Form A

IRB #	STU20250055

PROTOCOL FORM / RESEARCH DESCRIPTION

If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

Click once on the highlighted entry in each box to provide your response. Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

1. Purpose and objectives. *List the purpose and objectives:*

Purpose: Cerebellar ataxia can present with difficulties in walking, leading to risk for falls, limited mobility, and reduced independence. Several assistive devices are available to combat the risks associated. This study will explore the use of different devices and/or auditory cues to help improve the task of walking for individuals who are ambulatory.

Objectives: The researchers hope to learn about what device and/or auditory cues will optimally promote walking function, decrease fall risk, and improve independence in patients with cerebellar ataxia.

Hypothesis: Devices that provide postural/proximal stability will promote walking function and stability in patients with cerebellar ataxia.

2. Background.

- Describe past experimental and/or clinical findings leading to the formulation of your study.
- For research involving investigational drugs, describe the previously conducted animal and human studies.
- For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.
- Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (section number and/or title) or if none, ensure background includes references.

Please respond to all components of this item, or clearly indicate which components are not applicable.

a. Background

The literature for cerebellar ataxia does not encompass specific details on selecting assistive devices. Studies do indicate that providing assistive devices for trunk support may improve gait and stability in individuals with ataxia. However, there is no consensus on assistive device selection. In general, falls and instability are one of the primary factors impacting independence, safety, and functional mobility. Additionally, early literature has indicated that external cues may be very beneficial for gait in individuals with ataxia.

Buckley, E., Mazzà, C., & McNeill, A. (2018). A systematic review of the gait characteristics associated with Cerebellar Ataxia. Gait & posture, 60, 154-163.

Kelly, G., & Shanley, J. (2016). Rehabilitation of ataxic gait following cerebellar lesions: applying theory to practice. Physiotherapy theory and practice, 32(6), 430-437.

Moumdjian, L., Rosso, M., Moens, B., De Weerdt, N., Leman, M., & Feys, P. (2022). A case-study of a person with multiple sclerosis and cerebellar ataxia synchronizing finger-taps and foot-steps to music and metronomes. *Neuroimmunology Reports*, *2*, 100101.

Stephen, C. D., Brizzi, K. T., Bouffard, M. A., Gomery, P., Sullivan, S. L., Mello, J., ... & Schmahmann, J. D. (2019). The comprehensive management of cerebellar ataxia in adults. Current Treatment Options in Neurology, 21, 1-17.

Wright, R. L., Bevins, J. W., Pratt, D., Sackley, C. M., & Wing, A. M. (2016). Metronome cueing of walking reduces gait variability after a cerebellar stroke. *Frontiers in neurology*, *7*, 84.

b. Current practice

No focal literature on what device is best but many articles suggest using them

- Trunk instability = gait variability, wider BOS with walker is beneficial (Buckley, 2018; Kelly, 2016)
- Choosing the correct walking aid is important, canes to walkers and those with a heavy base to prevent retropulsion as well as all-terrain walkers (Stephen, 2019)

Additionally, aerobic, balance, core/strengthening, gait interventions are utilized via physical therapy.

3. Study Design.
Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

Prospective cohort study

Inclusion Criteria:

Cerebellar ataxia, gait impairment (gait velocity </= 110 cm/sec without an assistive device), ambulatory for 16 feet (Zeno mat) with assistance and without assistive device(s), 18 years or older

Exclusion Criteria:

Gait velocity >/= 110 cm/sec without an assistive device, Medically diagnosed orthopedic conditions or injuries that impact ambulation

4. Research Plan / Description of the Research Methods:

4.a. Provide a **comprehensive narrative** describing the **research methods**.

1) Provide the **order in which tests/procedures will be performed**,
2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.
3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Please respond to all components of this item, or clearly indicate which components are not applicable.

Order:

- Consent patient
- Complete intake forms
- Baseline SARA
- Baseline walking kinematic data across 20-foot computerized walkway (Zeno Walkway) without an assistive device
- Baseline 4 Square Step Test on Zeno
- Baseline portion of the DGI without an assistive device
- Re-test Zeno (gait and balance) and portion of DGI with rolling walker, platform rolling walker (UpWalker), posterior rolling walker (Nimbo)
- May require participant to walk with a metronome (10 minutes) with their assistive device of choice
- Re-test Zeno with assistive device used during metronome walking

Setting: outpatient neurologic physical therapy clinic and inpatient rehabilitation physical therapy unit

Methods used to protect privacy: encrypted, secured storage of patient forms, patients identified as “numbers”, access to health records not necessary

IRB #	STU20250055

Plan for data analysis: Correlation coefficient: gait spatiotemporal parameters WITHOUT a device vs gait velocity WITH a device (three graphs total), utilize a statistician to assess demographic data and the differences between gait trials as well as balance outcome measures

This is a sample of convenience which will be used to determine for a subsequent larger, sample study.

IRB #	STU20250055

4.b. List of the study intervention(s) being tested or evaluated under this protocol

☐ **N/A -** this study does not test or evaluate an intervention. Skip to item 4.d.

#	Study intervention(s) being tested or evaluated under the protocol *Add or delete rows as needed*	Affiliate Place a check next to institution(s) where the intervention will be performed	Local Standard Practice? Indicate whether the intervention is considered acceptable practice locally for applicable institutions
1	**Ambulating with 2-wheeled rolling walker**	☒ UTSW	☒ Yes
		☐ PHHS	☐ Yes
		☐CMC	☐ Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes
2	**Ambulating with upright walker**	☒ UTSW	☒ Yes
		☐ PHHS	☐ Yes
		☐CMC	☐ Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes
3	**Ambulating with posterior walker**	☒ UTSW	☒ Yes
		☐ PHHS	☐ Yes
		☐CMC	☐ Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes

4.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

IRB #	STU20250055

(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)

4.c.
Study Intervention #1
Ambulating with 2-wheeled rolling walker

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".
All Groups/Subjects	Contributes to subject's well being with improved walking function due to bilateral upper extremity support, increase in base of support and mild proximal stability, accessible

If you are requesting a Waiver of Informed Consent, complete the table below.

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

	Not serious	**Serious**
Likely These risks are expected to occur in more than **20** out of **100** subjects.	• Instability or loss of balance	• n/a
	Not serious	**Serious**
Less likely These risks are expected to occur in **5-20** subjects or less out of **100** subjects.	• Muscle soreness	• n/a
	Not serious	**Serious**
Rare These risks are expected to occur in less than **5** subjects out of **100**	• n/a	• Fall to the ground, which may lead to injuries such as but not limited to fractures, contusion, skin tears, concussion.

IRB #	STU20250055

4.c.
Study Intervention #2
Platform Rolling Walker

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".
All Groups/Subjects	Contributes to subject's well being with improved walking function due to bilateral upper extremity support, increase in base of support and moderate proximal stability, accessible

If you are requesting a Waiver of Informed Consent, complete the table below.

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

	Not serious	**Serious**
Likely These risks are expected to occur in more than **20** out of **100** subjects.	• Instability or loss of balance	• n/a
	Not serious	**Serious**
Less likely These risks are expected to occur in **5-20** subjects or less out of **100** subjects.	• Muscle soreness	• n/a
	Not serious	**Serious**
Rare These risks are expected to occur in less than **5** subjects out of **100**	• n/a	• Fall to the ground, which may lead to injuries such as but not limited to fractures, contusion, skin tears, concussion.

IRB #	STU20250055

4.c.
Study Intervention #3
Posterior Walker

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".
All Groups/Subjects	Contributes to subject's well being with improved walking function due to bilateral upper extremity support, increase in base of support and moderate proximal stability, accessible

If you are requesting a Waiver of Informed Consent, complete the table below.

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

	Not serious	**Serious**
Likely These risks are expected to occur in more than **20** out of **100** subjects.	• Instability or loss of balance	• n/a
	Not serious	**Serious**
Less likely These risks are expected to occur in **5-20** subjects or less out of **100** subjects.	• Muscle soreness	• n/a
	Not serious	**Serious**
Rare These risks are expected to occur in less than **5** subjects out of **100**	• n/a	• Fall to the ground which may lead to injuries such as but not limited to fractures, contusion, skin tears, concussion.

4.d. List ALL other research procedures or components not listed in table 4.b.
The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.

Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments)

#	**Research component** • **individual procedures** *example:* **Eligibility Assessments** • History and physical • Questionnaire • Laboratory tests *Add or delete rows as needed*	**Column A** **Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the study.**	**Column B** **Research Only** Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if they were not participating in the study)*	**Column D** **Risks** **If you are requesting a Waiver of Informed Consent, complete the table below.** List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate: • Serious and likely; • Serious and less likely; • Serious and rare; • Not serious and likely; • Not serious and less likely
1	**Completion of forms**			

	Consent	None	Once	
	Intake	None	Once	
2	**Ambulating without assistive device**			
	Zeno	None	Four	
	Portion of DGI	None	Once	
3	**Ambulating with rolling walker**			
	Zeno	None	Four	
	Portion of DGI	None	Once	
4	**Ambulating with upright walker**			
	Zeno	None	Four	
	Portion of DGI	None	Once	
5	**Ambulating with posterior walker**			
	Zeno	None	Four	
	Portion of DGI	None	Once	
6	**SARA**	None	Once	
7	**Four Square Step Test (Zeno)**	None	Once	
	Outcome measure	None	Once	

5. Safety Precautions. *(Describe safeguards to address the serious risks listed above.)*

a. Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

There will always be study staff (licensed physical therapists) ambulating next to the participants who will be wearing a gait belt (safety belt) on to help ensure safety. There will be rest breaks built in to minimize the impact of fatigue as well.

b. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

911, UTSW Emergency Contact

c. Will the safeguards be different between/among groups?

☐ No ☑ No

If yes, describe here