TEACHING YOUNG CHILDREN SWIM SURVIVAL SKILLS

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STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator will assure that no deviation from, or changes to, the protocol will take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Teaching Young Children Swim Survival Skills
Study Background:	Drowning is the leading cause of death for American toddlers ages 1-4, killing 482 children in 2022. Precise data are less available globally, but estimates suggest drowning is the leading cause of death for children in many countries, including Bangladesh, China, and Australia, and that drowning kills more children ages 1-4 than any other age cohort. Toddler drowning prevention must be multifaceted and include efforts for environmental change (e.g., fencing around swimming pools) and parental behavior (e.g., attentive supervision while children are near water). Another possible prevention strategy is to teach children themselves to survive in water.
Objectives:	The study will use a pre-post research design to evaluate whether self-rescue water training can effectively teach one-year-old children to survive independently in water. We hypothesized children would learn basic self-rescue survival skills and thus such training might form an additional aspect of multi-faceted efforts to prevent drowning among young children.
Study Population:	1 year old children
Phase:	I-II
Description of Study Intervention:	Self-rescue water training

2 INTRODUCTION

2.1 STUDY RATIONALE

Drowning is the leading cause of death for American toddlers ages 1-4, killing 482 children in 2022. Precise data are less available globally, but estimates suggest drowning is the leading cause of death for children in many countries, including Bangladesh, China, and Australia, and that drowning kills more children ages 1-4 than any other age cohort.

Toddler drowning prevention must be multifaceted and include efforts for environmental change (e.g., fencing around swimming pools) and parental behavior (e.g., attentive supervision while children are near water). Another possible prevention strategy is to teach children themselves to survive in water. This study was designed to evaluate whether teaching 1-year-old children self-rescue water survival skills could be effective.

2.2 BACKGROUND

Drowning among young children occurs in a wide range of circumstances and contexts. The prototypical situation, especially in high-income countries, follows a tragic pattern: the child wanders away from adult supervision and encounters a swimming pool, perhaps one the child has previously enjoyed while wearing floating devices and being supervised, or perhaps one with attractive toys floating in the water. The child enters the water undetected, is noticed missing, and is subsequently and sadly discovered minutes or hours later, drowned.

Prevention of such tragedies must be multifaceted. Installing barriers like fencing to prevent children's access to water is effective and has produced decreases in drowning incidents across multiple jurisdictions. Also presumed effective is appropriate adult supervision, which reduces injury risk if the adults are appropriately attentive and trained to assure safety.

A third possible prevention strategy, and one that is largely untested scientifically, is teaching children to protect their own safety in water. Swimming lessons are hesitatingly suggested to reduce drowning risk, and no negative consequences are reported from exposing young children and infants to water safety training. Further, initial evidence suggests that children ages 24-42 months can learn basic water competency skills. However, rigorous evaluation of efforts to teach children self-rescue survival skills in water are lacking.

Deliberately distinguished from lessons designed to teach children to swim, efforts to teach children self-rescue survival skills focus exclusively on skills like floating in the water and, as children grow older, self-propulsion to a safe location such as the side of the pool. Self-rescue training is widely advertised and promoted as effective, with proponents claiming children as young as 6 months old can learn to float when placed in water. If true, the learned skills would permit young children to survive for some indeterminate amount of time after falling in water, allowing adults to discover and rescue the child before a drowning occurs.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Physical risk involves placing 1-year-old children into a swimming pool. We expect the children will not know how to swim and they will not wear flotation devices.

Psychological risk involves separating 1-year-old children from their parent/caregiver and placing them in water. At times, the children will be unsupported (but closely supervised) by adults. Children may experience some anxiety, distress, or trauma from this situation.

We believe there is minimal social risk from participating in this study. The primary risk results from the possibility for a breach of confidentiality. No data we collect will be highly personal, but we will collect information that participants may wish to keep private (such as household income).

There are no anticipated economic or other risks.

2.3.2 KNOWN POTENTIAL BENEFITS

It is unknown, but children may be able to learn self-rescue survival skills in water, reducing their risk of drowning. This is why we are conducting the research.

3 STUDY DESIGN

3.1 OVERALL DESIGN

A pre-post clinical trial will be conducted.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

- Child age 1 year

4.2 EXCLUSION CRITERIA

- Inability of child or parent to communicate in English
- Participation of a sibling in the study
- Physical or mental condition that prohibits child from valid and safe participation in the study

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

Children will engage in standard training with a certified instructor according to Infant Swimming Resource (ISR) program guidelines (https://www.infantswim.com/). Lessons will be held for 10 minutes per day, 5 days per week, for 4 weeks, with the first lesson occurring following the baseline assessment and the last lesson comprised only of the post-training research assessment. All lessons will be individualized with the instructor. If the child is absent due to illness or other legitimate reason, make-up lessons will be permitted on weekends, but no more than 20 ten-minute lessons, occurring on 20 different days, will be conducted as part of the training program.

6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

Training will be conducted outside the research protocol. Research will only occur at baseline and after the training. Discontinuation of training will be determined by the instructor based on child distress or other reasons.

Upon completion of the study, training was discontinued for one child due to a fall injury sustained outside the training or research programs. The injury led to medical advice to refrain from entry into a swimming pool for several weeks.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Non-compliance to study protocol
- Indication from the young children that they demonstrated clear displeasure or discontent with the protocol, suggesting lack of assent for participation
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant

Upon completion of the study, one child was discontinued due to clear displeasure with the research protocol, as indicated by forceful, persistent and loud crying.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

Both at baseline and post-intervention, children's ability to self-rescue will be assessed using a structured and phased evaluation. At baseline, children will be assessed starting at Phase 1a; after

training, the assessment will initiate at Phase 3. If children pass a phase, they will progress to assessment at the subsequent phase. If children fail Phase 3 after training, they will regress to assessment at Phase 2. This strategy reduces burden of assessment on young children and increases the likelihood they will be assessed for abilities that were within their capacity to succeed.

All assessments will be conducted with an unfamiliar adult swim instructor, who will remain at all times within arm's reach of the child. A certified lifeguard will observe from the pool deck. All assessments will occur in warm (≥82° F) and sanitized water. During assessments, children will be released in the water 3-4 feet from a safe location (pool side or shallow stair), replicating locations where they might land if they were to fall into the water unintentionally.

The phased assessment was designed to be conducted without traumatizing children, essential for ethical reasons as well as to assure the initial assessment did not impact learning over the course of the 4-week training program. Phases 1 and 2 each will involve two assessments, one to measure children's ability to float safely or move to a safe location (pool stairs or side) following vertical placement in the water and the second to measure children's ability to float or move toward a safe location after horizontal, face-down placement in the water. In Phases 1 and 2, children will be held with a semi-release hold (gentle, soft, and light grip around the torso with a few fingers) and only released fully by the adult if they show evidence of safe movement in the water.

Phases 3 (vertical placement) and 4 (horizontal placement) extend earlier phases but involve full release of the child by the adult and expectations that children float with effective breathing and no adult assistance for 20 seconds (Phase 3) or 30 seconds (Phase 4), or else propel themselves to a safe location and wait.

Phase 5, unlike the other phases, will be conducted while children were clothed in a standardized outfit of a T-short, traditional non-swim diaper (which will rapidly fill and became heavy with pool water), and shorts. Children will be placed face down in the water and expected to float with effective breathing for 180 seconds (3 minutes), or propel themselves to a location of safety.

As children became more advanced in their skills during Phases 3, 4, and 5, they will be offered a second attempt to pass each phase if they fail the initial attempt.

We will collect other measures as potential covariates. Parents will report basic demographic data, history of children's swimming, and basic child development milestones. They also will provide impressions about the training program.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term “life-threatening” refers to an event in which the participant was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity:

- **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious.”

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the researchers who examine and evaluate the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.2.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events will be reported to the IRB according to regulatory requirements. The Principal Investigator will report to the sponsor any serious adverse event in a timely manner. All serious adverse events (SAEs) will be followed until satisfactory resolution.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;

- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

Self-rescue skill in water, as assessed through the phased behavioral assessment

8.2 SAMPLE SIZE DETERMINATION

To achieve .80 power to detect a medium effect size of d = .50, with a two-tailed repeated measures *t*-test and an alpha = .05, we require a sample size of 34. Given the possibility of some attrition during assessments, we conservatively adjusted for 15% attrition and planned to recruit 40 children to participate in the study. Full recruitment achieved 50 children and attrition of only 2 (4%).

8.3 STATISTICAL ANALYSES

Primary analyses will be descriptive: how many children succeed at each phase of the assessment at baseline, and how many succeed at follow-up. We will conduct paired-samples Wilcoxon matched-pairs signed rank T tests to supplement descriptive and graphical presentation of the data.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participants' parents and written documentation of informed consent is required prior to conducting study screening procedures.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant's parent or legal guardian will be asked to read and review the document. An investigator will explain the research study and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will sign the informed consent document prior to engaging in any study procedures, and prior to their child engaging in any study procedures. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. We also will monitor children closely and withdraw them if there are clear signs of lack of assent. The informed consent process will be conducted and documented in the source document (including the date), and the form signed.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants and the Institutional Review Board (IRB), will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, study documentation, data, and all other confidential information generated will be held in strict confidence. No information concerning data will be released to any unauthorized third party without prior written approval of the Principal Investigator.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator.

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

Study participant research data, which is used for purposes of statistical analysis and scientific reporting, will be stored securely. Individual participant research data will be identified by a unique study identification number.

9.1.4 DATA HANDLING AND RECORD KEEPING

9.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the research under the supervision of the Lab Manager and Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

9.1.4.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 3 years after the completion of the study or longer if required by local regulations.

9.1.5 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will developed and implemented.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator is responsible for knowing and adhering to the reviewing IRB requirements.