

Official Title: Tiny Cargo, Big Deal! An ED-Based Study of Child Passenger Safety Behaviors

NCT Number: NCT04238247

Consent and Parental Permission Form Date: 6/15/2022

Principal Investigator: Michelle Macy, MD, MS, Attending Physician, Division of Emergency Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago

Name of Federal Funding Agency: National Institutes of Health, National Institute of Child Health and Human Development (NICHD)



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MRN:

Parent Permission for a Child to Take Part in a Research Study

Study Name: Tiny Cargo, Big Deal! An ED-Based Study of Child Passenger Safety Behaviors

Sponsored by: National Institute of Child Health and Human Development

Name of Researcher: Michelle Macy, MD, MS, Division of Emergency Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago

This consent form describes a research study for which your child might qualify being conducted by a researcher at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care.

What are the purpose and goals of this study?

You and your child are being asked to take part in this study because:

- Your child is being seen in an Emergency Room (ER) or Immediate Care OR received care in an ER or Immediate Care in the past 6 months.
- You are the legal parent/caregiver/guardian (age 18 years or older) of this child (ages 6 months to 10 years).
- You have completed the screening survey and are eligible for part 2 of this study.

This study will test and compare two different ways to educate caregivers on child safety in and around cars. About 900 caregivers will complete part 2 of this study at Lurie Children's or remotely from a location such as their home. This study will help us understand how best to give caregivers education on this topic.

If I agree to have my child take part in this study, what would my child need to do?

- You and your child will complete a Tiny Cargo check-in. During this check-in, a study staff member will view how your child normally rides within the car. If you cannot do this check-in in-person, you will have 5 business days to send us photos. These photos will show us a few different views of your child as they normally ride in the car.
- We will use the age, weight, and height of your child to know what child passenger safety education to share with you. For children recruited from the Lurie Children's ER, we will also record the reason for their visit and, for families recruited in-person, how long you were in the ER before you were approached for the study. We will not otherwise go into your child's electronic medical record. The study team will not have access to the medical record of children who were not seen in the Lurie Children's ER.

Monthly photo requests:

- We will contact you again starting in 1 month. A member of our study team will send you a photo request via text message. This text message will ask you to share photos of your child as they normally ride in the car.



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- You, the parent/guardian, will send the photos of your child back to us via text message.
- You will get a total of 8 photo requests while taking part in this study (over the next 12 months). You will be asked for these photos during months 1, 2, 3, 5, 7, 8, 10, and 11 of the study. We will request that you submit views of the front of child, right side of child, left side of child for all plus a view of the back of the car seat for those using a forward-facing seat.
- You will get these photo requests only on the days and during the times that you tell us you are able to get messages from us. To update the days and times that you are free to be contacted, please reach out to our team at (312) 339-0888 or email us at TCBDstudy@luriechildrens.org.

6- and 12-month follow-up visits:

- Your child will be asked to do a 6- and 12-month (follow-up) visit with you.
- During the follow-up visits, we will re-measure your child's height and weight. Also, you and your child will complete a Tiny Cargo Check-in. During the check-in, a study team member will look to see how your child usually rides while in the car. Every effort will be made to meet with you and your child in person for the 6- and 12-month follow-up visit. This meeting can take place at Lurie Children's or at another location that is closer to you. If you are unable to meet with us in person, you may still be part of the study by using a video chat (e.g., Facetime, google hangout, Zoom, or Microsoft Teams) to check how the car seat is installed and texting photos to complete the Tiny Cargo check-in. If your follow-up visit is not in person, we will ask you for updated height and weight information from your child.

What are the risks, side effects, or discomforts related to the study?

The known or likely risks of this study are:

- Accidental public release of your survey data may occur due to unplanned data breaches outside of the procedures approved by this study.
 - The study team will make every effort to keep your/your child's data safe and secure. The University of Michigan Center for Health Communications Research has been subcontracted for work on this project. A formal review has been completed of the survey system and study website by the University of Michigan Information Assurance Office (<https://safecomputing.umich.edu/about>).
 - Survey data and photographs will be submitted by participants and sent to the study team through a third party platform called Twilio (see www.twilio.com for information about its privacy/security policies). Twilio will store information submitted on its servers and transmit messages, photos, and other data to the University of Michigan. Links to the photographs and text messages will be deleted on a regular basis and the other collected information will be deleted at the conclusion of participation in the study. Data collected for the study through the University of Michigan systems will be downloaded to Lurie Children's networks. Once transmitted to the University of Michigan and Lurie Children's they will be saved in password-protected folders on their secure networks. All



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photos will be de-identified – meaning faces will be blurred – when saved to Lurie Children’s network. Photos will be deleted from the University of Michigan server once they are successfully saved to Lurie Children’s network.

- The gift card distribution will be handled using Tango Card™, an electronic gift card distribution software. Tango Card™ will send an email to you each time a gift card is earned for this study. You will be able to redeem the gift card at a major retailer of your choice. Tango Card™ does not sell or distribute customer email addresses to any third party and Tango Card™ treats all personal data as completely confidential.

What are the benefits from this study?

You may learn information from being part of the study that leads you to make safer choices about how you are traveling with your child.

What other options does my child have?

You/your child may choose not to take part in this study.

What if the researcher or I do not think my child should stay in the study?

You/your child can stop taking part in this study at any time. Your decision will not affect your child’s regular care.

Returning Study Results:

The study team will return study results to you and your child if requested. After your 12-month follow-up visit, please send us an email at TCBDstudy@luriechildrens.org with “TCBD Final Report” in the subject line. A brief study results report will be created after the last family enrolled in the study completes their 12-month follow-up visit. It will be sent to you via email.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Important New Information:

We will tell you if we learn new information that may make you change your mind about your child being in this study.

Will my child’s information be used in future research studies?

The study team may share your child’s information for future research. They will remove identifiers such as your child’s name and other information that can be linked to your child before this is done. The study team and other researchers may use this for other studies without getting consent from you or your child.

Costs Related to this Study:

The study sponsor is paying for the following:

- Cost of text messages (both SMS and MMS) sent to your phone from the study team while taking part in the study (12 months).
- Cost of new car seats, if provided to families.

Parental Permission

Version Date: 3/24/21

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Approved by IRB on: 06/15/2022
IRB Approval Expires on: 05/31/2023
Lurie Children’s IRB#: 2020-3274
Stamped by: AGH


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You will be responsible for the following:

- Depending on your data plan, cost of text messages (both SMS and MMS) sent from your phone to the study team while taking part in the study (12 months).
- The cost of traveling to and from the 6 and 12-month follow-up visits (e.g., gas, public transportation).

You and/or your insurance company are responsible for the costs of normal care. Lurie Children's may be able to provide some financial help to patients. Ask your health team for more information about this program.

Payment for Taking Part in this Study:

You will be paid up to \$155 for taking part in this study. You will only be paid for completed study visits and clear, well-light photographs that contain the requested views (front of child, right side of child, left side of child for all plus a view of the back of the car seat for those using a forward-facing seat). You will receive gift cards electronically via email through Tango Card™, an electronic gift card distribution company. The study team will enter your email address and first and last name into the Tango Card website and Tango Card™ will email you each time you earn an incentive for completing a part of the study. The email from Tango Card™ will allow you to choose from a number of major retailers that partner with Tango to redeem the incentive.

Please refer to the incentive payments table below for details on the amounts you can earn for each of the tasks that you can finish while in the study.

Study Timeline	Task	Time to do task	Amount	Rate of payment	Type of payment	When payment is given	How payment is given
Baseline visit: up to \$25							
Enrollment in study	Survey & coaching session	Within 5 business days	\$20	1 time	Tango e-gift card	After completion	via email
	Tiny Cargo (TC) check-in	Within 5 business days	\$5	1 time	Tango e-gift card	After completion	via email
Monthly Photo Requests: up to \$50							
Photo requests (8 over 12 months)	Monthly photo request	Within 4 hours of receiving request	\$5/each month	Up to 8 times	Tango e-gift card	After review of photograph set quality and completeness	via email
	4 months of photo requests	4 months in a row	\$5/every 4 months	Up to 2 times	Tango e-gift card	After review of photograph set quality and completeness	via email
6-month follow-up visit: up to \$35							
6-month follow-up visit	Confirm 6-month visit	Prior to 6-month visit	\$5	1 time	Tango e-gift card	After 6-month follow-up visit	via email
	Survey & Tiny Cargo check-in	Within 1 month	Up to \$30 (\$15 survey/ \$10-15 TC check-in)	1 time	Tango e-gift card	After 6-month follow-up visit	via email
12-month follow-up visit: up to \$45							
12-month follow-up visit	Confirm 12-month visit	Prior to 12-month visit	\$5	1 time	Tango e-gift card	After 12-month follow-up visit	via email
	Survey & Tiny Cargo check-in	Within 1 month	Up to \$40 (\$25 survey/ \$10-15 TC check-in)	1 time	Tango e-gift card	After 12-month follow-up visit	via email



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Your and Your Child's Rights When Taking Part in this Study:

If you agree to have your child take part in this study, you are not giving up any of your or your child's legal rights. Your child can stop participating in this study at any time. Your choice will not affect your child's regular care at Lurie Children's in the future.

The study is covered by a Certificate of Confidentiality from the U.S. government. It adds special protections for your/your child's information. This document says that the study doctor cannot be forced to identify you/your child even if this is asked for by a court order. If you/your child need/needs medical help, or if you/your child could harm yourself/themselves or others, your/your child's information may be shared. The study doctor may also share your/your child's information if it is required by law. For example, study doctors must follow the laws about reporting suspected child abuse and infectious diseases. The government may also see your/your child's information if there is an audit of this study. You can still ask the study doctor to share your/your child's information, if needed.

This document does not stop you from choosing to share your child's information. If you want your child's information shared with an insurer, medical care provider, or any other person not part of this research, you must give consent to the study doctor to share it.

Additional Information:

Who can answer my questions about this study?

If you or your child have any questions, contact the researcher, Michelle Macy, MD at (312) 227-6676 or mmacy@luriechildrens.org during a workday or contacting the study team at (312) 339-0888 or TCBDstudy@luriechildrens.org at night or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

You will be given a copy of this consent form. Your child's name will not be included in any written or verbal reports of study results.

Planned Sharing of your Child's Information:

The study team will not have access to the medical record of children who were not seen in the Lurie Children's ER.

If your child does visit the Lurie Children's ER, the information that may be collected and shared will include your child's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls

If you agree to let your child take part in this study, you also give permission for the use and sharing of your child's information. This permission lasts until the study is completed.



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The study staff, employees, and Medical Staff of Lurie Children's may use your child's information for this study and share it with:

- The study sponsor, the National Institute of Child Health and Human Development, and those working with the sponsor.
- Study staff at University of Michigan, who will receive the photos of your child for research purposes.
- The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your child's other providers and their staff directly involved in your child's care, if your child's provider is a part of the Lurie Children's electronic health information exchange.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people to which we will give your child's information. We cannot guarantee that those listed above will not share it with others without your permission.

Your child's name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my child's information?

If you decide not to allow the release your child's information, your child will not be able to take part in this study. If you give permission to the use of your child's information, you can withdraw it at any time. Your request should be in writing and sent to the researcher. The study team can still use any information collected before you tell them to stop.

Can I review or copy my child's information?

You cannot see your child's study records while the study is ongoing. You still have a right to request a copy of your child's medical record and tests related to regular medical care that is given during the same time as the study.

Printed Name of Child:

Parent/LAR Signature:

By signing this form, I affirm:

- 1) I have read this form.
- 2) The research has been explained to me.
- 3) All of my questions have been answered. I give my consent for my child to take part in this research study.

Signature of Parent or Legally Authorized Representative (LAR):

Date:

Printed Full Name:

Relationship to Child:



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Signature of Authorized Person Obtaining Consent witness:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	

Signature of Interpreter/Witness*:

<input type="checkbox"/> Not applicable, no interpreter used.
I attest that the study information has been presented to the parent/LAR in their native language.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated “short form” (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

- The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.
- The parent/LAR should sign the short form (in the language they understand).
- The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.
- A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.



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PARENT/GUARDIAN PARTICIPATION ADDENDUM

Taking part in this research study is voluntary. It is your choice to take part in this research study. Please read this consent form and ask questions about anything you do not understand. Your decision will not affect your child's regular care.

Why are parents being asked to take part in this study?

As a part of this research study, we would like to complete the following:

We plan to use this information to better understand how to provide education to parents/caregivers on child passenger safety. Your part in the study should take about 12 months --See below for a breakdown of your participation over the course of the study.

TODAY in the ER or Immediate Care (or within 5 business days of screening eligible for the study after your child's visit)

- You will complete a baseline survey. This will take about 15-20 minutes. The survey will have questions about your use of car seats, and thoughts on child safety in and around vehicles. If you cannot finish the survey in person, you will have 5 business days to do this survey remotely.
- After you get done with the survey, you will be randomly assigned (like flipping a coin) to one of two groups. You cannot pick the group that you will be in. The groups are:
 - Group 1: A study team member will give you an informational handout.
 - Group 2: A study team member will give you an informational handout. Also, you will have about a 20-minute coaching session (in-person or over the phone) with a study team member. During this session, you will talk about how your child normally rides in the car, your goals for traveling safely with your child, and how you might reach these goals. To protect your privacy, we will do this session in a private place. Also, to make sure that we've recorded your answers correctly, we ask for your consent to audio tape this session. This recording will only be used for research and the audio tapes will not include information that someone could use to recognize you. You can give your consent to audio tape in the parent permission section of this consent.

We will also show you how to use the study's website called, the "Car Seat Compass" (about 5 minutes). This website will give you custom feedback based on your answers within the survey. This website will give you answers to common questions about traveling with children.

- Today or within 5 business days, you will also:
 - Fill out a form with your contact information that will be used to get in touch with you for future follow-up visits.
 - Complete a Tiny Cargo check-in where we review how your child is riding, either in-person or by photos you send in.



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AFTER TODAY:

Monthly photo requests (refer to info shown on the parent permission for more details)

Study text messages:

No matter which group you are randomly assigned to, everyone will get monthly text messages from our team while they are taking part in the study (12 months).

- Group 1: You will get about 3-4 text messages each month. Messages will include:
 - Reminders for upcoming follow-up visits
 - Feedback related to the photos you send us of your child riding in the car
 - General study information
- Group 2: You will get about 5-6 custom text messages each month. Messages will include:
 - Reminders for upcoming follow-up visits
 - Feedback related to the photos you send us of your child riding in the car
 - Custom tips and information based on your answers to study surveys

6- and 12-month follow-up visits:

- All subjects will be asked to do a 6- and 12-month (follow-up) visit. The follow-up visits include:
 - Taking an online survey (about 20-25 minutes)
 - Completing a Tiny Cargo check-in (about 10 minutes)
- Survey: The follow-up survey can be done in person or remotely, on your own device, or over the phone with a study team member. A team member will send you a link to take the survey so that you can do it before the visit. The follow-up survey will have questions that are like those asked on the baseline survey.
- Tiny Cargo Check-in (refer to the parent permission for more details)

Phone coaching session:

If you are currently in group 2, you may be randomly assigned (like flipping a coin) to one of two groups, after you get done with your 6-month follow-up visit. You cannot pick the group you will be in.

The groups are:

- Group 2: You will keep taking part in the study and nothing will change.
- Group 3: You will keep taking part in the study but will be asked to talk with a Car Seat Coach by phone for about 20 minutes. The phone call will cover some of the challenges and successes you are having with traveling safely with your child. You will also get 1 or 2 more study text messages each month. These extra text messages will include:
 - Feedback related to the photos you send us of your child riding in the car
 - Feedback related to survey answers



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What are the possible risks?

The known or likely risks of this study are:

- The survey may ask questions that make you feel uncomfortable. If this happens, tell us. You can decide not to answer any questions or stop taking part in the study at any time.
- Other people may see the study alerts (text messages) on your phone and realize you are enrolled in this study. This could make some people feel self-conscious. We urge all to protect their phones with passwords and keep all messages private.
- You will get study-related text messages over the course of the study. Please be safe – just as you would with any text – do not read or reply to any study text messages while driving.
- The Car Seat Compass website does not collect any personal information that can be used to identify you or your child, unless you provide that information voluntarily by responding to a survey or communicating with your study Coach during a coaching session. When visiting this website the following information is automatically collected: User client hostname, HTTP header, system date, full request, status code, content length, request method, the exact request the user made, universal resource identifier (URI), query string of the URI, and transport protocol. None of the foregoing information is deemed to constitute personal information.
 - The information that is collected automatically is used to improve this website's content, for statistical analysis, and to improve the utility of the material available on the website. The information is not collected for commercial marketing purposes and the Car Seat Compass website will not sell or otherwise disclose the information collected from the website for commercial marketing purposes.
- If you are randomly assigned to group 2 or 3, other people may overhear the coaching session in the ER or over the phone. To protect your privacy, others will be asked to leave the room during the sessions unless you prefer them to stay with you.
- The standard risks of transporting your child exist whether or not you choose to participate in this study. The child passenger safety information you will receive gives general guidance about legal requirements for use of child passenger restraints in Illinois and practices recommended by national organizations such as the American Academy of Pediatrics and the National Highway Traffic Safety Administration. The study team will observe behaviors but will not physically step into your vehicle, touch your child's seat, or conduct a formal car seat inspection. We will provide you with information about how to check your car seat or booster seat expiration date and how to check for recalls. If damage is observed, we will provide you with a coupon or code that can be used to receive a replacement seat from the study team. Only one replacement seat will be provided per family during the study. The replacement seat will be selected by the study team based on your child's age and size.
- If you receive a replacement seat from the study, you are responsible for following the installation and use instructions of the car seat manufacturer and your vehicle manufacturer. You are responsible [and not the study team] for any injuries sustained in a crash, including those that are because of improper installation or if you use an expired, recalled, or damaged car seat.



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- If you share anything with the study team that indicates you are causing harm or injury to your child, we will, as mandated reporters, make a report to the Illinois Department of Children and Family Services (DCFS). DCFS will decide about the need to investigate based on their protocols and procedures.

What are the possible benefits?

Depending on which group you are randomly assigned to you, you may or may not get any benefit from taking part in this study.

Benefits may include:

- Access to the study's website ("Car Seat Compass") with information on car seat safety.
- A new car seat, if certain conditions are met.
- Feedback from a study team member about safer ways to travel with your child. You may get this feedback via text message or verbally from a staff member.
- A private coaching session with a Car Seat Coach (in the ER or via phone). You would discuss how you feel about car seats and how your child usually rides while in the car.

How will you protect my information and what are my rights?

The same procedures that are in place to protect your child's information are also in place to protect your information given during this study. You can find these in the form under the section **"Planned Sharing of Your Child's Information."** This section also describes with whom your study information will be shared.

You may cancel your consent and take yourself out of this study at any time. It will not affect your child's regular care. Your child may still be able to continue in this study. If you want to stop the study, tell the researcher. Your request should be in writing and sent to the researcher. The study team can still use any information collected before you tell them to stop.

If you wish, you may ask for a copy of your study information when the study is over or when you are no longer taking part in the study. You will not be able to see your study information while the study is ongoing. If you have questions about the study, your rights, or feel you have been harmed by the study, please contact the study team members listed above in this form.

Optional Research:

You can still take part in the study if you do not agree to the optional research below.

What are the purpose and procedures of this optional research?

To make sure that we've recorded your information correctly, we would like to audio tape the coaching session(s). The audio files will be used for research and training purposes only.

What information or samples will be kept for this optional research?

De-identified audio files of your coaching sessions will be stored by the study team. Audio files will not include information that someone could use to recognize you (e.g., name).



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Who will have access to my information or samples for this optional research and how will it be kept private?

Only staff on the study team will have access to the de-identified audio files. All files will be kept on a safe and secure network that is password protected at Lurie Children's.

Can I take back (withdraw) my permission for this optional research?

You can take back (withdraw) your permission at any time. If you would like to withdraw, please tell a study team member. You can still be a part of the study even if you withdraw your permission.

Please **initial** next to your choice below regarding the optional testing:

	YES – I agree to let the study team audio record my coaching session(s) as part of this study.
Initials	
	NO – I do not agree to let the study team audio record my coaching session(s) as part of this study.
Initials	

Parent/LAR Signature:

By signing this form, I affirm:	
1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. 4) I consent to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	