Title: Improving Asthma Care Together (IMPACT): A Shared Management Pilot Study

NCT #: NCT04908384

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The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: Improving Asthma Care Together (IMPACT): A Pilot RCT

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP Use of the UW IRB**.*

University of Washington School of Nursing

1.2 Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[X] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

The IMPACT intervention has been developed in collaboration with participants under UW IRB: STUDY00003144: Improving Asthma Care Together (IMPACT): A Usability and Acceptability Study (short title - IMPACT Study). PI Jennifer Sonney. This protocol proposes to test the IMPACT intervention in an RCT.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[X] **No**

[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The purpose of this project is to pilot test the **IMPACT** mHealth application with a sample of sixty children (7-11 years) with persistent asthma and one of their parents.

The specific aims are to:

1. **Determine the feasibility, acceptability and initial efficacy of IMPACT with 60 parent-child dyads in an eight-week pilot randomized controlled trial (RCT).**
    a. We will use a priori benchmarks to determine the feasibility of IMPACT based on study eligibility, enrollment, and retention.
    b. Acceptability of IMPACT features and engagement will be determined via exit surveys and semi-structured interviews.
    c. Preliminary effect sizes compared to control will be reported on primary outcomes (asthma responsibility, self-efficacy) and secondary outcomes (medication adherence, asthma control and quality of life).
    d. We will also conduct preliminary testing of dyadic interdependence of asthma responsibility over time.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This study will use a randomized controlled trial design with two parallel study arms, intervention and control (usual care)

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☒	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device
☐	11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

This is a minimal risk study that involves a clinical trial.

Asthma is most common chronic condition of childhood, affecting over six million US children. Asthma is an incurable, lifelong condition that places children at increased risk for functional impairments, decreased quality of life, school absences, increased healthcare utilization, and irreversible structural airway remodeling. Asthma management involves symptom monitoring and response, trigger avoidance, and timely and appropriate medication use. Unfortunately, fewer than 50% of children with asthma are adherent to asthma management regimens, leading to increased disease morbidity and mortality and potentially irreversible airway damage. Improving pediatric asthma management represents a critical health need.

Children with asthma are missing a voice in their own care. The school-age years (7-11) represent a natural transition in asthma management, as children must assume some responsibility for asthma-related care while they spend increasing time away from parents at school and other extracurricular activities. Developmentally, school-age children are rule-driven, understand right and wrong, and are able to problem solve, which supports their capability to be active participants in their own asthma management. Yet, existing interventions focus on parents alone and use prescriptive approaches, telling the parent what to "do" to the child to manage their asthma. As a result, our current strategies are failing to provide children with asthma and their families the tools they need to manage asthma successfully within the realities of their daily lives. The answer to this problem lies in shared asthma management by the parent-child dyad, with the school-age years (7-11) the ideal developmental period for children to begin sharing responsibility with their parents and establishing lifelong health behaviors.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

This proposal builds on the study team's prior studies seeking to understand asthma management challenges faced by school-age children and their parents. We have also developed and tested other technology-based behavioral interventions in this population.

Our previous work sought to understand asthma management challenges from the perspective of parents and children (7-11 years). Three challenges emerged: 1) symptom monitoring, 2) medication use and tracking, and 3) shared asthma management responsibilities. Using a Human-Centered Design (HCD) framework, we collaborated with parent-child dyads to co-design Improving Asthma Care Together (IMPACT), a tailored shared management mobile health (mHealth) application that pairs the parent and child together as a shared management team. IMPACT helps families tailor asthma management strategies to fit the realities of their social environments while facilitating intentional transition of asthma management to the child. In other words, IMPACT was designed by the end-users, which suggests a high likelihood of feasibility and acceptability for study subjects.

Strengths of this study include: 1) prior successful recruitment of children with asthma and their parents; 2) established interdisciplinary study team with complimentary areas of expertise in asthma, spirometry, family informatics, and dyadic intervention expertise; 3) building logically on our prior work; 4) co-designing our intervention alongside parents and children that will use it; and 5) extensive usability testing during intervention development (prior IRB).

1.9 Supplements. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research	SUPPLEMENT Drugs

☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified	SUPPLEMENT Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	SUPPLEMENT Devices
☐	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT Multi-site or Collaborative Research
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT Non-UW Individual Investigators
☐	**Other REDCap Installation Attestation for Electronic Consent** The research will use a non-UW installation of REDCap for conducting and/or documenting informed consent.	SUPPLEMENT Other REDCap Installation
☐	None of the above	

1.10 Confirm by checking the box below that you will comply with these basic COVID infection and risk control measures, OR that you have an exception granted by the HSD Director: (a) the only in-person interactions are essential for the study; (b) study team members and participants will wear face coverings throughout all procedures; (c) all study staff and participants will be screened for COVID-19 just prior to each research visit; and (d) no participants over the age of 85 years will be enrolled if their in-person participation is not connected with a clinical visit. See this webpage for details, including what "screening" means.

Review the HSD website for current guidelines about which in-person research activities are allowable.

X Confirmed

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

60 children, ages 7-11 years, with persistent asthma and one parent will be recruited for this study. Participants will need to live in King, Pierce, or Snohomish County in Washington State.

Every effort will be made to recruit racial and ethnic minorities; asthma affects all races and ethnicities, with boys and non-Hispanic black children experiencing the highest prevalence. To ensure inclusion of racial and ethnic

minority participants, advertising will particularly target diverse population areas as identified by census tract data.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Parent/Caregiver Inclusion Criteria
Child's primary caregiver residing with the child (50% or more); ≥ 18 years; speaks and reads English; has a smartphone with data plan; and has a parent-reported asthma responsibility mean score ≤ 2.5 (parent assumes the majority of asthma management responsibility). Participants seeking in person visits must reside within King, Pierce, and Snohomish Counties in Washington State, remote visits will be offered outside of those areas.

Child Inclusion Criteria
1) aged 7-11 years, 2) diagnosis of persistent asthma, defined as a prescription for a daily asthma medication; 3) speak English.

b. Exclusion criteria. Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Parent/Caregiver Exclusion Criteria
None.

Child Exclusion Criteria
Parent report of conditions that impair the child's ability to learn shared-management including: 1) developmental delay (e.g., language < 5-year level), 2) co-morbid condition (cancer, diabetes, autism); or 3) current asthma exacerbation at the time of recruitment (defined as a prescription for oral corticosteroids) as this is a serious health event and not an opportune time for learning shared management.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection that will continue with prisoner subjects

2.4 Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

*For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the **GUIDANCE Prisoners** for the definition of "prisoner", which is not necessarily tied to the type of facility in which a person is residing.*

[X] **No**

☐ **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and their location(s):

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research is funded by one of these federal departments and agencies (Health & Human Services; Energy; Defense; Homeland Security; CIA; Social Security Administration), and/or will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole or pardon decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole or pardon.

☐ **Confirmed**

2.5 **Protected populations**. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
☐ Fetuses in utero	WORKSHEET Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET Neonates
☐ Non-viable neonates	WORKSHEET Neonates
☐ Pregnant women	WORKSHEET Pregnant Women

a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

2.6 Native Americans or non-U.S. indigenous populations. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**

[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

2.7 Third party subjects. Will the research collect private identifiable information about *other individuals* from the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

[X] **No**

[ ] **Yes** → If yes, these individuals are considered human subjects in the study. Describe them and what data will be collected about them.

2.8 Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

☒ **Yes** → If yes, for each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research ***Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100***
Children with asthma	65 (to account for anticipated attrition)
Parents of child with asthma	65 (to account for anticipated attrition)

2.9 COVID-19 Screening. If there will be any in-person interactions with the subjects, describe how you will screen them for COVID-19 symptoms within the 24 hours before the interaction. Also, describe the COVID-19 screening procedures for the study staff who will interact with the subjects.

Acceptable procedures include some type of symptom check or attestation, or a SARS-CoV-2 test with quick access to results. Symptom attestation involves an individual reviewing a list of symptoms and declaring the presence or absence of those symptoms. HSD strongly encourages adapting this Washington State Department of Health Screening Tool https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Employervisitorscreeningguidance.pdf or the UW EH&S Example Symptom Self-Attestation in this document: https://www.ehs.washington.edu/system/files/resources/guidance-symptom-monitoring-COVID-19.pdf. If you will test for the virus, you must also describe here whether the testing lab is CLIA-certified and how the results will be reported to the subjects.

At this time, we anticipate offering in-person sessions. For in-person sessions, we will complete a symptom attestation using the WA DOH questions. Attestation will be sent to study subject parents via REDCap SMS message or email (whatever participants prefer) 24 hours before their study visit.

3 NON-UW RESEARCH SETTING

Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1 Reason for locations. Describe the reason(s) for choosing the locations.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

3.2 Local context. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

3.3 Location-specific laws. Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

3.4 Location-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

3.5 If the PI is a student: Does the research involve traveling outside of the US?

☐ **No**

☐ **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes.

Recruitment may use one or several of the following methods:

- Social media posts via Facebook, Instagram, Google AdWords and/or NextDoor. Posts will guide potential participants to the IMPACT Study eligibility screening webpage.
- Recruitment flyers posted in community-based pediatric clinics, recreational centers, boys and girls clubs, and elementary schools will have a QR code and weblink directing to the study eligibility screening webpage.
- ITHS Patient cohort identification. We will submit a request to the ITHS biomedical informatics team to assist us with identifying prospective participants from the UW Medicine electronic medical records – search criteria will include child age (7-11 years) with asthma diagnosis ICD9 or ICD10 code. Among

those that fit our criteria, we will request the extracted cohort information include: child name and age, parent name, parent email and home address. We will opt in to the ITHS compliance "add on" such that UW compliance will be notified of all extracted participants. Parents will be contacted by the study team via email and/or direct mailing to include information about the study, a link to the IMPACT study webpage (where parents may choose to complete eligibility screening), and PI contact information (phone, email).

- Institute of Translational Health Sciences "Participate in Research" online webpage https://www.iths.org/participate/studies/. A brief description of the study, eligibility, website, and contact information

Screening

Interested potential participants will visit the IMPACT study webpage and complete eligibility screening. The screening will be automatically scored within REDCap and indicate whether participants appear to meet eligibility criteria or not. Those who are not eligible are thanked for their time. Those who are eligible will be advised that the study team will contact them (see recruitment follow-up description) to invite subjects to an in-person data collection session. REDCap uses unique identifiers for potential participants and only the study team has the master list connecting potential participant emails, names, and identifiers.

For prospective participants that have questions, the PI phone and email will be provided on all recruitment materials.

4.2 Recruitment materials.

a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Recruitment flyers, emails, web-postings, social media posts, direct mailings and study webpage will be used to recruit and screen subjects.

b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter. The text of these letters and emails must be uploaded to ***Zipline*** (i.e., a description will not suffice).

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

X	**No**
	Yes → If yes, describe the nature of the relationship.

4.4 Payment to participants. The IRB must evaluate subject payment for the possibility that it will unduly influence subjects to participate. Refer to GUIDANCE Subject Payment when designing subject payment plans. Provide the following information about your plans for paying research subjects in the text box below or note that the information can be found in the consent form.

- The total amount/value of the payment
- Schedule/timing of the payment [i.e., when will subjects receive the payment(s)]
- Purpose of the payment [e.g., reimbursement, compensation, incentive]
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include all of the above-listed information about payment, including the number and amount of payments, and especially when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Participant dyads (parent and child) will receive graduated incentive payments in the form of digital gift cards:

- $50 upon completion of the baseline study visit (T0)
- $100 upon completion of the post-intervention visit (T1)
- $150 upon completion of the 8-week follow-up visit (T2)

OPTIONAL
Participants will also be given the option to opt-in to completing a child cognitive (executive functioning) battery. This will be indicated as optional on the consent, but is available only to those who have in person visits. Cognitive battery completion will be paid an additional $25 per timepoint. This additional incentive payment will be a digital gift card.

4.5 Non-monetary compensation. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

All families will receive a home spirometry device, which is used to measure lung functioning in children. Families will use this periodically throughout the study but also keep it for future use. Children may also receive stickers or another small token during/following in-person sessions (e.g., bubbles, pencil).

4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[X] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

Screening information includes:

Parent

- First name, email address, phone number, and preferred mode of contact (text, phone, email) for follow-up.
- Confirmation that parent/child live in King, Pierce, or Snohomish county (if in person visit desired). Those outside of King, Pierce, or Snohomish counties will have a remote visit option.
- Child's primary caregiver residing with the child (50% or more)
- ≥ 18 years
- Speaks/reads English
- Has smartphone with data plan
- Parent-reported asthma responsibility mean score ≤ 2.5 (per screening survey)

Child

- First name, age, confirmation of prescription for daily asthma medication
- NO parent report of conditions that impair the child's ability to learn shared-management including: 1) developmental delay (e.g., language < 5-year level), 2) co-morbid condition (cancer, diabetes, autism); or 3) current asthma exacerbation at the time of recruitment (defined as a prescription for oral corticosteroids) as this is a serious health event and not an opportune time for learning shared management.

Study data will be collected and stored in REDCap database, accessible only to the study team.

4.7 Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[X] **Yes** → If yes, describe the consent process.

See uploaded recruitment descriptions.

a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the **recruiting and screening procedures**?

☐ **No** → If no, describe the information that will be provided during the consent process and for which procedures.

☐ **Yes, written** → If yes, and a **written** signature will be used to document consent:
- Upload the consent form to ***Zipline***.

☐ **Yes, electronic** → If yes, and an **electronic** signature will be used to document consent:
- Upload the consent form to ***Zipline***.
- **If the eSignature process or method for recruiting and screening is different than for the main study procedures**, use the questions about electronic consent in Section 8.3 and 8.4 to differentiate between recruiting/screening and main study electronic consent. **If electronic consent will be used for recruiting/screening but not main study consent**, use 8.3 and 8.4 to describe eConsent and note that it is only for recruiting/screening.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*
*Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** on the Seattle Children's IRB website.*

T0 BASELINE ASSESSMENT

Consent/Assent

Eligible participants will be contacted by the study team to schedule a data collection session, either at participant homes or convenient quiet location such as a community library. Once scheduled, the study team will email a copy of the consent form for review. IF REQUIRED (temporary) - 24 hours prior to any data collection session, participants will be sent a COVID-19 screening attestation. At the T0 session, the study team will describe the purpose of the study and obtain informed consent from the parent by iPad via the REDCap e-consent module (consenting for parent and child both to participate). The consent will include the optional cognitive battery for an additional $25 per timepoint. Parents will receive an automated emailed PDF copy of their consent form after completion. After this, child assent will be obtained – a recording from the PI will be played via iPad. If the recording does not function, the study team will read the assent materials to the child. The child will indicate whether they agree or disagree via REDCap (green check mark and "Yes, I'll join the study or red 'x' and "no, I do not want to join the study").

Data collection

Following consent and assent, the study team member will perform the direct child measures (height and weight). Next, the study team will assist the parent with pairing the spirometer with their phone. Note, to calculate

expected lung functioning, spirometers use a reference database that requires patient details including age, gender, height, weight. The parent will be instructed to input the study # (instead of name), year of birth (not date) to avoid unnecessary PHI disclosure. The study team will coach the child through spirometry and request that the results be sent to the study team (via email or text). Note, study team will make every effort to perform spirometry outside (weather permitting) and remain socially distanced and advised to wear masks for spirometry, since it is considered an aerosolizing procedure.

Next, individual data collection will commence. Parent participants will be provided an iPad with the electronic instruments preloaded and instructed to complete the instruments to the best of their ability. If questions arise, the study team will answer as needed. The study team will then work 1:1 with the child and assist with instrument completion (reading items, if requested). This technique has been used successfully in Dr. Sonney's other prior dyadic study designs to preclude parental interference in child items. Full instrument descriptions and timepoints are outlined in table below. Estimated time burden: Parent: 50-55 minutes; Child: 40-50 (plus 30-40 if cognitives added).

Assignment
REDCap randomization module will be used to assign dyads to groups using an externally generated block randomization scheme (stratified by sex). After surveys are complete, the study team will assign dyads to intervention or control by selecting "randomize" within REDCap and proceeding with the following, depending on assignment:

Control
Dyads assigned to the usual care control group will be advised of their assignment. An information sheet will be provided that outlines the upcoming data collection sessions (T1 at 8 weeks and T2 and 16 weeks) with compensation amounts. They will be advised to keep the spirometer to use in future visits, and more frequently if they choose. The PI will send the parent an asthma control assessment, based upon spirometry and asthma status questions (C-ACT), with interpretation using the national asthma guideline standards. This report may be shared with the child's health care provider, if desired. Finally, the family will be advised that at the end of the 16 week study period, they will be offered access to the IMPACT system, including the app and wearable device, should they wish to use it.

Intervention
Dyads assigned to the intervention group will be advised of their assignment. An information sheet will be provided that outlines the intervention tasks (weekly activities) as well as upcoming data collection sessions and compensation amounts. Next, the study team will assist the parent with accessing/downloading the IMPACT app. The family will be encouraged to follow the onboarding screens once downloaded, including pairing the app with the event marker watch (symptom watch) and spirometer device. The symptom watch is a commercially available event marker button that resembles a wristwatch. Children will be taught to press the button when asthma symptoms occur. These events are stored by the watch and synced with the app when connected to the parent phone's Bluetooth.

IMPACT intervention overview:

- Families will be asked to check in on the child's asthma daily (they may use the app to set SMS notifications, if desired) to review symptoms reported by the watch (tracked in the app dashboard).
- They will also be asked to log in weekly to select asthma shared management goals (provided), anticipated barriers, and problem solving. Each subsequent week, dyads will report on their goal progress and select new goals or retain the previous ones.
- To monitor asthma control, families will be prompted to complete the C-ACT (7 item questionnaire) and for the child to complete spirometry. C-ACT and spirometry scores are tracked in the app dashboard (see image)

- The intervention concludes after 8 weeks. The app is configured such that after the 8-week intervention, the goal-setting/monitoring feature is "muted", but dyads may continue to use the monitoring features (medication use, symptoms, asthma control).

T1 POST-INTERVENTION ASSESSMENT (8 WEEK)
The study team will schedule the T1 data collection session at week 8. The child will be asked to complete spirometry and export results to the study team, as in T0. Dyads will be asked to complete parent and child instruments outlined in the table below, again using the iPads as described above. Families assigned to the intervention will complete short intervention questionnaires and a brief semi-structured interview. Parent: 65-75 minutes; Child: 60-75 (plus 30-40 if cognitives added).

T2 FOLLOW-UP ASSESSMENT (16 WEEKS)
T2 data collection is nearly identical to week 8, with children performing spirometry followed by parents and children individually completing iPad instruments. Intervention families will be advised that they may continue using the app if they are interested, though study involvement has concluded (app will remain active). Control families will be given the option to access the app. For those interested, the study team will assist with app download and setup as described in T0. Estimated time burden: Parent: 45-50 minutes; Child: 40-50 (plus 30-40 if cognitives added).

This study requires in person sessions for data integrity and to facilitate participant use of new technologies (app, spirometer, symptom watches). Should the COVID-19 situation evolve, the following remote protocol will be used. Additionally, cognitive measures may only be collected in person.

Remote protocol (due to COVID-19 restrictions or participant family preference)
Remote protocol (if needed): Should remote study visits be required or preferred by participants, the study team will mail study materials (spirometer, paper tape measure) and arrange for web conferencing sessions via Zoom. A link to the study e-Consent and assent form (with video of the PI reading the assent script) will be sent at that time. Families may complete consent and assent asynchronously. If not completed prior to the web conference, the study team will display the REDCap e-Consent module using screen share and allow the parent time to review and complete. Once completed, the study team will read the study assent to the child. After consent and assent, the parent will be sent a personalized weblink to their visit surveys via REDCap. For child survey data – the study personnel will display the surveys using screen share during the web conference. The child may either use "mouse control" to self-select their responses or verbally indicate their responses and study personnel will enter them. Next, the study team member will assist dyads with connecting the previously mailed spirometer to the parent's smart phone via Bluetooth and mobile app. The app automatically prompts the user to enter sex at birth, age, height (paper tape measure provided) and weight (based upon recall). The family will be instructed to enter the child's participant ID in the "name" field. The dyad will follow the app instructions for performing spirometry. The final spirometry report will be emailed to the study email. After baseline measures, dyads will be assigned either to the intervention or control group. For those assigned to the intervention group, the study personnel will remotely assist intervention dyads with downloading IMPACT, pairing the symptom watch and reader with app, and reviewing written instructions for use. For dyads assigned to the control arm, they will keep the spirometer for future study sessions.

Future data collection sessions will use a similar Zoom protocol. Note, optional cognitive evaluations are only available in person.

5.2 Recordings. Does the research involve creating audio or video recordings?

[X] **No** → If no, go to question **5.3.**

☐ **Yes** → If yes, verify that you have described what will be recorded in 5.1 and answer question **a**.

a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

☐ **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

☐ **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No** → If no, go to question **5.4**.

☐ **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

- ☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
- ☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
- ☐ CHN Center for Human Neuroscience MRI Center (Arts & Sciences research facility)
- ☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
- ☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
- ☐ SCCA Imaging Services
- ☐ Northwest Diagnostic Imaging
- ☐ Other: identify in the text box below:

c. Personnel. For MRI scans that will be conducted at the DISC, CHN or BMIC research facilities: Indicate who will be responsible for operating the MRI scanner by checking all that apply.

- ☐ MRI technician who is formally qualified
- ☐ Researcher who has completed scanner operator training provided by a qualified MRI operator

5.4 Data variables. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

App usage – login date and duration, management goals selected, anticipated barriers, progress reports, asthma check ins, C-ACT scores, spirometer results, reported medication use.

Instrument details

Construct	Instrument	Time	T0	T1	T2
Demographics					
NINR Demographics	Parent (race, ethnicity, marital status, employment); Child (birthdate, education, race, ethnicity, asthma history) (P)	5	X		
Child Weight, Height	Stadiometer (D) to measure child height (for spirometry), Scale (D) to measure child weight	5	X X	X X	X X
Shared Management					
Asthma Responsibility	Asthma Responsibility Questionnaire (ARQ) (P, C): 10-items, 5-point scale to report asthma management task responsibility, higher scores indicate higher asthma management responsibility for child. Established construct validity; IC reliability α= .78 (child), .84 (parent).	<5	X	X	X
Asthma Management					
	Brief Illness Perception Questionnaire (BIPQ) (P,C): 8-item scale to assess beliefs about asthma, with higher scores indicating more burdensome perception.	<5	X	X	X
	Beliefs about Medicines Questionnaire (BMQ) (P,C): 10-item, 5-point scale to assess medication beliefs and concerns, with higher scores indicating higher perceived necessity or concerns.	<5	X	X	X
Self-Efficacy	Asthma Management Self-Efficacy (P, C): 13-items (parent) and 12-items (child), 5-point scale assesses asthma self-efficacy, higher scores indicate higher self-efficacy. Construct validity; IC reliability α=.87 (child), .87 (parent).	<5	X	X	X
Medication Adherence	Medication Adherence Report Scale for Asthma (MARS-A) (P, C): 10-items, 5-point scale assessing reported asthma controller medication adherence. *M* ≥4.5 indicates adherence; IC reliability α=.68 (child); .74 (parent).	<5	X	X	X
Family Functioning	Family Assessment Device (P): 60-item validated instrument using 4-point Likert scale, with higher scores indicating worse levels of family functioning.	10-15	X	X	X
Daytime Function & Health Outcomes					
Asthma control	Childhood Asthma Control Test (C-ACT) (P, C): 7 total items--3 parent (5-point scale) and 4 child (3-point scale)-- assess asthma control, higher scores indicate better control. IC reliability α=.79.	<5	X	X	X
	Child spirometry (D) – objective measure of expiratory lung function.[2] Asthma control (FEV_1:FVC) will follow national spirometry guideline cutpoints.[2]	5	X	X	X
Asthma-Related Quality of Life					
	Pediatric Asthma Quality of Life Questionnaire (P, C): 13 items, 7-point scale, parent or child-reported tools measuring quality of life of child/parent of child with asthma. Higher scores indicate higher QOL.	<5	X	X	X
OPTIONAL COGNITIVE BATTERY – in person only					
Executive Functioning	NIH Toolbox Cognition Battery (C): 30 min battery measures attention, processing speed and working memory in game-like format. Validated for ages 3-15 years, administered via iPad.	30-40	X	X	X
IMPACT Usability & Acceptability					
Acceptability	Feasibility and Acceptability of Intervention Measures (FIM, AIM) (P, C): 8 items using 5-point scale; higher scores indicate higher feasibility or acceptability. Established validity, reliability.	<5		I	
Usability	System Usability Scale (P): 10-items, 5-point scale to report usability of system. Higher scores indicates higher usability. Established validity, reliability.	<5		I	
Overall	Semi-structured Interview (P,C): 12 semi-structured questions to be used in post-intervention interview with parent and child.	10-15		I	
(P) Parent report, (C) child report, (D) direct measurement; I= intervention group only; C= control group only					

5.5 Data sources. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

Direct measurement: child weight, height, spirometry, NIH Cognitive battery (optional)
Self-report: all surveys/questionnaires
IMPACT app use – site tracks unique ID logon date, time, duration, use (goals selected, progress, asthma symptom reports, asthma control – C-ACT and spirometry, medication use)

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

☐ **Yes** → If yes, describe which identifiers and for which data/specimens.

☒ **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- ☐ There will be no identifiers.
- ☐ Identifiers or the key have been (or will have been) destroyed before access.
- ☐ There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

  This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- ☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

b. Will you or any study team members obtain any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

Parent: Legal first, last name; parent email address; telephone number; home address; for study communication, study mailings

Child: First and last name; date of birth

Intervention dyads: IMPACT app will track IP address for website login dates, usage

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before access.

☐ There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

☐ Identifiers will be stored with the data. Describe the data to which this applies:

☒ Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

The master list linking study ID with identifier will be kept in a locked file cabinet inside the PI's locked office.

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

5.7 Protected Health Information (PHI). Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

☐ **No** → If no, skip the rest of this question; go to question **5.8**

☒ **Yes** → If yes, answer all of the questions below.

a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

We will identify prospective participants through the ITHS biomedical informatics team and UW Medicine electronic medical records. Search criteria include: child age (7-11 years), asthma diagnosis, in Pierce, Snohomish and King county.
Specific PHI to be exported include:

- Child name
- Child age
- Parent name
- Parent email
- Parent home address

We will collect child and parent names to clearly indicate eligible individuals within the household.

Parent email and home address requested in order to send study flyer/recruitment materials

Child age included in order to ensure eligible for study

b. Is any of the PHI located in Washington State?

☐ **No**

☒ **Yes**

c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

UW Electronic Medical Records will be accessed by the ITHS biomedical informatics team using the search criteria designated above. For those records that meet criteria, the ITHS team will export the PHI into a secure REDCap database, which will be shared with the Study PI.

d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

None

Confirm by checking the box that the UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access, obtain, use, or disclose any UW Medicine PHI.

☐ **Confirmed**

e. Will you obtain any HIPAA authorizations electronically (i.e., e-signature)?

☒ **No**

☐ **Yes**

If 'Yes', confirm by checking the box that you have read and understand the 'Special Considerations' section of the **GUIDANCE Electronic Informed Consent** for information regarding the use of electronic signatures and HIPAA authorizations.

☐ **Confirmed**

f. For which PHI will HIPAA authorization NOT be obtained from the subjects?

- Child name
- Child age
- Parent name
- Parent email
- Parent home address

Provide the following assurances by checking the boxes.

☒ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☒ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will the research obtain or generate genomic data?

[X] **No**
[ ] **Yes** → If yes, answer the question below.

a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

[ ] **No**
[ ] **Yes** → If yes, complete the **SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

[X] **No**
[ ] **Yes**

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**
[X] **Yes** → If yes, answer all of the questions below.

a. Describe <u>what will be stored for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

The study consent form provides an option for parent participants to opt-in to being contacted for future study opportunities. Those who opt in will have the following contact information saved: parent name, phone, email, address; child name, age.

All study data collected (instruments, app usage, interviews) will be stored for future use. These data will be deidentified.

b. Describe what will be shared with other researchers or with a repository/database/registry, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Not applicable

c. Who will oversee and/or manage the sharing?

Principal Investigator

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

The study PI may use stored data for future secondary analyses, including mentoring of PhD students analyzing these data. Only investigators supervised by the PI will be provided deidentified data access.

e. Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

[ ] **No**

[X] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

[X] **No**

[ ] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them

[X] **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Subjects will indicate their preferred method of communication, including phone, text, or email. The study team will use the preferred method of communication for reminders, scheduling visits, and troubleshooting as needed. In-person visits will include T0, T1, and T2 visits described above.

5.12 Future contact with subjects. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

[ ] **No**
[X] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Consent includes section where parent may opt in/out of retaining contact information for future research studies. If they opt in, subject provides preferred method of contact (phone, email, mailing address). If opt in, information will be stored on PI's secure network and accessible only to the PI and her research team

5.13 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[X] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.14 Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples**: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those*

interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

Primary data collection method will be via REDCap surveys – PDF versions of these surveys will be attached.

5.15 SARS-CoV-2 testing. Will the subjects be tested for the SARS-CoV-2 coronavirus?

If the only testing is to screen the subjects (question 2.8), you do not need to answer this question

[X] **No**
[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

5.16 Research equipment and COVID-19. Does you research involve any equipment that will be used on more than one subject that is not part of a clinical facility?

Examples: a computer tablet, a portable research ultra-sound device).

[ ] **No**
[X] **Yes** → If yes: confirm by checking the box below that the disinfection and cleaning of the equipment will meet the enhanced UW Environmental Health & Safety requirements described here: https://www.ehs.washington.edu/system/files/resources/cleaning-disinfection-protocols-covid-19.pdf

[X] **Confirmed**

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

☐ **No** → If no, go to Section 8.

☒ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

Child subjects range from 7-11 years. Child subjects will not be legal age to consent.

☐ **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will parental permission be obtained for:

☒ All of the research procedures → Go to question **6.2b.**

☐ None of the research procedures → Use the table below to provide justification, and skip question 6.2b.

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐

	☐	☐
	☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☒ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both boxes are checked, explain:

Research is minimal risk, one parent will provide consent.

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☒ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

6.4 UW Office for Youth Programs Development and Support. If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with **UW Administrative Policy Statement 10.13** and the requirements listed at this website. This includes activities that are deemed to be Not Research or Exempt. It does not apply to third-party led research (i.e., research conducted by a non-UW PI). Information and FAQs for researchers are available.

This point is advisory only; there is no need to provide a response.

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will assent be obtained for:

[X] All research procedures and child groups	→ Go to question **7.2.**
[ ] None of the research procedures and child groups	→ Use the table below to provide justification, then skip to question **7.6**
[ ] Some of your research procedures and child groups	→ Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why assent will not be obtained

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

Following parental consent, research team member will play a recorded video of the PI reading the assent form (or read assent form if video unavailable). Research team member will answer any questions, and will emphasize that participation is voluntary, and they can stop anytime. The child will indicate whether they agree or disagree via REDCap (green check mark and "Yes, I'll join the study or red 'x' and "no, I do not want to join the study").

7.3 Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

If the child does not assent to participate, the parent and child will not be enrolled in the study. If already enrolled, the child/parent may withdraw at any time.

7.4 E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

REDCap e-consent framework will be used for electronic consent.
Child assent information will be read by PI via video in REDCap, with the child indicating their agreement/disagreement with joining in REDCap.

7.5 Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups	→ Use the table below to provide justification, then go to question **7.5.b**
☒ All of the research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of the research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse the answer across the groups and/or procedures.*

a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

The child will indicate whether they agree or disagree via REDCap survey (green check mark and "Yes, I'll join the study or red 'x' and "no, I do not want to join the study").

b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe the plans (if any) to re-obtain assent from children.

Not applicable

b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

Study data collection will end in 2022, though it is possible that data analyses may last for more than 7 years, at which point some child subjects may reach the age of consent. There are no plans to obtain consent for children who reach the legal age of consent. The study team will not have contact information for the child subjects (all outreach will have been conducted via the parent phone or email). Additionally, there will not be any ongoing interventions or data collection. Data analyses will only use deidentified data.

7.7 Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.

CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ Not ask or appear to ask subjects to waive their rights

PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which the answers in this section apply.

[X] Adult subjects

[X] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which consent will not be obtained?

[X] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all groups, collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

The study team (PI, student assistant) will meet with potential parent participants and their child at their home or community library. There, the study team will describe the study and review the consent form with the parent, answering any questions, and emphasizing that their participation is voluntary. An iPad with the preloaded consent form will be provided to the parent for review. Should the parent wish to delay signing the consent form, they may reschedule the T0 visit and will be provided an electronic copy of the form to review.

The parent consent form will include consent for the parent to participate as well as parent consent for their child to participate in the study. Both the parent and child will need to participate in order to be enrolled in the study. The parent will sign via REDCap e-consent module, which will automatically provide an emailed PDF copy of the consent form for parent records.

Remote protocol (due to COVID-19 restrictions or participant family preference)
Remote protocol (if needed): Should remote study visits be required or preferred by participants, a link to the study e-Consent and assent form (with video of the PI reading the assent script) will be sent ahead of time. Families may complete consent and assent asynchronously. If not completed prior to the web conference, the study team will display the REDCap e-Consent module using screen share and allow the parent time to review and complete. Once completed, the study team will read the study assent to the child.

c. Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Ask if the subject has any questions. Ask the subject to review the basic study procedure, providing prompts if needed (baseline visits, study duration, follow-up visits). Intervention involves weekly online activities, control just visits.

d. Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[X] **No**

[ ] **Yes** → If yes, describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE Key Information for Consent Materials**.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

Dr. Sonney, the study PI, has over 16 years of experience working as a Pediatric Nurse Practitioner and caring for children with asthma and their parents. Dr. Sonney also has over 7 years of research experience with this population, which makes her well qualified to understand essential information to provide prospective subjects.

f. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

Prior to any subject interaction, study team will ask parent/child if they have any questions or concerns about participating. They will be reminded that they may stop at any time. During online participation, written prompts remind that they may stop at any time.

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE Electronic Informed Consent for information about electronic consent requirements at UW.

☐ **No** → If no, skip to question 8.4

☒ **Yes** → If yes, answer questions **a** through **e**

a. Describe the electronic consent methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

After scheduling the T0 data collection session, the study team will email the parent a copy of the consent form for review (not signature.

T0 visit - The study team (PI, student assistant) will meet with potential parent participants and their child at their home or community library. There, the study team will describe the study and review the consent form with the parent, answering any questions, and emphasizing that their participation is voluntary. An iPad with the preloaded consent form will be provided to the parent for review and the parent will be advised it will take 5-10 minutes to complete. Should the parent wish to delay signing the consent form, they may reschedule the T0 visit and will be provided an electronic copy of the form to review.

The parent consent form will include consent for the parent to participate as well as parent consent for their child to participate in the study. Both the parent and child will need to participate in order to be enrolled in the study. The parent will sign via REDCap e-consent module via REDCap, which will automatically provide an emailed PDF copy of the consent form for parent records.

Remote protocol (due to COVID-19 restrictions or participant family preference)
Remote protocol (if needed): Should remote study visits be required or preferred by participants, the study team will follow similar procedures outlined above, only displaying the e-consent form via Zoom videoconference if not previously completed.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

Subject will be able to scroll to view entire consent on single page.

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

Subjects will have the opportunity to ask the study team questions at any time, including during the consent process. Data collection sessions are in person, therefore the study team is available for questions. IF remote sessions are required or preferred by participants, consent will still be collected live via videoconference (synchronously) and the team will be available for questions during the Zoom meeting.

The study team will ask if the subject has any questions. The team will ask the subject to review the basic study procedure, providing prompts if needed (baseline visits, study duration, follow-up visits). Intervention involves weekly online activities, control just visits.

d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

In case of REDCap downtime, iPad failure, or other unanticipated issue, the study team will have paper copies of consent and assent materials (and all questionnaires) during in-person visits. Such paper-based consent, assent and data collection will be used if necessary.

e. How will the research team ensure continued accessibility of consent materials and information during the study?

Parents will be emailed a copy of the consent form automatically via REDCap (in PDF format). Should parents request it, a paper copy will be mailed at no cost to the subject.

f. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

Families will be notified of any significant new findings (i.e. risk information) via their preferred communication modality, email, phone or text. Given that such details are difficult to convey over text, the subject will be texted to arrange a time to discuss the findings at a convenient time.

8.4 Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Is written documentation of consent being obtained for:

☐ None of the research procedures	→ Use the table below to provide justification then go to question **8.5.**
☒ All of the research procedures	→ Do not complete the table; go to question **8.4.b.**
☐ Some of the research procedures	→ Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *See the GUIDANCE Electronic Informed Consent for information about options (including REDCap e-signature and the DocuSign system) and any associated requirements.*
- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☐ **No**

[X] **Yes** → If yes, indicate which methodology will be used.

- [X] **UW ITHS REDCap**
- [ ] **Other REDCap installation** → Please name the institutional version you will be using (e.g. Vanderbilt, Univ. of Cincinnati) in the field below and provide a completed **SUPPLEMENT Other REDCap Installation** with your submission.
- [ ] **UW DocuSign**
- [ ] **Other** → Please describe in the field below and provide a signed **TEMPLATE Other E-signature Attestation Letter** with your submission.

b.1 Is this method legally valid in the jurisdiction where the research will occur?
NOTE: UW ITHS REDCap and UW DocuSign have been vetted for compliance with WA State and federal laws regarding electronic signatures.

- [ ] **No**
- [ ] **Yes** → If yes, what is the source of information about legal validity?

b.2 Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE Electronic Informed Consent for information and examples

- [ ] **No** →If no, provide the rationale for why this is not required or necessary to protect subjects or the integrity of the research. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?
- [ ] **Yes** →If yes, describe how subject identity will be verified, providing a non- technical description that the reviewer will understand.

b.3 How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

[X] **No**
[ ] **Yes** → If yes, describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if written documentation of consent is not being obtained for any part of the research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

Eligibility requirements for the study include written/spoken English for adults and spoken English for children. Those who are functionally illiterate will not be eligible. For those who have sensory or motor impairments, it is presumed that such individuals would have been unable to read and complete the web-based online eligibility screening. However, in the event that parent has such impairments at the time of enrollment, such individuals likely would not meet the eligibility requirements of the study and would not be enrolled.

8.7 Deception. Will information be deliberately withheld, or will false information be provided, to any of the subjects?
Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

[X] **No**

☐ **Yes** → If yes, describe what information and why.

Example: It may be necessary to deceive subjects about the purpose of the study (describe why).

a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes**

b. Will subjects be debriefed later? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

☒ **No** → If no, go to question **8.9**.
☐ **Yes** → If yes, answer the following questions.

a. Rationale. Provide the rationale for including this population.

b. Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **GUIDANCE Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

8.9 Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the woman and the person who obtains the informed consent.

8.10 Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

Recruitment concerns related to prospective subjects exported from the UW Electronic Health Record. The recruitment letter will explain how the contact information was obtained and that minimal data were accessed, including diagnostic codes, age, name and contact information for the parent. All data were accessed in accordance with UW Medicine protocols and only the study team has access to the data, which are securely stored.

This research will gather several types of sensitive information, around which special care must be taken. We will take measures to ensure that this information is handled appropriately, safely, and only for the scope of this research. There are additional privacy and confidentiality concerns with reporting health-related information in the study.

Confidentiality. We have several safeguards planned to protect against the loss of confidentiality. All electronic questionnaire or audio taped data will be coded with a study specific identifying number and all data (quantitative and qualitative) will be de-identified. The identifying number will be kept on a password-protected, secure and encrypted server through the Learning & Information Technology (L&IT) department at the School of Nursing. The majority of data will be collected electronically via the REDCap server. Subject contact information will also be stored separate from study data and identifying numbers in a file on a password protected server. Consent and assent are all completed online via REDCap e-consent framework and are therefore encrypted and secure. In person data collection sessions will be conducted either at the dyad's home or private community space (e.g., library study room). If necessary, web conference sessions will be conducted at the dyad's preferred location. Parents and children may choose not to answer questions or to stop surveys at any time. Parents and children may discontinue participation in the study at any time. Study data will be compiled from all subjects in the study and, when published, data will be reported in aggregate form; no participants will be identified in any report or publication.

The subject's identity as a participant in this study will remain confidential; the research records kept confidential; and protected health information safeguarded as required by the UW IRB and HIPAA regulations.

The research staff and the UW IRB will be allowed to inspect the information collected from this study. Only study identification numbers will be used to identify participants. Subjects in the intervention group will be given unique user logins and passwords to access the app and will be asked not to share these with anyone else. The software will be hosted on a secure server which has extensive safeguards in place with two firewalls, the latest virus protection, and daily back up of data. All contact information, identifying data and subject codebook will be kept on a password protected server to which only study staff has access.

Web-based Security. Use of Secure Hyper Text Transmission Protocol (HTTPS) will provide an encrypted communication channel for all communications between the subject and the study staff, thereby minimizing the

likelihood of interception or modification of data. Specifically, the encrypted connections will be used between the subject and the UW server where the data are housed, and between the study staff and the UW server.

The system will identify individuals responsible for input by maintaining an audit trail associated with any creation, modification, or deletion of data. The audit trail will also require an explanation of why the data were changed, deleted, or added. The security of the UW web database servers, which only allow secure and restricted access to authorized individuals and is maintained by the UW Information Technology Group, makes the theft, alteration, or access of data extremely unlikely. Additionally, the IMPACT data will be housed in a Microsoft Azure SQL database that uses a HIPAA compliant, cutting-edge layered security and encryption (SSL, encryption-in-use, dynamic data masking).

9.2 Identification of individuals in publications and presentations. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[X] **No**
[ ] **Yes** → If yes, will subject consent be obtained for this use?
- [ ] **Yes**
- [ ] **No** → If no, describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

[X] **No**
[ ] **Yes** → If yes, the UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 Retention of identifiers and data. Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

[X] **Confirm**

9.5 Certificates of Confidentiality. Will a federal Certificate of Confidentiality be obtained for the research data? *NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.*

[X] **No**
[ ] **Yes**

9.6 Data and specimen security protections. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the **GUIDANCE Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

Level 3 data protections will be used for all study data

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

Not applicable

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Ensure applicable risk information from any Investigator Brochures, Drug Package Inserts, and/or Device Manuals is included in your description.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Potential loss of confidentiality and invasion of privacy:
This study team will gather several types of sensitive information, around which special care must be taken. We will take measures to ensure that this information is handled appropriately, safely, and only for the scope of this research. There are additional privacy and confidentiality concerns with reporting health-related information in the study.

Asthma Exacerbation
It is a reasonable expectation that some child subjects may experience an asthma exacerbation (attack) during the study. Study subjects will be told that the intervention does not replace medical advice and that any concerns with their treatment should be discussed with the child's health care provider. For an emergency, call 911. While the IMPACT app tracks asthma data (spirometry and C-ACT data regarding asthma control), a disclaimer is present on the app that advises the app does not replace sound clinical judgement and provider recommended care. Should a family contact the 24- hour study team phone number, they will be advised to contact their provider and/or seek immediate care.

Mild discomfort related to symptom watch (intervention child subjects only):
The watchband may irritate the skin and participants will have the option to wear it over a long sleeve shirt. Skin reactions of this kind are unusual, and Dr. Sonney will be available to troubleshoot with participants as needed. Alternative watch bands may also be provided.

Anxiety or fatigue while completing surveys:
Questionnaires are routinely used in research, and pose no risks, though certain questions in the questionnaires explore health history of medical and/or psychological illness, family functioning. Participants may choose not to answer any questions causing discomfort, and may stop questionnaires at any time. If fatigued, subjects will be offered breaks. Additionally, subjects will be advised that there are no "correct" or "right" answers.

Stress about completing spirometry (child participants):
Spirometry is a routine measure of lung function used in both clinical practice and research, and poses no risks. However, children may feel fatigued or stressed when performing the maximal exhalations. The spirometer has visual incentives (such as blowing out candles or inflating a balloon) to assist with completion. However, the child participants may choose to discontinue at any time.

Social Risks
To minimize embarrassment or anxiety about the symptom watch, child intervention participants may wear a long sleeve shirt over the watch.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3
[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?

10.3 MRI risk management. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

[X] **No**
[ ] **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
[ ]	Dotarem	Gadoterate meglumine	Macrocylic
[ ]	Eovist / Primovist	Gadoxetate disodium	Linear
[ ]	Gadavist	Gadobutro	Macrocyclic
[ ]	Magnevist	Gadpentetate dimeglumine	Linear
[ ]	MultiHance	Gadobenate dimeglumine	Linear
[ ]	Omniscan	Gadodiamide	Linear

☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

b. Who will (1) calculate the dose of GBCA; (2) prepare it for injection; (3) insert and remove the IV catheter; (4) administer the GBCA; and (5) monitor for any adverse effects of the GCBA? Also, what are the qualifications and training of these individual(s)?

c. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

d. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

☒ **No**

☐ **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**

[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

Uploaded

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

The study statistician will be blinded to group assignment until dissemination of study findings. No other anticipated need to unblind.

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Participants may withdraw from the study at any time. Participants will also be asked to provide rationale behind their decision to withdraw, though they may choose not to provide rationale. The PI will ask if the participants are willing to continue with follow-up assessments (T2 and/or T3), participants may choose to participate in data collection or not.

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Participation in this research may or may not benefit the subject. Participation may help improve asthma management, asthma control, self-/shared-management skills, and improve health-related outcomes.

10.10 Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

☐ **No**

☒ **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

Spirometry results may indicate poor lung functioning, which is associated with higher risk of an asthma exacerbation. These results would be shared with the parent with the advice that they contact their health care provider.

a.2. Explain which of these results will be offered to subjects.

Parents of child participants will receive an asthma control report for all study visits (T0, T1, T2), based upon spirometry and C-ACT data and interpreted based upon the national asthma guidelines (of which Dr. Sonney is expert).

a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

N/A

b. Is there a plan for offering subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

[X] **No**

[ ] **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

Spirometry, C-ACT are both valid and reliable measures of asthma control and are considered "gold standard" within the national asthma management guidelines. All have been validated down to age 4 years.

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

Dr. Sonney will be responsible for communicating all asthma control findings. She will email the report to all study subjects with the offer to discuss via phone or videoconference, should the family request to do so. These reports will be sent within 2 weeks of the study visit.

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

Not applicable

f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[X] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[ ] **No**

[X] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

Subjects will not receive any compensation beyond what is outlined above related to study timepoints.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

Not applicable

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

None

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, residents, fellows, or post-docs.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

Not applicable

12.2 UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/

[X] **The CV will be uploaded.**

12.3 UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to

subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:
Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.
Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.
Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.
Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

PI will oversee all study procedures, data collection and monitoring. The PI will be responsible for training any study team members on protocols. PI may obtain consent, administer surveys.

Student Assistant – will receive CITI training and mandatory UW background checks, youth training. Will receive training from PI on all study procedures, including strategies for working with parent-child dyads. Obtain consent, perform study procedures, recruit, schedule study sessions, troubleshoot as necessary.

Co-Investigator – review study procedures, enrollment tracking, deidentified data access, interpretation, analyses and dissemination.

12.4 Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

Procedure manuals will be used and checklists for data collection sessions. Any student assistants will be trained by the PI and monitored for adherence to procedures.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

NIH/NCATS will review & approve the proposed IMPACT RCT protocol

13.2 Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination

☐ **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.