

**Investigator Application – Instructions**

The principal investigator must submit a **complete application package** to apply for IRB review. A complete application package includes the completed and signed Investigator Application **and** the required attachments. **Your application cannot be reviewed until the IRB has received your complete application package.**

*Use the checklist below to ensure that your application package is complete.*

**Principal Investigator Name:** \_\_\_\_\_  
**Protocol Number:** \_\_\_\_\_

**Complete Application Checklist**

**Completed, Signed Investigator Application Form** Required.

**Attachments – use to collect the attachments that must accompany your Application Form**

- Copy(ies) CVs / other relevant certifications for PI and all research personnel.** Required for the principal investigator and all research personnel assisting with this research study.
- Copy of medical license for PI.** Required for the principal investigator.
- Copies of letters / reports about any FDA audit(s) during the past 5 years.** Required if you have been audited by the FDA in the last 5 years
- A copy of your signed FDA form 1572 or other Statement of Investigator.** Required if a FDA Form 1572 or other type of Statement of Investigator is required for this study. Contact the sponsor if you are uncertain.
- A copy of your signed Protocol Signature Page / Investigator Agreement.** Required. Contact the sponsor if you do not have this page or are uncertain about what it is.
- Proposed subject compensation (below).** Required only when you will compensate subjects for participation.
- Proposed consent language.** Required only when you are proposing consent language [new language or additional/alternative language to a template (**you must highlight or mark any changes**)].
- Proposed written subject material AND written pre-approval by the sponsor (if required).** Required only when you will use materials for subject recruitment or information. Contact the sponsor regarding their requirements for pre-approval.
- Documentation of deferral of jurisdiction to Goodwyn IRB (if you are under the jurisdiction of another IRB).** Required only when you, or any of your research personnel or research locations are under the jurisdiction of another IRB
- Copy of any correspondence from another IRB.** Required only if you have previously submitted an application to conduct this study to another IRB.
- Personnel Attachment Page.** Required only if needed to complete your list of research personnel.
- Location Attachment Page(s).** Required only if needed to complete your list of research locations.



**Your time is valuable. Make sure that you have collected all the required attachments before submitting.**

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**Investigator Application**

**Section I: Principal Investigator and Site Personnel**

Principal Investigator Name: \_\_\_\_\_ 1°Specialty: \_\_\_\_\_  
 Primary Research Facility: \_\_\_\_\_ 2°Specialty: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 Street Address (2): \_\_\_\_\_  
 City, State, Zip \_\_\_\_\_  
 Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_  
 Fax: \_\_\_\_\_  
 Emergency Phone: \_\_\_\_\_

◀ **You must provide 24-hour contact number(s) for questions or emergencies.**

Medical License Number: \_\_\_\_\_ ◀ **You must attach a copy of the PI's medical license.**  
 Expiration Date: \_\_\_\_\_  
 Driver's License Number: \_\_\_\_\_  
 Website: \_\_\_\_\_

**Contact for Communication with Goodwyn IRB**

Name: \_\_\_\_\_  
 Phone: \_\_\_\_\_  
 Fax: \_\_\_\_\_  
 E-mail: \_\_\_\_\_

**History**

1. Do you OR your research facility have less than one year of clinical research experience:  Yes  No  
 2. Have you ever had an IRB suspend or terminate its approval of your conduct of a study:  Yes  No  
 If yes, please explain: \_\_\_\_\_

3a. Have you ever had any subject seek compensation for injury as a result of participation in a study:  Yes  No  
 3b. Was there any problem resolving it:  Yes  No  
 If there was a problem resolving it, explain: \_\_\_\_\_

4a. Have any of the Investigators participating in research with you at this site ever been charged or sanctioned by any state Medical board, i.e., has a license to practice medicine ever been suspended, revoked or restricted in any state:  Yes  No

4b. Have any of these Investigator(s) ever had privileges at any hospital suspended, revoked or restricted:  Yes  No

4c. Have any of these Investigators withdrawn privileges during or in anticipation of an investigation:  Yes  No

4d. Are there any criminal charges or medical board complaints pending against any of these Investigators:  Yes  No

If you answered yes to any of the last 4 questions above, please explain: \_\_\_\_\_

**Resources for Communication and Management of Information Across Research Locations**

5a. Will the Principal Investigator (PI) conduct research at more than one location:  Yes  No

If yes, how often will the PI visit the additional locations:  Daily  
 Only on the days subjects are seen  
 Other

If yes, how often will the PI communicate with the Sub-Investigator(s) / study staff at the additional locations:  Daily  
 Only on the days subjects are seen  
 Other



If you checked "other" for either of the 2 questions immediately above, please explain the alternative schedule:

5b. Systems (standard practices / operating procedures / policies) relevant to the protection of subjects are in place for communication and management of information across the research locations and for reporting such information to the IRB:  Yes  No

**Audit History**

6. Have you been audited by the FDA in the past 5 years:  Yes  No

*If yes, you must attach copies of letters / reports about the audit(s) to your completed application.*

**Sub-Investigators / Research Coordinators / Key Personnel (List)**

7. List any individual who has responsibility for subject recruitment, consent process, direct data collection from research subjects, and/or clinical evaluation / examination / procedures and follow-up. **Please also include** any specialist(s) (e.g. radiologist, etc.) who will be involved in your research project(s). The complete list should include (but may not be limited to) all personnel listed on the 1572 (if applicable). Use the additional sheet attached if needed.

Name: \_\_\_\_\_  
Role: \_\_\_\_\_  
Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_  
Role: \_\_\_\_\_  
Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_  
Role: \_\_\_\_\_  
Responsibility(ies): \_\_\_\_\_

For additional staff, continue this information on the separate attachment page.

*For the PI and each individual named, you must attach copies of CVs and other relevant certifications.*

**Section II: Research Location(s) and Local Context**

**24-Hour Contact**

8. Is someone available on 24-hour call to answer subjects' questions or to provide information pertaining to the research study to Emergency Care providers:  Yes  No

**Non-English Speaking Subjects**

9a. Will you enroll non-English speaking subjects in research studies:  Yes  No

If yes, specify language(s): \_\_\_\_\_

9b. Will you have someone at your research location(s) who is capable of answering questions in their language and who is available to them during the study:  Yes  No

9c. Will a native speaking advocate or family member be available at the time of consent to answer any questions for the non-English speaking subjects:  Yes  No

**Pediatric Subjects**

10a. Will you enroll pediatric subjects in research studies:  Yes  No

10b. Do you have experience with pediatric subjects:  Yes  No

10c. What is your procedure to verify the age of consent (or other status) required under your state and local law to give consent for the treatments or procedures involved in a research study (e.g., check with legal counsel, check other reliable reference (describe the reference)): \_\_\_\_\_

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**Vulnerable Populations**

11. Will you enroll subjects at your research locations from any of these vulnerable groups (check all that apply):

(The measures outlined in the *Principal Investigator Responsibilities Handbook* must be employed for these populations.)

- Adults with diminished decision-making capability
- Children / Minors
- Economically disadvantaged
- Illiterate / Educationally disadvantaged
- Physically handicapped
- Pregnant women
- Prisoners
- Sponsors / site employees or their family members

**Legally Authorized Representatives**

A legally authorized representative (LAR) may be required to provide consent when an adult, non-minor does not have the legal capacity to consent to participate in the study. If you are uncertain of your state's requirements, check with legal counsel.

12. Do you allow a LAR to consent on behalf of an adult, non-minor subject who cannot consent for him/herself:  Yes  No

If yes, how do you identify who meets the criteria to be a LAR under your state/local law (e.g., check with legal counsel, check other reliable reference (describe the reference)):

If yes, specify your state's requirement(s) for how the LAR must demonstrate his/her authority to you, e.g., presentation of letter of guardianship, affidavit, familial relationship, etc.:

**Description of Location Where Research Will Be Conducted**

13. **You must provide information for all research location(s).** (Location(s) must match those listed on associated FDA Form 1572, if required.) For additional locations, continue this information on the separate attachment page.

**Location 1**

Facility Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City, State, Zip: \_\_\_\_\_

- Facility Description: (check one)
- Administrative (records only, no study procedures performed here)
  - Private / hospital / clinic office where study visits will be conducted
  - Research only office where study visits will be conducted
  - Testing center only (i.e., Radiology, Phlebotomy)
  - Residential Facility

Covered Entity (under HIPAA)  Yes  No Distance to a Hospital: \_\_\_\_\_  
911 Response time: \_\_\_\_\_ Name of the Hospital: \_\_\_\_\_

- Emergency Equipment: (check all that apply)
- CPR Certified Individual on Premises
  - Oxygen
  - Ambu Bag
  - Oral / Nasal Airways
  - Intubation Equipment
  - Defibrillator
  - IV Equipment
  - None
  - Other

- Emergency Medications: (check all that apply)
- Epinephrine
  - Diphenhydramine (Benadryl)
  - IM or IV Glucagon
  - Glucose (oral, fast-acting)
  - Glucose (IV - D50)
  - None
  - Other

If you checked "other" in your response above, please describe the additional equipment / medications: \_\_\_\_\_

**Section III: Study-Specific Information**

Sponsor: \_\_\_\_\_  
Protocol Number: \_\_\_\_\_

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14. Are the Principal Investigator / site locations / sub-investigators under the jurisdiction of another review board for this study:  Yes  No

**If yes, you must attach documentation of deferral of jurisdiction to Goodwyn IRB to your completed application.**

15. Have you submitted an application to conduct this protocol to any other IRB for review:  Yes  No

**If yes, you must attach a copy of the review correspondence from that IRB.**

16. Have you signed a FDA Form 1572 (or other Statement of Investigator) for this research protocol:  Yes  No

**If yes, you must attach a copy of your signed FDA form 1572 (or other Statement) to your completed application.**

17. Have you signed an "Investigator Study Protocol Agreement" ("Protocol Signature Page") for this research protocol:  Yes  No

**You must attach a copy of your signed Protocol Signature Page to your completed application.**

**Conflict of Interest**

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18. Does the Principal Investigator or any Sub-Investigator with assigned responsibilities in this study (or any member of their immediate family defined as spouse or dependent child) or the research site business entity have any of the significant interests listed below:  Yes  No If yes, check all that apply:

- A current or recent arrangement (within the last 2 years) to serve as a speaker for the sponsor.
- Board or executive relationship related to the research regardless of compensation.
- Compensation related to the research where the amount is affected by the outcome or the total is greater than \$10,000 when aggregated for the immediate family.
- Involvement in the design, conduct, or reporting of the research.
- Ownership interest, stock options, or other financial interest related to the research where the value is affected by the outcome or is greater than \$10,000 when aggregated for the immediate family.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

*Note: "Related to the research" means related to the sponsor, product or service being tested, or competitor of the sponsor.*

**State and Local Laws**

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**The IRB expects the investigator and study staff to know the state and local laws relative to this research study.**

19. Are there any state or local regulations/laws that have an impact on this research study (e.g., effective time period of consent; additional consent requirements for HIV/AIDs testing, special populations; etc.) at your site(s):  Yes  No

*(If uncertain, please contact your legal counsel.)*

If yes, please summarize: \_\_\_\_\_

20. Are there any strong demographic, religious or cultural attitudes in your community/research site that would impact the conduct of this study:  Yes  No

If yes, please describe: \_\_\_\_\_

**Recruitment Incentives**

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21. Are you aware of any bonus payments or other incentives, beyond the original contractual agreement, being offered by the sponsor for additional/accelerated subject recruitment:  Yes  No

If yes, please explain: \_\_\_\_\_

**Costs to Subjects**

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22a. Will the subjects be charged for the costs of the investigational product and/or associated treatment:  Yes  No

22b. Is there any conflict between any clinical trial Agreement (between the sponsor and the

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investigator/institution) and the IRB-approved consent template regarding the compensation for injury:  Yes  No

If yes to either of the above

2 questions, explain:

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### Subject Compensation

23. Will subjects be compensated for participation:  Yes  No

**If subjects will be compensated for participation in this study, you must complete the Compensation Worksheet at the end of this application.**

Compensation will occur:  At each study visit.  Monthly  
(Check one)  At or shortly after a subject's final visit.  Quarterly  
 Every two weeks.  Yearly

### Informed Consent Document

*When a consent template has been developed by the sponsor and IRB, your address(es), contact and compensation information will be transferred from your application forms to the template to create your site-specific informed consent document.*

24. Do you want to submit (add/change) language to the informed consent document:  Yes  No

**If yes, you must attach a proposed document to your completed application. If proposing additional/alternative language to a consent template, you must highlight or mark the changes. (If the additional/alternative language to be considered is not highlighted/marked, it will not be reviewed or approved).**

### Written Materials for Subjects

25. Are you submitting any recruitment or other written subject materials for this study at this time:  Yes  No

**If yes, you must attach these material(s) for subjects AND written confirmation of pre-approval from the sponsor (if required by the sponsor) to your completed application.**

### Terms of IRB Oversight

1. The information provided in this and other application(s)/ reports to Goodwyn IRB is complete and correct.
2. The Principal Investigator (PI) and his/her research staff are familiar with federal, state and local laws having impact on research, Good Clinical Practices, and must comply with all federal, state and local regulations regarding the conduct of research in addition to Goodwyn IRB's requirements as outlined here and in the "[Primary Investigator Responsibilities Handbook](#)".
3. The PI and any personnel under the PI's supervision will complete training in Good Clinical Practices /human subject protections before engaging in any research study procedures including the informed consent process. The PI must provide time for prospective subjects to read an informed consent document, and must ensure that all information within an informed consent document will also be orally explained to all prospective subjects before obtaining their signature. Prospective subjects must be given the opportunity to ask questions and have them answered, and be able to take the consent document home to consider with family / friends / personal physician. The PI must develop and use a process to determine whether the subject (or legally authorized representative) has an understanding of what was explained about the research during the informed consent process. The PI must ensure that all subjects provide (voluntary and fully informed) consent prior to participating in any research activities.
4. The PI must use measures to protect vulnerable populations, including any patient for which the PI is also the Primary Care Provider, as outlined in the "[Principal Investigator Responsibilities Handbook](#)."
5. The PI will delegate research responsibilities only to those individuals appropriately qualified and trained to perform those delegated responsibilities.
6. The PI will ensure that procedures required only for research (as opposed to treatment) purposes will not be performed prior to obtaining informed consent for the research study.
7. The PI will ensure that all research-related personal interactions will occur in a private setting, and that all information from subjects will be collected in such setting.
8. The PI will collect from subjects only information necessary for the research.
9. The PI authorizes release of IRB review documentation and correspondence to the sponsor and / or any designated agent of the sponsor, if requested.
10. The PI will maintain records of research according to federal and state regulations and guidelines.
11. Any study drug(s) / device(s) (including placebo, approved drugs or approved comparators) will be stored in a secure area with access limited to authorized research personnel.
12. Administrative, technical and physical safeguards must be in place to protect the privacy of protected health information. All study records must be physically / technologically secured with access limited to authorized research personnel (e.g.,

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- separated from subjects' medical records, locked area, firewall, strong passwords, etc.), and must be available for inspection by the IRB.
13. Approved research is subject to continuing review by the IRB. The PI will submit continuing review reports to Goodwyn IRB by the due date requested.
  14. If a location where research will be conducted includes a nursing home/care facility, school or any facility where the subject may be a resident or student, the PI must have a written agreement in place with an authorized representative of the facility to permit the conduct of research at the facility.
  15. Correspondence and notifications from Goodwyn IRB may be generated and signed in electronic form. You will receive hard copy (printouts) of such electronic documents and any such printout accurately reflects the electronic original. The PI will treat all such printouts in all ways as originals.
  16. The PI is accountable and accepts responsibility for the veracity and security of information submitted under his/her electronic signature. The password assigned to the PI is private and highly confidential, and no one else must use it. The PI must immediately report loss or compromise of his/her password to Goodwyn IRB.

▶ **The Principal Investigator will conduct research according to the terms presented above:**       Agreed  
 Not Agreed

**Protocol Commitments**

1. The Principal Investigator (PI) has sufficient time and an adequate number of qualified study personnel to properly and safely conduct and complete this research study within the period defined by the protocol and sponsor.
2. The PI will ensure that each member of the study staff will be adequately informed about this research study and its requirements before participating in study conduct.
3. The PI will not initiate this research study until s/he has received final written approval documentation from Goodwyn IRB.
4. The PI will seek and obtain prior written approval from Goodwyn IRB for any changes to this research study (except where necessary to eliminate immediate hazard to the subjects). This includes changes in procedures, study staff, payments to subjects and addition of research locations.
5. The PI and study staff are qualified to use equipment available, including any acquired, to address potential research risks.
6. The PI must report any unexpected and related adverse events involving the research subjects to Goodwyn IRB within 10 working days.
7. The PI must report any protocol deviations or exceptions that involve the consent process or subjects' safety, and any unanticipated problems to subjects or others identified during the course of this research to Goodwyn IRB within 10 working days.
8. The PI will comply with all other Goodwyn IRB requests to report, within 10 working days, on the status of this research study.
9. The PI must notify Goodwyn IRB immediately if a subject participating in this research study becomes incarcerated.
10. The PI will submit new recruitment material or changes to previously approved recruitment material to Goodwyn IRB prior to use. Audio visual ads should be submitted in final form after receiving IRB approval for the written script.
11. Any payments to subjects must be provided no later than the end of each subject's participation in the study. Goodwyn IRB does not allow payment to be withheld until all enrolled subjects complete their participation. Goodwyn IRB also does not allow payment to be withheld until the research site's receipt of payment from the sponsor/CRO. Payment to subjects who do not complete the study must be prorated based on the portion completed, e.g. number of completed study visits.
12. If the PI plans to utilize a "finder's fee" in recruitment efforts, the PI will notify Goodwyn IRB. If the PI/site plans to participate in any sponsor/CRO arranged incentive/bonus program for subject enrollment/retention, the PI will notify Goodwyn IRB.

▶ **I agree and confirm that I will comply with all of the above terms and commitments:**       Agreed  
 Not Agreed

**Signature of Principal Investigator**

\_\_\_\_\_ Date: \_\_\_\_\_

Printed name of Principal Investigator (including middle initial and highest earned degree)

\_\_\_\_\_



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**7. Investigator Application Attachment - Personnel**

**Sub-Investigators / Research Coordinators / Key Personnel (List Continued from Investigator Application)**

Principal Investigator Name: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

*Continue to list any individual who has responsibility for subject recruitment, consent process, direct data collection from research subjects, and/or clinical evaluation / examination / procedures and follow-up. **Please also include** any specialist(s) (e.g. radiologist, etc.) who will be involved in your research project(s). The complete list should include (but may not be limited to) all personnel listed on the 1572 (if applicable).*

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_

Responsibility(ies): \_\_\_\_\_

**For each individual named, you must attach copies of his/her CV / other relevant certifications.**

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**13. Investigator Application Attachment - Locations**

**Description of Locations Where Research Will Be Conducted (Continued from Investigator Application)**

Principal Investigator Name: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

**Location No.**

Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Facility Description: (check one)

<input type="checkbox"/> Administrative (records only, no study procedures performed here)	<input type="checkbox"/> Residential Facility
<input type="checkbox"/> Private / hospital / clinic office where study visits will be conducted	
<input type="checkbox"/> Research only office where study visits will be conducted	
<input type="checkbox"/> Testing center only (i.e., Radiology, Phlebotomy)	

Covered Entity (under HIPAA)  Yes  No      Distance to a Hospital: \_\_\_\_\_

911 Response time: \_\_\_\_\_      Name of the Hospital: \_\_\_\_\_

Emergency Equipment: (check all that apply)

<input type="checkbox"/> CPR Certified Individual on Premises	<input type="checkbox"/> Defibrillator
<input type="checkbox"/> Oxygen	<input type="checkbox"/> IV Equipment
<input type="checkbox"/> Ambu Bag	<input type="checkbox"/> None
<input type="checkbox"/> Oral / Nasal Airways	<input type="checkbox"/> Other
<input type="checkbox"/> Intubation Equipment	

Emergency Medications: (check all that apply)

<input type="checkbox"/> Epinephrine	<input type="checkbox"/> Glucose (oral, fast-acting)
<input type="checkbox"/> Diphenhydramine (Benedryl)	<input type="checkbox"/> Glucose (IV - D50)
<input type="checkbox"/> IM or IV Glucagon	<input type="checkbox"/> None
	<input type="checkbox"/> Other

If you checked "other" in your response above, please describe the additional equipment / medications: \_\_\_\_\_

**Location No.**

Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Facility Description: (check one)

<input type="checkbox"/> Administrative (records only, no study procedures performed here)	<input type="checkbox"/> Residential Facility
<input type="checkbox"/> Private / hospital / clinic office where study visits will be conducted	
<input type="checkbox"/> Research only office where study visits will be conducted	
<input type="checkbox"/> Testing center only (i.e., Radiology, Phlebotomy)	

Covered Entity (under HIPAA)  Yes  No      Distance to a Hospital: \_\_\_\_\_

911 Response time: \_\_\_\_\_      Name of the Hospital: \_\_\_\_\_

Emergency Equipment: (check all that apply)

<input type="checkbox"/> CPR Certified Individual on Premises	<input type="checkbox"/> Defibrillator
<input type="checkbox"/> Oxygen	<input type="checkbox"/> IV Equipment
<input type="checkbox"/> Ambu Bag	<input type="checkbox"/> None
<input type="checkbox"/> Oral / Nasal Airways	<input type="checkbox"/> Other
<input type="checkbox"/> Intubation Equipment	

Emergency Medications: (check all that apply)

<input type="checkbox"/> Epinephrine	<input type="checkbox"/> Glucose (oral, fast-acting)
<input type="checkbox"/> Diphenhydramine (Benedryl)	<input type="checkbox"/> Glucose (IV - D50)
<input type="checkbox"/> IM or IV Glucagon	<input type="checkbox"/> None
	<input type="checkbox"/> Other

If you checked "other" in your response above, please describe the additional equipment / medications: \_\_\_\_\_