Cover Page for Protocol, Statistical Plan and ICF

Official Title:	Outcomes Comparison Between Baerveldt 350 and Ahmed ClearPath 250 Tube Shunts for the Treatment of Glaucoma
NCT number:	NCT04542616
Document Type:	Study Protocol
Date of the Document:	08/12/2020

Complete Research Protocol (HRP-503)

Table of Contents

Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response Example
Intervention Group:
Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response:

Outcomes comparison between Baerveldt 350 and Ahmed ClearPath 250 tube shunts for the treatment of glaucoma

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Asher Weiner, MD

Department of Ophthalmology/Ross Eye Institute

(716) 881 7900

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

Version 1: 12Aug2020

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response:

This study is not funded

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

Protocol is not funded by a grant

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: Ross Eye Institute

Address: 1176 Main Street, Buffalo, NY, 14209

Department: Department of Ophthalmology

1.0 Study Summary

Study Title	Outcomes comparison between the Baerveldt 350 and Ahmed ClearPath 250 tube shunts for the treatment of glaucoma
Study Design	Prospective randomized clinical trial
Primary Objective	To compare will compare the safety and efficacy of Baerveldt 350 and Ahmed ClearPath 250 tube shunts in lowering Intraocular pressure (IOP).
Secondary Objective(s)	N/A
Research Intervention(s)/ Investigational Agent(s)	Standard of care tube shunt implantation; comparison between two types of FDA-approved, commercially available, commonly used glaucoma tube shunts.
IND/IDE #	N/A
Study Population	Patients from the Ross Eye Institute glaucoma clinic
Sample Size	70 eyes of 70 patients
Study Duration for individual participants	24 months

Study Specific Abbreviations/ Definitions	Intraocular pressure (IOP)

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives of this research.

Response:

We will compare the safety and efficacy of Baerveldt 350 and Ahmed ClearPath 250 tube shunts in lowering IOP in glaucoma patients.

2.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

We hypothesize that the ClearPath 250 tube shunt is as effective as Baerveldt 350 in IOP reduction despite the difference in plate size (250 vs. 350 mm^2), and as safe with a similar rate of post-operative complications.

3.0 Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

Primary endpoint is postoperative IOP with a reduction of ≥20% from baseline and IOP ranging between 6-21 mmHg.

Secondary endpoints are reduced need for glaucoma medications, and postoperative complications including corneal edema, iritis, hyphema, hypotony, vitreous hemorrhage, cystoid macular edema, vision loss and others.

4.0 Background*

4.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response:

Tube shunt implantation is a common type of surgery considered standard of care for treating significant potentially-blinding glaucoma where medical and laser treatment, and previous surgeries, have failed to control IOP sufficiently to stop glaucoma progression towards blindness.

Since a larger plate tube (e.g., Baerveldt 350) is more difficult to implant requiring longer surgical time and intraoperative ocular muscle manipulation with possible patient discomfort, a smaller plate tube shunt (e.g., Ahmed ClearPath 250) requiring shorter surgical time and no ocular muscle manipulation may have an advantage if the long term surgical outcomes were the same.

However, the literature is lacking regarding the effect of the tube plate size on the final outcomes of tube shunt implantation. Most published comparisons are between totally different types of tube shunts regardless of plate size, often made of different materials,[1,2] often comparing valved vs. non-valved tube shunts,[3-5] combining different plate sizes in the same study groups,[5] mixing tubes with or without combined cataract surgery in the same study groups,[5] or comparing surgeries performed by several surgeons utilizing different surgical methods.[1-5] Further, all these studies utilize tubes implanted into the anterior chamber (AC) thus increasing the risk of corneal failure, with no comparisons al all between tube shunts implanted through the ciliary sulcus of the eye designed to reduce the risk of corneal failure. Our Principle Investigator (AW) is specializing and well-published in this type of tube shunt implantation.[6-8]

This prospective randomized trial is designed to resolve all these confusing factors in the literature and finally provide the answer of whether tube plate size has an effect on the final outcomes of tube shunt implantation by performing a "clean" study that would isolate the effect of tube plate size on long term outcomes. To achieve this goal our study will utilize two non-valved tube shunts with a different plate size (350 vs. 250 mm^2) made of identical materials, in eyes that have already had cataract surgery, and all performed by the same surgeon (AW) through the ciliary sulcus.

4.2 Include complete citations or references.

Response:

Pandav SS, Seth NG, Thattaruthody F, Kaur M, Akella M, Vats A, Kaushik S. Long-term outcome of low-cost glaucoma drainage device (Aurolab aqueous drainage implant) compared with Ahmed glaucoma valve. Br J Ophthalmol 2020;104:557–562. doi:10.1136/bjophthalmol-2019-313942

2. Hafeezullah N, AlHilali S, Alghulaydhawi F, Edward DP, Ahmad S, Malik R. A preliminary comparison of the Aravind aurolab drainage implant with the Baerveldt glaucoma implant: A matched case-control study. European Journal of Ophthalmology 2020;https://doi.org/10.1177/1120672120912383

3. Budenz DL, Barton K, Gedde SJ, Feuer WJ, Schiffman J, Costa VP, Godfrey DG, Buys YM. Five-Year Treatment Outcomes in the Ahmed Baerveldt Comparison Study. Ophthalmology 2015;122:308-316. https://doi.org/10.1016/j.ophtha.2014.08.043.

4. Tsai JC, Johnson CC, Kammer JA, Dietrich MS. The Ahmed Shunt versus the Baerveldt Shunt for Refractory Glaucoma II: Longer-term

Outcomes from a Single Surgeon. Ophthalmology 2006;113:913-917. https://doi.org/10.1016/j.ophtha.2006.02.029.

5. Dixon MW, Moulin TA, Margolis MS, Palko JR, Mortensen P, Conner IP, Sheybani A. Comparative Outcomes of the Molteno3 and Baerveldt Glaucoma Implants. Ophthalmology Glaucoma 2020;3:40-50. https://doi.org/10.1016/j.ogla.2019.10.003.

6. Weiner A, Cohn AD†, Balasubramaniam M, Weiner AJ. Glaucoma tube shunt implantation through the ciliary sulcus in pseudophakic eyes with high risk of corneal decompensation J Glaucoma. 2010;19:405-411. PMID: 19907341.

7. Weiner Y, Faridi O†, Weiner A. Clinical experience with sulcus-implanted Baerveldt glaucoma tube shunts fully concealed behind the iris in undilated pseudophakic eyes J Glaucoma. 2013;22:667-671. PMID: 23787336

8. Weiner AJ, Weiner Y, Severson ML, Weiner A•. (March) Clinical experience with urgent tube shunt implantation through the ciliary sulcus in phakic eyes. Int Ophthalmol. 2019;39:639–649. https://doi.org/10.1007/s10792-018-0863-9. PMID: 29426968

5.0 Study Design*

5.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

This is a prospective randomized interventional clinical study. Only patients requiring tube shunt implantation as their next standard-of-care treatment for their significant uncontrolled glaucoma will be recruited as long as they meet the inclusion/exclusion criteria. However, the patients will be randomized as to which tube shunt will be implanted. More than one eye per patient may be included in the study.

All patients with significant uncontrolled glaucoma will be recruited from the Ross Eye Institute, University at Buffalo glaucoma clinic. The patients will be screened to see if they meet the inclusion/exclusion criteria. Informed consent will be obtained from all candidates prior to participation in the study. All surgeries will be performed by the same surgeon (AW). IOP, IOP-lowering medications and visual acuity and all standard glaucoma parameters will be measured preoperatively and during follow up visits. All intra and post-operative complications such as hypotony, corneal edema, hyphema and posterior segment complications will be recorded.

6.0 Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response:

Comparison between Baerveldt 350 tube shunt (Advanced Medical Optics, Santa Ana, CA) and Ahmed ClearPath 250 tube shunt (New World Medical, Rancho Cucamonga, CA).

6.2 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response:

One of the two tube shunts will be implanted in an ambulatory surgery center (ASC) as done routinely, and only in patients that require tube shunt implantation as their standard-of-care for their uncontrolled glaucoma. Both tubes are FDA-approved and commercially available and the ASC will order the tubes from the corresponding companies as done routinely. The tube shunts will be implanted as usual by Dr. Asher Weiner who is an experienced glaucoma surgeon who has implanted many of these two devices as part of his routine glaucoma practice. None of the devices or procedures is experimental.

6.3 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: N/A

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response:

70 subjects (70 eyes) will be recruited. The minimum "*n*" required based on the UB statistician's recommendation is 24 patients in each of the two groups to a total of 48 patients, and we're adding a safety margin expecting that some patients will fail to return for follow-up during the full length of the study due to illness, death, noncompliance, moving away, etc.

7.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response:

All patients will be recruited from the glaucoma clinic of the Ross Eye Institute. Only patients that require tube shunt implantation based on the clinical course of their disease and the mutual decision of the surgeon and patient, and meet the inclusion and exclusion criteria will be offered to participate in this study.

7.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

The glaucoma clinic of the Ross Eye Institute is caring for large numbers of patients with severe glaucoma, the typical population that requires tube shunt implantation. Since the principle investigator's practice focuses on the care of patients with significant glaucoma, a large portion of the patients in this practice are expected to be good candidates for tube shunt implantation.

8.0 Inclusion and Exclusion Criteria*

*8.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Inclusion criteria:

1. Significant uncontrolled glaucoma despite medical, laser or previous surgical therapy that requires tube shunt implantation as standard-of-care to stabilize the glaucoma and preserve vision.

2. Pseudophakia

3. Patients who are willing to participate and are able to understand and sign the study consent form.

4. Age ≥18 years.

*8.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

1. Phakic eyes (no previous cataract surgery).

2. Age <18 years.

3. Women of child-bearing age.

4. Patients unable to comprehend and sign the study consent form.

5. Patients without or with well-controlled glaucoma.

6. Women who are pregnant.

8.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response: None of these vulnerable populations will be used for this study

☒ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☒ Pregnant women

☒ Prisoners

8.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

We would not include non-English speaking individuals for the following reasons:

The majority of the Principal Investigator's patients are English-speaking and we will be able to easily reach the targeted sample size in this population.

Understanding the study risks, outcomes and benefits is paramount and dependent on any candidate's linguistic skills. As this is an unfunded study, there are no resources available to hire a translation service to produce all of the necessary study documents in other languages, in the unlikely event that we encounter an eligible non-English speaker.

Additionally, the procedures used in this study are considered Standard of Care and are available to any non-English speaking patient as part of their regular treatment. Excluding non-English speakers will not inequitably withhold any benefit from them. These non-English speakers, as well as anyone else excluded for any reason, or is unwilling to participate in this study, will still receive the surgery they need as Standard of Care regardless of their participation in this study.

9.0 Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

*9.1 For research that involves **pregnant women,** safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

It is relatively rare to have patients at a child-bearing age needing glaucoma surgery in our practice due to age. As a safety measure, we plan to exclude any woman who can or might be pregnant any time throughout the study. Women will be asked when their last menstrual period was to determine if they are of child bearing potential. To that end, we find it insufficient to test a candidate for pregnancy before the study since pregnancy may occur any time during our study two-year follow-up.

☒ **N/A**: This research does not involve pregnant women.

*9.2 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*9.3 For research that involves **prisoners**, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

*9.4 For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*9.5 For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

9.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

This research will not target any vulnerable populations

10.0 Eligibility Screening*

10.1 Describe ***screening procedures*** *for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response:

As part of routine clinical care, the principal investigator will perform clinical examination on new and follow up patients presenting to the Ross Eye Institute glaucoma service during the study recruitment period.

After a detailed eye examination and comparison with previous visits results, if significant glaucoma is diagnosed or confirmed and is not properly controlled, and if the next most appropriate therapeutic step per standard-of-care is to proceed with tube shunt implantation with the goal of stabilizing the glaucoma and preventing further vision loss, the principal investigator will discuss the next treatment options with the patients.

Once a mutual (surgeon and patient) decision is made to proceed with tube shunt implantation, the surgeon (principal investigator) will evaluate the clinical patient data to determine if the patient meets the inclusion and exclusion criteria. If so, the principal investigator will explain the surgical procedure, clinical outcome and informed consent process to the patients in detail. The patients will then be given an opportunity to read the informed consent form and make their decision whether to participate in the study.

Patients who decline to participate in the study will still be treated in the exact same manner, including tube shunt implantation, as we follow routine clinical practice standard-of-care.

All patients regardless of study participation will be contacted by the surgical coordinator to schedule their surgery.

☐ **N/A:** There is no screening as part of this protocol.

11.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that

all records review procedures and inclusion/exclusion screening are adequately described in other sections.

11.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

Once a patient has been determined eligible to participate in this study, the principle investigator will approach the patient one-on-one in the glaucoma clinic at the Ross Eye Institute and explain the study. Participants will be given sufficient time to reply verbally to the one-on-one communication after being provided with the relevant study information and having any questions answered by the principal investigator. The consent process will follow once the participant affirmatively agrees to participate in the study

11.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response:

Every care will be taken to ensure that the recruitment procedures are conducted only in a private clinical workroom setting and only in the presence of the principal investigator, study coordinator and those authorized by the patient.

11.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

All subjects will be recruited during the usual course of their regularly scheduled standard-of-care appointments at Ross Eye Institute.

12.0 Procedures Involved*

*12.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

-The study will be explained to and discussed with eligible patients by the principal investigator

-Inform consents will be obtained once the patients inform the principal investigator of their interest to participate in the study.

- Pre and post-surgical follow up visits will be scheduled the same regardless of study participation. Visits will be scheduled for before, and day 1 after surgery, and continuously as needed over at least the following 24 months at the frequency determined by the glaucoma status and clinical course.

- Patients vision, IOP, visual field testing, fundus photos, OCT measurements and any post-surgical complications will be noted at scheduled visits.

- These measurements will be performed by trained ophthalmic assistants under the supervision of the principal Investigator. This is a standard-of-care process.

- Pre-operative and post-operative data will be collected from the patients EMR and will be used for data analysis.

- All the above mentioned steps are done as a part of standard-of-care, except:

a. the randomization process to decide if the patient receives the Baerveldt 350 shunt or the ClearPath 250 shunt. You will have a 1:1 chance of receiving either Baerveldt 350 or ClearPath 250. It will be similar to flipping a coin. Every other patient will received Baerveldt 350.

b. the final step where the research data is extracted from the patients' EMR and transferred into an Excel sheet at each follow up visit.

- The extracted data will be statistically analyzed to illustrate the results and findings of the study

- The data will be presented at conferences and publications with all the patient identifiers removed.

12.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

Patient EMR/ID, Gender, Date of Birth, Age at Baseline, Race, Medical Hx, conditions, Eye, Pre-Op Diagnosis, Glaucoma stage, Procedure and Procedure date.

Pre-Op Findings include: Intra Ocular Pressure (IOP), Max IOP, Visual Acuity (VA), number of Medications, Cup-Disc Ratio, Visual Field parameters, OCT global RNFL and GCC, Central Corneal Thickness, Axial Length, Anterior Chamber Depth, Refraction (Sph Eq).

Post-Op Findings include: IOP, VA, number of medications, measured at least on Day1, Week1, 2,3 and Months 1, 3, 6, 12, 18 and 24. Cup to disc ratio and visual fields parameters measured at least at month 6, 12, 18 and 24. OCT RNFL and GCC will be collected post-op at year 1, year 2.

Complications such as hypotony, corneal edema, hyphema, iritis, vit. hemorrhage and CME will be recorded. Additional information would include information about secondary procedures or surgery, and random notes.

The relevant research data from the patients EMR will be entered into a spreadsheet excluding private information and identifiers.

12.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response:

Snellen/LogMAR Visual Acuity chart, Slit Lamp, Applanation Tonometer, Gonioscope, Visual Field Analyzer and Spectralis OCT Device. These instruments are generally used on all patients during their routine clinical visits. A data collection form will be submitted on "Click" along with the protocol.

12.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response:

Electronic Medical Records, NexTech, HIPAA compliant used at the Ross Eye Institute, maintained by UBMD, will be used to collect the study data

*12.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response:

No, nothing beyond routine care will be collected and shared with the subject

*12.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response:

We plan to share aggregate study results in peer reviewed journal articles and meeting presentations

13.0 Study Timelines*

13.1 Describe the anticipated duration needed to enroll all study subjects.

Response:

2 years from the date of study approval.

13.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response:

Pre-op/surgery then postsurgical follow up visits on at least 1 day, week 1, 2 3, months1, 3 months, 6 months, 12 months, 18 months, and 24 months after surgery.

13.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response:

The cumulative study enrollment and post-surgical observation follow-up would last between 4-5 years

14.0 Setting

14.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response:

The research procedures will be conducted in a clinical work room setting within the 3 offices of University at Buffalo Department of Ophthalmology, Ross Eye Institute

1176 Main Street, Buffalo, NY 14209

3580 Sheridan Dr, 150 Amherst, NY 14226

301 Sterling Drive, Orchard Park, NY 14127

The surgery is performed as usual at an ASC in West Seneca, NY.

The work room setting has controlled access and includes a computer that has access to the EMR and that is secure and locked between each use. The patient data are stored on password-protected network computers as required by University at Buffalo. The data analysis will be carried out in private office of principal investigator or research coordinator or with a statistician.

14.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

There are no site specific regulations or customs and no scientific or ethical review requirements beyond what is required by the organization

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

15.0 Community-Based Participatory Research

15.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

15.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

16.0 Resources and Qualifications

*16.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

Primary Investigator: Asher Weiner, MD: A Board-certified Ophthalmologist with sub-specialty in glaucoma, working at UBMD Ross Eye Institute, who has been performing glaucoma procedures including tube shunt implantation routinely for many years, and is the only surgeon for this study.

Research Coordinator: Sharon Michalovic, CCRC (CITI/GCP certified and assist in patient recruitment, taking consent, data compiling)

Resident: Tyler Junttila, MD will assist with data management, overseeing visit schedules and taking patients' consent.

Statistician (for assistance in data analysis)

Describe other resources available to conduct the research.

16.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response:

5-6 hours per week: may be more or less weekly depending on the extent of extracting information from the EMR, finding the patients that meet the eligibility criteria, number of surgeries scheduled during each week, and transferring the data into spread sheet for data analysis

16.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response:

The study is being conducted at Ross Eye Institute and arrangements with the principal investigator have been made to provide treatment for any post-surgical event or complications. The principle investigator will provide all surgical and post-surgical care as performed routinely, and he and other Ophthalmologists on-call will be available 24/7, 365 days a year, to evaluate and treat all study subjects in case of an emergency

16.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:

All persons involved with the research will sit one-on-one with the primary investigator to discuss the background of the project, the IRB application, and the study protocol. There will also be built in time for questions, as well as freedom to ask questions at any time during their involvement in the project

The ophthalmic technicians are extensively trained by the principal investigator to measure visual acuity and visual field tests. The intraocular pressure, slit lamp findings and cup disc ratio will be measured either by the principal investigator or a resident physician under the supervision of the principal investigator

17.0 Other Approvals

17.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the

participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response:

Patients are informed during the consent process that they can voluntarily withdraw their participation from the research study without penalty or denial of any further care. Patients are reminded that they are free to refuse to answer any questions that they are not comfortable answering. Privacy is maintained all the time where the patient communicates with the principal investigator or research coordinator in a clinical work room setting that no one can over hear

18.2 Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response:

The screening occurs during a patient's regularly scheduled Standard-of-care (SOC) appointment and the principal investigator will evaluate the clinical patient data to determine if the patient meets the inclusion and exclusion criteria. Once the eligible patients have been identified and have indicated willingness to participate, the patients will provide their signed consent and HIPAA authorization for continued access to their EMR data for this study.

19.0 Data Management and Analysis*

19.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

Quantitative analysis of the data will be done using the built-in features of Microsoft™ Excel or other software tools including T-test, Linear Regression, Kaplan-Meier survival analysis and Chi-Squared test. Further statistical analysis would involve a statistician.

19.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response:

A power analysis was done and a sample size was determined by the Statistician at University at Buffalo. 70 subjects (70 eyes) will be recruited. The minimum "*n*" required based on the UB statistician's recommendation is 24 patients (more than one eye per patient may be included) in each of the two groups to a total of 48 patients, and we're adding a safety margin expecting that some patients will fail to

return for follow-up during the full length of the study due to illness, death, noncompliance, moving away, etc.

19.3 Describe any procedures that will be used for quality control of collected data.

Response:

Visual acuity will be measured in a sufficient room illumination that is normally used in every clinical routine eye examination

Measures are taken to make sure that the applanation tonometer instrument to measure intraocular pressure is calibrated once every two weeks

The visual field tests and the optic nerve imaging will be conducted by a trained Ophthalmic Assistant

20.0 Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*20.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response:

The clinical staff will enter the clinical findings into the patient EMR during routine eye examination. The relevant study data from the clinical findings will be transcribed into a spread sheet and stored in password protected electronic files on a password protected network computer. The Excel data will include patient MRN to refer back to patients EMR to enter the study data. The MRN and DOB, and dates of surgery are the identifiers and the data is accessible only to the principal investigator, research coordinator and study team members. However, all identifiers will be removed once all the data of all the patients is extracted. A separate code key is not maintained.

20.2 A. How long will the data be stored?

Response:

Most of the study data include information that is usually collected in a routine eye examination. The relevant study data will be extracted from the EMR and transcribed into a spread sheet for data analysis. The de-identified transcribed data and any study related electronic file will be stored for at-least 3 years after the study has ended or kept indefinitely if the PI desires, or deleted at the PI's discretion. Identifiers will be removed from this spreadsheet once all of the data is extracted from the EMR. The signed consent forms and IRB correspondence letters will be stored for 3 years after the study has been closed.

20.3 A. Who will have access to the data?

Response:

Principal Investigator, Study Coordinator and other authorized research personnel involved in the study. De-identified data will be given to statistician for data analysis

20.4 A. Who is responsible for receipt or transmission of the data?

Response:

Principal Investigator and Study Coordinator are responsible for authorization of transmission and for any communication of information

20.5 A. How will the data be transported?

Response:

The research data from the EMR will be transferred to electronic files by manually entering the required data points into a spread sheet. The electronic files will be accessible only to Principal Investigator, Study Coordinator and other research personnel involved in the study

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 21.0)*

20.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

20.7 B. How long will the specimens be stored?

Response:

20.8 B. Who will have access to the specimens?

Response:

20.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

20.10 B. How will the specimens be transported?

Response:

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

21.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response:

The intraocular pressure, visual acuity, cup-disc ratio, visual field testing, optic nerve imaging and medication list will be periodically evaluated for any changes. If the intraocular pressure seems elevated, or if any worsening in visual field testing or optic nerve imaging is detected, then the frequency of glaucoma medication will be changed to normalize the intraocular pressure.

21.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response:

The intraocular pressure, visual acuity, visual field testing, optic nerve imaging, medication frequency and any surgical related complications will be reviewed

21.3 Describe any safety endpoints.

Response:

Intra ocular pressure is attempted to be maintained to be less than 21mm Hg and is considered to be within normal limits. Any worsening of the glaucoma as determined by intraocular pressure elevation, reduced visual acuity, visual field testing, and optic nerve imaging will be monitored in follow-up visits

21.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

The information will be collected at patients follow up visits

21.5 Describe the frequency of safety data collection.

Response:

Post-surgical Day 1, Week 1, Month 1, Month 3, Month 6, Month 12, Month 18, and Month 24

21.6 Describe who will review the safety data.

Response:

Principal Investigator

21.7 Describe the frequency or periodicity of review of cumulative safety data.

Response:

Once every (at least) 6 months

21.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

Mean percentage change in intraocular pressure, changes to visual acuity, increase or decrease in the medication and other surgical related complications will be analyzed

21.9 Describe any conditions that trigger an immediate suspension of the research.

Response:

The research involves a post-surgical follow up observation and there is no trigger for immediate suspension of study

22.0 Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*22.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response:

If a participant is unavailable for follow up visits and do not respond to contact requests

22.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

There will be no need for termination procedures as the data involves post-surgical follow up observation as a part of routine clinical follow up after surgery

22.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

There will be no need for withdrawal procedures because record collected during routine eye examination can be used for continued evaluation of the treatment provided. The de-identified data up to the time of withdrawal will be retained and analyzed.

23.0 Risks to Subjects*

23.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response:

There is risk of intra and post-operative complications and discomfort as in any routine eye surgery in general, and in any routine tube implantation procedure in particular as part of a patient's standard of care. There is also risk of a breach of confidentiality of identifiable subject data. This risk is low as data will be stored on a network-connected, password protected computer. Also, the data is extracted from HIPPA compliant EMR records

Economic Risk: Since tube shunt implantation is a routine surgical procedure for glaucoma and not experimental you and your insurance company will be billed for the health care services that you would ordinarily be responsible to pay for. In some cases, insurance will not pay for services ordinarily covered because these services were performed in relation to a research study. You should always check with your insurance to verify which services will be covered by your insurance and which you will be responsible to pay for.

23.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response:

In case of post-operative complication immediate treatment will be provided by the investigator to resolve the complication. Also, the primary and secondary end points will be monitored as per the scheduled visits to notify any deviation from the normal measurements. Clinical finding data of the patient is stored on the UB EMR. Data will be collected and stored on a password- protected, network computers as required by UB.

Please see section 20.1 for procedures performed to mitigate the risk of breach of confidentiality.

*23.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

There are no procedures in this research study that may have risks to the subjects that are currently unforeseeable

23.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response:

There are no procedures in this research study that may have risks to an embryo or fetus should the subject be or become pregnant. However, some SOC

medications may have an effect and we would exclude young females from the study to avoid such an issue.

23.5 If applicable, describe risks to others who are not subjects.

Response:

There are no procedures in this research study that may have risks to others who are not subjects

24.0 Potential Benefits to Subjects*

24.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response:

There is no direct benefit to the participant by taking part in this study, which compares two available Standard of Care procedures. Possible benefits to patients are to identify which shunt is safer or more successful in lowering intraocular pressure.

25.0 Compensation for Research-Related Injury

☐ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*25.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

Research related injury is not anticipated and therefore there is no plan to compensate for study related injury

25.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

This is unfunded research and done as a part of clinical care and therefore there is no contract regarding compensation for research related injury

26.0 Economic Burden to Subjects

26.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response:

The patient's private or public health insurance company (for example Medicare) will be billed for the procedure and the patient will be responsible for any co-payment, co-insurance or deductible. The patient will not be charged for the cost of collecting the data for this study and other clinic visits and diagnostic tests done solely for the purposes of this study

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

27.0 Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response:

There is not compensation to subjects for participating in this study

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☒ **N/A:** There is no compensation for participation. This section does not apply.

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 29.0)*

28.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response:

The consent will be taken by the Principal Investigator, Study Coordinator or research team member in a private examination room at the Ross Eye Institute with the door closed to respect the patient's privacy

28.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response:

After providing subjects with information about the study and reviewing the consent documentation, patients will be given time to consider their participation, ask questions and sign the consent form before being enrolled in the study. If they would still like to review the consent documentation further they will be allowed to take the document home to review. Study staff will contact that individual within a week to answer any further questions and the subject will be provided study staff contact information if they decide to proceed at a later time.

28.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response:

The patients are informed that their participation is voluntary and that they are free to withdraw from the study at any time and it will not be held against them. If a participant withdraws from the study, there will be no need for any withdrawal procedures because record collected during routine eye examination and follow-up procedures will be used for continued evaluation of the treatment provided as a part of SOC. However, any data collected prior to withdrawal will be used for data analysis. Any future clinical notes after study withdrawal will not be used for data analysis

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 28.8)

28.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

28.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Non English speaking subjects will not be recruited

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

28.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

28.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

*28.10 **For research conducted outside of New York State**, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

This study will only take place in NY State

*28.11 Describe the process for **assent of the adults**:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. **If some, indicate which adults will be required to assent and which will not.***

Response:

None

- ***If assent will not be obtained from some or all subjects, provide an explanation of why not.***

Response:

It is not anticipated that the persons with cognitive impairment will be enrolled in this study

*28.12 Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

It is not anticipated that the persons with cognitive impairment will be enrolled in this study

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 29.0)*

*28.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

This study does not involve children under age 18, who will be screened out during eligibility assessment by means of DOB verification from the medical record.

*28.14**For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

This study will only take place in NY State

28.15 Describe whether parental permission will be obtained from:

Response:

This study does not involve children

☐ 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.

☐ 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.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*28.16 Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

This study does not involve children

*28.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

This study does not involve children

28.18 When assent of children is obtained, describe how it will be documented.

Response:

This study does not involve children

29.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

29.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

A waiver is not being requested

29.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

A waiver is not being requested

30.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

30.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

31.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*31.2 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

31.3 Describe the method for communicating to engaged participating sites.

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response:

*31.4 If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

31.5 If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national

advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

32.0 Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*32.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

32.2 List the data to be stored or associated with each specimen.

Response:

32.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: