana PCPs to identify high priority topics for initial educational resources.

A.5.5. Impact on Applicants’ Career Development. The aims of this project and the line of research that will follow align with the co-PIs’ career goals, which include reducing the massive burden of mental illness and substance use through research, clinical service, and education. Successful completion of this project would
provide a springboard for Dr. Adams to pursue larger-scale studies testing key questions about how empirically supported behavioral health interventions can be disseminated and implemented most effectively in clinical and, eventually, non-clinical (e.g., schools, home-based telehealth) settings. Dr. Hulvershorn is interested in developing a line of research address polypharmacy in children with disruptive behavior disorders and would benefit from a recruitment pipeline from the IN-BeHAPY, as would many other pediatric mental health researchers. Through this work, we will build valuable collaborations with primary care practices and other key stakeholders around the state, as well as with leadership in other CPAPs around the country. The applicants will leverage these resources and relationships for future large-scale research, education, and clinical service initiatives designed to promote pediatric behavioral health. The future grant-funded projects, deliverables (publications, presentations, web-based trainings, mobile applications, etc.), and predicted impact on PCP and patient outcomes will not only advance science and public health, but will also help build the applicants’ reputation as experts in this field.

**A.6. Applying best practice implementation science will promote successful uptake and sustainability.** This project draws on the Consolidated Framework for Implementation Research (CFIR),\(^\text{17}\) which outlines an empirically grounded set of key domains and constructs that should be considered and evaluated in the course of health services implementation studies (see Table 2). In line with contemporary implementation science principles, our evaluation plan also emphasizes implementation outcomes spelled out in Proctor’s influential framework, namely: acceptability, adoption, appropriateness, feasibility, fidelity, implementation costs, penetration, and sustainability.\(^\text{18}\) Findings from this initial development and pilot feasibility study will be critical in designing future research and service expansions.

| Table 2. Consolidated Framework for Implementation Research (CFIR) Domains and Constructs\(^\text{17}\) |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| I. Intervention Characteristics | II. Outer Setting | III. Inner Setting | IV. Characteristics of Individuals | V. Process |
| A. Intervention source | A. Patient needs & resources | A. Structural characteristics | A. Knowledge & beliefs about the intervention | A. Planning |
| B. Evidence strength & quality | B. Cosmopolitanism | B. Networks & communications | B. Self-efficacy | B. Engaging |
| C. Relative advantage | C. Peer pressure | C. Culture | C. Individual stage of change | C. Executing |
| D. Adaptability | D. External policy & incentives | D. Implementation climate | D. Individual identification with organization | D. Reflecting & evaluating |
| E. Trialability | E. Readiness for implementation | E. Other personal attributes |
| F. Complexity |
| G. Design quality & packaging |
| H. Cost |

**B. INNOVATION**

This proposal applies our multidisciplinary team’s demonstrated skill and expertise (see Biosketches) to the significant arena of pediatric behavioral health care. We aim to increase access to high quality behavioral health care through pediatric primary care clinics alongside a rigorous evaluation of the implementation process. Several innovative aspects of the proposed research include its methodology and deliverables:

**B.1. Development of the first and only Indiana Child Psychiatry Access Program.** Indiana is currently one of only 22 states without an active CPAP. Some pediatric care practices are piloting in-person integrated health care models, but this would be the first and only CPAP in Indiana. The program will be designed for statewide expansion to promote broad population health impact, especially in underserved communities.

**B.2. Informing best practices for use of technology in pediatric behavioral health care.** Despite rapid growth in technical capability to deliver behavioral health care via telemedicine and web-based and mobile technologies, the empirical evidence for these approaches lags behind. There is active debate regarding ethical, legal, clinical, and research considerations pertaining to the use of web-based and mobile technologies in the assessment, prevention, and treatment of pediatric behavioral health problems. Very few CPAPs offer teletherapy “e-visits” for patients, in part because insurance providers rarely pay for these services due to limited published evidence on treatment effects. Rigorous research is needed to identify optimal strategies for implementing and maintaining these programs at scale (i.e., in major health systems) and for determining which elements are most useful, acceptable, appropriate, and cost-effective when implemented in primary care settings. This study will provide essential data on the feasibility and utility of delivering behavioral health interventions via telemedicine in outpatient pediatric primary care, as well as user attitudes about potential future offerings, such as online and mobile tools for promoting pediatric behavioral health. We will be strongly positioned to address such questions in future projects (see Plan for Securing Extramural Support).

**B.3. Capacity to focus on pediatric substance use.** The current investigative team has particular expertise in evidence-based assessment and interventions for pediatric mental health and substance use disorders (see Hulvershorn & Adams Biosketches). There is a national effort to increase screening, brief interventions, and
referrals to treatment for youth substance use in primary care settings, but many PCPs report low rates of substance use screening and intervention in their practices. This project will be a vehicle for expanding PCP access to consultation and treatment for youth substance use concerns in addition to other behavioral health problems, which also would be a novel contribution of this program compared to other CPAPs. Specifically, we anticipate this will be accomplished during consultation calls when behavioral health specialists provide screening and assessment recommendations for PCPs working with adolescent patients.

C. APPROACH

C.1. Overview. We propose the development and initial open pilot feasibility trial of an integrative, technology-enhanced child psychiatry access program to be launched in the IUH system. This hybrid study will evaluate both implementation and clinical outcomes. Phase I of the project will involve surveys and focus groups with key stakeholders to inform the design and launch of IN-BeHAPY in two pilot sites (1 rural; 1 urban) within the IUH system. Phase II will involve an open pilot trial of IN-BeHAPY. At the end of this two-year project, the investigative team will be uniquely positioned to propose research and clinical service grant proposals extending this programmatic line of work in pediatric behavioral health with the ultimate, long-term aims of improving access to high-quality behavioral health care across the state of Indiana and minimizing the burden of behavioral health concerns for Hoosier families.

C.2. Preliminary Studies, Data, and/or Experience

C.2.1 Investigative Team. Our multidisciplinary investigative team and our partners are ideally suited to carry out this program (see Biosketches, Letters of Support, and Budget Justification). This project brings together experts from multiple IU/IUH Departments (Psychiatry, Public Health, Communications) in partnership with providers at multiple IU sites (i.e., IUH-Riley, IUH-Bloomington, IUH-Fishers/Noblesville). In addition to their NIH funded work, both PIs are involved in the following clinical/research programs relevant to this work:

C.2.1. DCS Psychotropic Consultation Program. Dr. Hulvershorn (co-PI) is program director for the Indiana Department of Child Services (DCS) Psychotropic Consultation Program. The overall goal of this project is to conduct reviews of psychotropic medication prescribing and provide expert psychiatric consultation to therapists working with youth who are part of the DCS system. There are 4 classification categories reflecting different levels of review, from RN review only to full peer-to-peer intervention plus follow-up review. The number and percent of cases in each category are presented for the current period and for the project period to date (Table 3). Since the inception of the Program, IU Psychiatry has been involved with a total of 357 cases, and an additional 46 cases in are various stages of data collection, scheduling, and review. A total of 157 peer-to-peer medication reviews have been completed with physicians.

The most prevalent concern cited by reviewing clinicians is medication quantity, and specifically 4+ psychotropic medications being prescribed simultaneously (69%). Another common concern is inadequate documentation and monitoring, with failure to appropriately monitor laboratory values and vital signs in 44% of cases, and insufficient documentation of physical exams, vital signs, or side effects in 49% of cases. Indication is also a common problem, with 44% of children in the review group being prescribed medications with insufficient evidence of effectiveness. Many cases (33%) are flagged for insufficient psychotherapeutic interventions. In addition to bolstering our team’s familiarity with commonly encountered prescription and treatment practices in clinics statewide, involvement in this state-funded program has provided us with firsthand experience consulting with physicians, therapists, case workers, and other pediatric care professionals.

C.2.2. IU/Riley Adolescent Dual Diagnosis Clinic (ADDC). Dr. Hulvershorn (co-PI) is ADDC Director, and Dr. Adams serves as the ADDC Director of Training. Over the past 2 years, the ADDC has expanded to 8 telemental health sites located in underserved IN communities. In addition to the care provided at the Riley

| Table 3. Classification categories for the IN DCS Psychotropic Consultation Program |
|---------------------------------|---------|---------|
| Category                        | N (%) current | N (%) to date |
| A. Does not meet criteria for peer-to-peer review after RN review of Rx data | 42 (39%) | 76 (20%) |
| B. Does not meet criteria for peer-to-peer review after psychiatrist or psychologist review of full medical records | 10 (9%) | 43 (12%) |
| C. Meets criteria for peer-to-peer review of Rx data |
| Randomized to delayed intervention | 18 (17%) | 81 (22%) |
| Randomized to immediate intervention | 24 (22%) | 131 (35%) |
| Direct referral | 13 (12%) | 41 (11%) |
| D. Additional review requested following intervention |
| Follow-up records review | 7 (7%) | 33 (9%) |
| Secondary full peer-to-peer review | 5 (5%) | 10 (3%) |
| **Total unique cases processed (A+B+C)** | **107** | **372** |
Hospital for Children site, youth from these satellite sites can complete an in person evaluation and then receive the remainder of their psychotherapy and medication management sessions via computerized telemedicine from a mental health or medical facility in their community. Patients and their families report high satisfaction with the quality and convenience of the telemental health program. The program has also added 4 school-based primary care sites in Indianapolis charter middle and high schools in partnership with Adolescent Medicine and Eskenazi TeenCare. The ADDC has assessed and/or treated over 248 adolescents. We have a treatment completion rate of 50% and a substantial decrease in use of substances in 70% of completers.

Through ADDC, we have demonstrated capacity to deliver behavioral health services via telemedicine, manage a multisite clinical infrastructure, and integrate behavioral health specialty care into non-traditional settings (school-based primary care clinics; consultations with nursing, pediatrics, etc.). We have also learned a great deal about behavioral health care access barriers for youth and families across the state and how to manage and overcome those barriers. These skills and knowledge will be invaluable in carrying out the proposed activities in the current IUHV application.

C.3. Aim 1: Develop and launch the IN-BeHAPY program in selected IUH primary care clinics.

C.3.1. Developmental Evaluation Model. CPAPs are complex interventions requiring interaction between multiple individuals (e.g., behavioral health specialists, PCPs, case managers, patients), organizations (e.g., academic medical center, primary care clinics) and systems (e.g., medical, mental health) to be successful. As such, we have chosen a learning-focused developmental evaluation as the overall design for this research project, in line with other implementation work carried out by Co-Is Drs. Watson and Brann (see Biosketches). Developmental evaluation approaches are appropriate in the case of complex interventions that need additional refinements and when scalability is a future goal. Learning evaluation is a related approach that uses continuous data collection and rapid-response cycles to facilitate continuous quality improvements.

Figure 3 shows our guiding framework. The arrows around the outer circle represent the forces that influence an intervention’s development. This process starts with (a) bottom-up, local innovation/initial development of an intervention. The next step is to (b) make the intervention scalable so that it can handle a larger workflow and/or be transferred to other contexts. After going to scale, interventions often intersect with top-down decision makers who (c) standardize it for policy and/or professional purposes. After standardization, the intervention can be widely (d) disseminated. As it is disseminated, the intervention is adopted by local contexts that will (e) adapt it to their particular conditions and needs. The square in the center represents learning evaluation process we will take to develop IN-BeHAPY from existing CPAP models. This process will be facilitated by plan-do-study-action (PDSA) cycles, which involve continuous reflection and adjustments to the program model through regular learning meetings of the investigative team.

In addition to testing the feasibility of the research instruments and protocols, our research questions and hypotheses are: (1) How can the IN-BeHAPY program best be delivered? We will utilize survey and focus group data from IUH PCPs and families to determine how to best develop IN-BeHAPY’s policies and procedures (Aim 1). (2) Does the IN-BeHAPY program lead to changes in PCP clinical practices and patient outcomes? Qualitative and quantitative pilot data will illustrate what effect IN-BeHAPY has on clients (Aim 2). We expect the program will have a positive effect on client outcomes and we will be able to identify specific program aspects driving these outcomes. (3) How can IN-BeHAPY be developed so that it is a sustainable, scalable, and transferable intervention? We will regularly collect information on factors influencing local use of the intervention during learning meetings and conduct interviews with IN-BeHAPY users and non-users to identify potential facilitators and barriers to implementation and sustainability beyond the pilot sites for future state-wide dissemination and implementation efforts.

C.3.1. Objective 1a. Collect qualitative and quantitative formative data from patients, providers, and clinic staff to inform development and refinement of program offerings and structure.

C.3.1.1. PCP Surveys. In the early months of the award period, we will recruit IUH/IUHP PCPs who
serve pediatric patients to participate in a brief, voluntary, online web survey. Recruitment will be performed via email, in-person recruitment at IUH/IUHP clinical sites, and notices on pertinent announcement boards directed at PCPs. PCPs from all IUH/IUHP primary care sites will be eligible to participate. Although the open pilot feasibility trial will include two IUH sites, we will attempt to gather initial responses from PCPs at all IUH/IUHP primary care sites to maximize input, increase system-wide applicability and investment, and gain multiple views regarding the program design and implementation strategy. Surveys will be designed to identify and prioritize initial IN-BeHAPY components and program offerings, and to characterize PCPs’ preferences regarding general logistical details (e.g., program hours) and resource format (e.g., webinars, printer-friendly handouts, mobile decision support tools, etc.). We will assess PCP attitudes and current practices related to delivering behavioral health care in their clinics using an expanded version of the Evidence-Based Practice Attitudes Scale (Aarons, 2007). Given the enthusiastic response we received from IUH/IUHP primary care sites, who indicated willingness to participate in this study, we are confident we will be able to recruit enough participants to yield diverse perspectives. There are currently 128 physicians at IUH Primary Care who care for children, not counting PCPs in other IUH Systems (e.g., Ball, Arnett, Southern Indiana Physicians); a conservative predicted 60% response rate would yield 77 respondents to this initial quantitative evaluation.

C.3.1.2. PCP Focus Groups. During the formative stage, we will develop an interview guide to assess primary care staff members’ motivations, barriers, and design preferences to utilizing a CPAP to enhance behavioral health care in their practices. Focus groups will be used in addition to surveys, because focus groups allow participants to respond to each others’ comments in order to elicit a variety of views so they may sharpen the focus of the group and take the discussion in highly informative and unforeseen directions, thus improving accuracy of the data.23 Primary care staff members at each site will be recruited through in-person, email, and written invitations to participate in one of two on-site focus group discussions. We will recruit 8-12 primary care staff members (PCPs, nurses, clinic managers) per focus group and facilitate focus group discussions. There are approximately 30-40 PCPs who treat children and adolescents at the identified sites; we anticipate a 75% participation rate, which will yield 22-30 PCP participants (~10-20 per site). Sessions will be scheduled at convenient times identified by practice leaders. During each 60-90 minute focus group session, facilitated by Drs. Brann, Adams, and their students, we will provide information about existing CPAPs for context before asking interview questions. We will also present a list of potential program features and procedural options and ask a series of questions to elicit participants’ reactions. After completion of the discussions, the audio-recorded conversations will be transcribed by a professional service for qualitative analysis described below (see Qualitative Data Analysis and Evaluation).24 The results of the data analysis will be used to make any necessary refinements to the IN-BeHAPY CPAP operating procedures, clinical and consultation service offerings, web resources, marketing materials for practice recruitment and retention, and Aim 2 evaluation methods.

C.3.1.3. Patient caregiver surveys. We will also administer brief, voluntary, REDCap surveys to caregivers of children and adolescents who visit IU/IUH primary care clinics in months 3-6 of the award period. Caregivers will be asked about their knowledge, attitudes, and beliefs about behavioral health care and potential approaches to improving access to behavioral health care, such as a CPAP, in-person integrated care, and telepsychiatry modalities. Caregivers also will be asked to provide demographic and behavioral health information (e.g., diagnosis, service utilization) about their children; this information will be used to identify factors that may influence caregiver reactions to IN-BeHAPY and guide program refinements. Caregivers will be recruited via flyers posted in IUH/IUHP primary care clinics. To assess reactions to the proposed CPAP, questions will be adapted from existing questionnaires designed to assess acceptability of new interventions, including the 8-item Abbreviated Acceptability Rating Profile (Tarnowski et al., 1992) and 13-item Acceptability of Intervention Measure (Henninger, 2010). Additional measures will include the Child and Adolescent Services Assessment (Ascher et al., 1996), which gathers information from caregivers about a range of child-focused behavioral health services, and an adapted version of the Verona Expectations for Care Scale (VECS; Ruggieri & Dall’Agnola, 1993), which has been used widely as a measure of consumer expectations for community-based psychiatric services.

C.3.2. Objective 1b. Develop IN-BeHAPY operating procedures and website with user input. Using data from Objective 1a and in consultation with Consultant Dr. Sarver and through membership in the National Network of CPAPs (www.nncpap.org), we will produce IN-BeHAPY operating procedures and accompanying resources in anticipation of post-award expansions.

C.3.2.1. Operating procedures. We will document procedures for all key tasks associated with operating IN-BeHAPY, including primary care practice enrollment, care coordinator and psychiatrist training,
telephone consultation protocols, telepsychiatry procedures (set-up, security, implementation, documentation),
and website maintenance. Some of these resources will be for internal use only, while others will be made
available more widely to PCPs and/or the public. Operating procedures will be updated and revised over the
course of the program to improve clarity and promote sustainability. Because a standard CPAP fidelity
monitoring tool is not currently available, a novel CPAP fidelity monitoring tool will be developed here based on
participant input and consultation with Dr. Sarvet and the National CPAP Network.

C.3.2.2. Dedicated phone and email. We will obtain a dedicated phone-line that will serve as the main
entry point into the IN-BeHAPY system for PCPs. A program dedicated email account will also be secured for
non-time-sensitive communication with PCPs, as well as correspondence with the investigative team and other
stakeholders. The phone-line and email account will be staffed during business hours by the care coordinator.

C.3.2.3. IN-BeHAPY Website. A program website will be designed and built. Initial site structure and
content will be derived from existing CPAP sites with capacity to add features with future funding. We
anticipate the IN-BeHAPY website will be similar to other major health-focused online resources available via
IU/IUH, such as the Indiana Prevention Resource Center (drugs.indiana.edu) and Indiana SBIRT
(indianasbirt.org) sites, which house multimedia resources for administrators, providers, and patients.

C.3.3. Objective 1c. Launch IN-BeHAPY in two IU Health pediatric primary care sites and
conduct 1-mo surveillance and refinement procedures ahead of pilot feasibility trial. In month 9, after
formalizing IN-BeHAPY’s policies and procedures, we will conduct a one-month pre-implementation pilot test of
the effect of the intervention among a sample of participants. It is necessary for the program to have stability
during this testing phase and during the subsequent pilot feasibility trial. As such, we will note issues arising
out of the developmental evaluation process indicating necessary program refinements and act on them after
the surveillance period. During the period, we will utilize the Plan-Do-Study-Act (PDSA) process primarily for
quality assurance purposes (e.g., making sure policies and practices are followed, identifying and fixing flaws
in the data collection system) in anticipation of the pilot feasibility trial.

The second phase of the study will involve a feasibility trial of the IN-BeHAPY program at 2 IUH primary care
sites. We will use a mixed method approach to assess implementation outcomes of IN-BeHAPY. At the end of
this phase, our team will have the data and experience necessary to overcome identified implementation
barriers in preparation for a large-scale roll-out and program of externally funded research on the use and
relative impact of CPAPs and other technology-based behavioral health methods to improve pediatric
behavioral care state- and nation-wide. Experts strongly recommend that pilot studies be used only to evaluate
the feasibility of novel methods. Researchers are cautioned to avoid testing hypotheses of efficacy or to
attempt to calibrate effect sizes due to the inflated risk of Type I or Type II error with small samples.
Accordingly, we propose to evaluate the feasibility of research and implementation procedures we plan to use in
future trials, informed by the CFIR.

C.4.1. Objective 2a. Collect quantitative data at baseline, 3, 6, 9, and 12 months post-baseline on
utilization patterns and other implementation outcomes of IN-BeHAPY participants. During this award
period, we will solidify evaluation plans and procedures and gather critical preliminary data to use in future
studies compare process and outcome metrics across models. Selection of measures was guided by prior
CPAP evaluations, and evaluation measures used in the current IUH Integrated Care pilot. Several pieces of
quantitative data will be collected during Phase II of this project. Some metrics will be recorded by project staff
during each encounter, while others will be obtained via PCP- and patient-completed surveys.

C.4.1.1. Utilization patterns: Utilization patterns will be assessed and characterized using several
variables that have been used in previous studies investigating CPAPs and other integrated behavioral health
models: (i) number of calls to IN-BeHAPY (per 3-mo assessment period), by provider and by clinic; (ii)
frequency of calls (per 1000 empanelled patients); (iii) adoption or days to first call from baseline, by provider
and by clinic; (iv) number of telepsychiatry ‘e-visits’ per clinic.

C.4.1.2. PCP characteristics: At each call, we will record PCP characteristics, including (i) PCP
discipline and specialty (family medicine, pediatrics, med-peds); (ii) years experience; (iii) age; & (iv) sex.

C.4.1.3. Patient characteristics and outcomes: Several clinically relevant variables will also be collected
via patient and provider report (during calls, surveys), including (i) patient behavioral health diagnosis and
severity; (ii) consultation topic (iii) psychotropic medication prescription/order practices; (iv) patient insurance
provider; and (v) patient demographics (age, sex, race, ethnicity).

C.4.1.4. PCP Satisfaction: We will assess PCP satisfaction with IN-BeHAPY and suggestions for
improvement as part of the scheduled web surveys. We will use the 12-item PCP Satisfaction Scale developed by Hilt et al. (2013) specifically for evaluating satisfaction with CPAP consultation services. Respondents rate items on a 5-point Likert scale, and responses are averaged for each participant across items (Cronbach’s alpha in validation study = 0.93). The PCP Satisfaction Scale will be completed by participating providers after each consultation call during the award period. This will allow evaluation of overall satisfaction, as well as trends in individual PCP satisfaction over time as they gain more experience with the program.

C.4.1.5. Patient Satisfaction: Families who participate in teletherapy services will be invited to complete a brief web survey on their satisfaction, perceived barriers, and suggestions for improvement. Surveys will include the Verona Service Satisfaction Scale (VSSS; Ruggieri & Dall’Agnola, 1993), which assesses overall satisfaction in addition ratings of several domains including professionals’ skills and behaviors, information/access, and efficacy. The VSSS has been used widely in studies of community-based psychiatric care. Based on estimates derived from prior published reports of CPAP activities in other states, we anticipate only 10-20% of consultations will result in any form of direct contact with families, such as telephone communication or telehealth services. All families who receive telehealth services will be eligible to participate in this component of the project. After completion of the telehealth service, families will be notified that they qualify for a brief research survey via phone and email.

C.4.1.6. Implementation Outcomes: Surveys will measure key implementation outcomes, as outlined by Proctor18, including (i) acceptability (Treatment Acceptability Questionnaire, Hunsley, 1992; Technology Acceptance Model Questionnaire, Van Schaik et al., 2002), (ii) adoption (use or intent to use; Evidence-Based Practice Attitude Scale, EBPAS; Aarons, 2004), (iii) appropriateness (perceived fit with PCPs; Scott Innovation Scale, Scott et al., 2008; Intervention Profile Rating Scale, Kutsick et al., 1991), (iv) feasibility (usefulness of IN-BeHAPY in primary care), & (v) penetration (degree of routine use, indicated by frequency of calls per n encounters). Measures were selected from the Society for Implementation Research Collaborative (SIRC) Instrument Repository, which catalogs and rates tools designed to assess CFIR domains and constructs.

C.4.1.7. Quantitative data collection system. We will develop a data collection system that seamlessly integrates research & clinical data collection activities. We will use the Research Electronic Data Capture (REDCap) software package as the foundation for our data collection system to streamline data management.

C.4.1.8. Quantitative data analysis and evaluation. We will adopt a similar evaluation model as the ongoing IUH Integrated Care program to promote future cross-program comparisons. The program evaluation will take a pre- and post- observational approach, with data measurements occurring at baseline, and 3, 6, 9, and 12-months post-baseline. Implementation variables, program utilization characteristics, patient and provider characteristics, and user satisfaction will be key outcomes in this initial IN-BeHAPY evaluation. We will monitor these outcomes through the award period; their relative utility in characterizing the program will also guide decisions about which variables to include in future studies extending from this project.

C.4.2. Objective 2b. Collect, code, and analyze qualitative process data from audio-recorded consultation interactions between PCPs and IN-BeHAPY staff to identify key consultation themes and user experiences. The process evaluation during months 10-18 will include the analysis of the audio-recorded behavioral health specialist-PCP consultations. Each call to the IN-BeHAPY program will be audio-recorded. Quantitative information such frequency of calls and call lengths will be tracked, and qualitative analysis (described below) will be used to evaluate the content of the consultations. The results will be used to assess patterns of use (e.g., types of consults) to guide future program offerings such as targeted PCP education modules or web/mobile tools to help PCPs address the most common or challenging behavioral health issues.

C.4.3. Objective 2c. Collect summative quantitative and qualitative data from IN-BeHAPY users to better understand their experiences with the program and identify barriers and facilitators of use.

C.4.3.1. Focus groups and telephone interviews. Upon completion of the IN-BeHAPY pilot trial, we will gather summative evaluation data by conducting (1) follow-up focus group discussions with primary care staff who used the program, and (2) brief telephone interviews with non-participating PCPs. Additionally, family members who participated in any services offered by IN-BeHAPY (e.g., telemedicine-delivery therapy) will be contacted via phone, email, and/or letter and asked to participate in a brief telephone interview about their experience. Interview guides for each of the target audiences will be developed and participants will be recruited through the participating clinics. Much like in the formative stage, the primary care staff participants will be invited to participate in one of two focus groups conducted on-site to provide their perceptions of using IN-BeHAPY services. We will facilitate discussions to assess their access patterns, motivations, barriers, opinions, and recommendations regarding the use of IN-BeHAPY. PCPs who elected not to participate in any IN-BeHAPY services will be contacted to participate in a brief (~15 minute) telephone survey addressing their
reasons for their non-participation and to garner any information that might persuade them to participate in a CPAP in the future. Finally, caregiver-youth dyads who received any telehealth services from the CPAP will be contacted to participate in a brief telephone interview about their experiences. They will be asked to share what was useful about the service, any barriers to the service, and suggestions for improvement. All data will be independently analyzed using coding procedures specific to each target audience (described below).

C.4.3.2. Qualitative data analysis and evaluation. Each phase of research will follow similar analysis procedures tailored to specific data collection techniques and target audiences. Transcripts of all interactions will be used for analysis. After reading the transcripts, Dr. Brann will conduct open coding (i.e., initial, unrestricted coding) on 50% of the data for each phase (i.e., focus group discussions; interviews). Then, axial coding will be used to collapse open codes into larger categories and themes. Owen’s criteria for theme identification (recurrence, repetition, forcefulness) will be used in this process. This axial coding will be used to create a separate codebook for each dataset. After training a research assistant to use the codebooks, s/he will code all of the data with the codebook. The qualitative researcher will code a portion of the data (i.e., at least 25% of data) using the codebooks to assess intercoder reliability, which will be calculated using Scott’s pi. Disagreements will be discussed and resolved. Identified themes will be summarized in a report.

C.5. Additional Considerations

C.5.1. Potential Problems.

C.5.1.1. Underutilization by PCPs. PCPs at selected sites may use IN-BeHAPY services infrequently during the pilot trial. Though we expect lower use rates at the start of the program per published data from other CPAPs (Sarvet et al., 2010; Hilt et al., 2013), we predict more frequent utilization as the program matures and PCP familiarity and experience with the program grows. We have designed the study with scheduled assessments at 3-month intervals to monitor utilization patterns and make iterative, data-driven adjustments to improve implementation outcomes and optimize procedures. For instance, if lack of awareness of the program is commonly endorsed, we will increase marketing. If PCPs identify practice-level utilization barriers, we will confer with practice administrators. If volume is low due to too few sites, we will enroll additional PCPs from sites that expressed interest during development of this proposal.

C.5.1.2. Overutilization by PCPs. Alternatively, our team may be inundated with requests from participating PCPs for consultations, evaluations, and telehealth treatment visits during the award period. Between the full-time clinical coordinator, the on-call psychiatrists, and PIs Drs. Hulvershorn and Adams – as well as existing community resources – we are confident we have the personnel required to staff IN-BeHAPY at the two pilot sites. Indeed, a major reason for selecting two sites for this feasibility pilot trial was to ensure we would have the capacity to meet the needs of identified sites while simultaneously refining implementation and research procedures in the course of this 2-year project. If we learn that capacity is a challenge, we will convene the Primary Care leadership team (see Szczepaniak Letter), study site leaders, and administrative leaders in Psychiatry to troubleshoot solutions. Such strong enthusiasm for and utilization of the model would be encouraging for future expansion and sustainability.

C.5.1.3. Variability in Primary Care Operations & Procedures. Practice-level differences in operations, policies, procedures, and general culture may impact use and effects of IN-BeHAPY. We do not view the two pilot sites selected here as the only sources of input nor do we anticipate pilot outcomes to generalize fully. Rather, we will solicit input from PCPs throughout the IUH system to guide design decisions, identification of core vs. flexible operating procedures, & future program offerings. At the recommendation of senior clinical researchers, we selected two practice sites to (1) establish feasibility in different communities & practice settings, and (2) begin to adapt IN-BeHAPY for the needs of Indiana youth with behavioral health concerns.

C.5.1.4. Availability of Selected Sites. Although highly unlikely, it is possible that the identified clinics will not be available to participate in the feasibility due to unforeseen factors such as changes in clinic leadership. With support from primary care leadership (see Letters of Support), there is very low risk of losing buy-in from selected sites. Several more IUH pediatric primary care practices expressed strong interest in participating in this project (e.g., IUH Paoli). In the unlikely event the selected sites cannot participate, we will recruit one or more of those sites to join the study.


C.5.2.1. In-Person Integrated Care. The most common alternative to CPAPs for increasing behavioral health care access in primary care settings is to embed full- or part-time behavioral health specialists in primary care clinics, with varying degrees of coordination among providers and services. This is a promising approach, particularly in sub-/urban practices. IUH is currently sponsoring the CHOICE integrated
care pilot program in 3 Indianapolis-area primary care practices. Rather than compare IN-BeHAPY to CHOICE prematurely, we focus solely on development and open pilot evaluation of the CPAP here. In future studies, we will leverage the presence of both initiatives in IUH to collect pilot data to compare preliminary utilization, costs, and outcomes between practices assigned to participate in IN-BeHAPY or CHOICE and usual care.

C.5.2.2. Inclusion of All IUH Pediatric Primary Care Sites or Open Availability to Non-IUH PPC Sites. Fully implemented CPAPs offer consultation, evaluation, treatment, and educational services universally to pediatric PCPs in their state or catchment areas. Although most CPAPs are operated through academic centers, none limit their services exclusively to university health system participants. The long-range goal of this program is to offer IN-BeHAPY access to all Indiana pediatric PCPs. However, in the interest of adhering to thoughtful, user-centered design and development principles, and iterative refinement and evaluation procedures, we have elected to pilot the program in two carefully selected sites within the IUH system. As described above, these two sites were selected due to their volume, motivation to participate, and differing practice characteristics that may help generalizability in future projects. We will apply the lessons learned in this critical development and initial pilot phase to future expansion and implementation in more sites across the state. To secure future extramural funding to support the next stages of this program of research, it will be critical for the investigative team to demonstrate feasibility of procedures on a small scale, as proposed here.

C.5.2.3. Randomized Controlled Trial. Experts in clinical trial design and analysis argue that pilot studies should be used only to evaluate, refine, and demonstrate the feasibility and implementation of novel methods, rather than as small-scale tests of between-conditions effects. Hence, the primary goal of the pilot trial is to test the feasibility of participant recruitment and retention and protocol implementation in the context of a CPAP model. A secondary goal is to obtain preliminary estimates of effects on key process variables and outcomes. Reviewers may be concerned about the implications of the relatively small number of pilot sites and PCPs for estimating between-conditions effects and drawing conclusions about the utility of the IN-BeHAPY program relative to CHOICE and usual care. Small samples yield biased standard errors and unreliable effects in significance tests. Thus between-groups analyses will focus on descriptive comparisons.

C.5.3. Benchmarks for Success. A primary goal of this project will be to develop operational protocols and establish feasibility of IN-BeHAPY and related research procedures using best practice implementation science methods. We used Kraemer’s guidelines to identify appropriate benchmarks for feasibility, which include (a) recruitment of 25 PCPs across two sites into the feasibility trial over a 12-mo period; (b) Completion 50 consultations and 10 telepsychiatry sessions; (c) Audiotape at least 90% of all IN-BeHAPY consultation sessions; (d) PCPs, caregivers, and youth express high satisfaction with IN-BeHAPY services & procedures.

C.5.4. Strategy for Establishing Feasibility & Managing High Risk Aspects of the Project. Our approach blends quality improvement principles with rigorous mixed method research techniques to address key implementation questions about increasing pediatric behavioral health care access. We will use an iterative, user-informed approach that incorporates data-based refinements to program and study procedures, yielding improved knowledge about methods to retain or investigate in future studies. As described above, we have plans for addressing the most likely challenges that may arise. The PIs will convene the investigative team on a weekly to monthly basis throughout the award period (varying frequency per project demands). A standing agenda item will be to troubleshoot barriers to meeting project objectives. Because this study focuses on behavioral health and materials will be promoted online, there is also a risk that some non-providers may contact the IN-BeHAPY program for crisis management or direct services from our clinical team. We will be clear in our marketing materials that this initial project will target PCP-initiated (not patient-initiated) consultation and televideo-delivered evaluations and brief therapy. In the event of crisis calls, we will use protocols in place at IU/Riley Child and Adolescent Psychiatry, where Drs. Hulvershorn and Adams work.

D.5.5. Relevant Biological Variables. There are no eligibility criteria based on sex, race, ethnicity, or other socio-demographic or biological variables. We expect proportions of males/females and racial/ethnic minorities to reflect the selected clinics’ census. This research does not involve Human Embryonic Stem Cells.

C.5.6. Inclusion of Children. This project focuses on pediatric behavioral health. All patients will be youth presenting to IUH primary care clinics. Consultations will be available for providers delivering care to families with youth aged birth to 18. Patient- and caregiver-reported data will be gathered in surveys and interviews. Consent/assent procedures will be used as guided by pertinent IRB and practice regulations.

C.5.7. Anticipated Hazards. No procedures, situations, materials, or equipment are predicted to be hazardous to personnel beyond what would be encountered in typical pediatric primary care clinic. We do not expect elevated risk of distress or discomfort beyond what would be expected in routine care. Recent analysis of behavioral health consultation models note CPAPs have fewer legal risks than in-person or integrated care
models, since PCPs generally retain responsibility for patients' care.\textsuperscript{13,32}