Section 1 Site Selection Plan and Pre-Site Visit Monitoring Plan

Prior to selecting the sites and investigators that are to follow, we took a careful, rigorous selection process looking at several different aspects of the site: the investigator, supporting and collaborative staff, IRB, and site facility. Specific criteria for some aspect is listed below:

Investigator

- Ethical principles (vulnerable population)
- Participant safety (minors)
- Quality and timely data
- Qualified, trained, experienced
- Frequently encounters strep throat in children
- Accessible

IRB

- Appropriately constituted group
- Timely study decisions
- Operates in compliance to regulation

Site Facility

- Adequate patient population
- Sufficient enrollment period
- Satisfactory facility
- Knowledgeable and trained staff and coordinators
- Investigator site performance

Section 2 Table of Contents

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)

(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See PRA Statement on page 3.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor
National Institute of Allergy and Infectious Disease

2. Date of Submission *(mm/dd/yyyy)*
10/12/2014

3. Sponsor Address

Address 1 *(Street address, P.O. box, company name c/o)*
5601 Fishers Lane, MSC 9806

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City: Bethesda
State/Province/Region: MD
Country: United States
ZIP or Postal Code: 20892

4. Telephone Number *(Include country code if applicable and area code)*
301-496-5717

5. Name(s) of Drug *(Include all available names: Trade, Generic, Chemical, or Code)*
Bugs9993

Continuation Page for #5

6. IND Number *(If previously assigned)*

7. (Proposed) Indication for Use
Antibiotic study of Bugs9993 compared to Azithromycin for pediatric patients for confirmed strep throat

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☑ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☑ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

8. Phase(s) of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☑ Phase 3 ☐ Other *(Specify)*: _____

9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314) , Drug Master Files (21 CFR Part 314.420) , and Biologics License Applications (21 CFR Part 601) referred to in this application.
None

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..

Serial Number: 0000

11. This submission contains the following *(Select all that apply)*

☑ Initial Investigational New Drug Application (IND)
☐ Request For Reactivation Or Reinstatement
☐ Development Safety Update Report (DSUR)
☐ Response to Clinical Hold
☐ Annual Report
☐ Other *(Specify)*: _____
☐ Response To FDA Request For Information
☐ General Correspondence

Protocol Amendment(s)
☐ New Protocol
☐ Change in Protocol
☐ New Investigator
☐ PMR/PMC Protocol

Information Amendment(s)
☐ Chemistry/Microbiology
☐ Pharmacology/Toxicology
☐ Clinical ☐ Statistics
☐ Clinical Pharmacology

Request for
☐ Meeting
☐ Proprietary Name Review
☐ Special Protocol Assessment
☐ Formal Dispute Resolution

IND Safety Report(s)
☐ Initial Written Report
☐ Follow-up to a Written Report

12. Select the following only if applicable. *(Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)*

Expanded Access Use, 21 CFR 312.300

☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)
☐ Charge Request, 21 CFR 312.8
☐ Individual Patient, Non-Emergency 21 CFR 312.310
☐ Individual Patient, Emergency 21 CFR 312.310(d)
☐ Intermediate Size Patient Population, 21 CFR 312.315
☐ Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp	DDR Receipt Stamp	Division Assignment
		IND Number Assigned

PSC Publishing Services (301) 443-6740 EF

Previous Page | Next Page

13. Contents of Application – This application contains the following items *(Select all that apply)*

- [x] 1. Form FDA 1571 *(21 CFR 312.23(a)(1))*
- [x] 2. Table of Contents *(21 CFR 312.23(a)(2))*
- [x] 3. Introductory statement *(21 CFR 312.23(a)(3))*
- [x] 4. General Investigational plan *(21 CFR 312.23(a)(3))*
- [x] 5. Investigator's brochure *(21 CFR 312.23(a)(5))*
- [x] 6. Protocol(s) *(21 CFR 312.23(a)(6))*
  - [x] a. Study protocol(s) *(21 CFR 312.23(a)(6))*
  - [x] b. Investigator data *(21 CFR 312.23(a)(6)(iii)(b))* or completed Form(s) FDA 1572
  - [x] c. Facilities data *(21 CFR 312.23(a)(6)(iii)(b))* or completed Form(s) FDA 1572
- 6. Protocol(s) *(Continued)*
  - [x] d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form(s) FDA 1572
- [x] 7. Chemistry, manufacturing, and control data *(21 CFR 312.23(a)(7))*
  - [x] Environmental assessment or claim for exclusion *(21 CFR 312.23(a)(7)(iv)(e))*
- [x] 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
- [x] 9. Previous human experience *(21 CFR 312.23(a)(9))*
- [x] 10. Additional information *(21 CFR 312.23(a)(10))*
- [ ] 11. Biosimilar User Fee Cover Sheet *(Form FDA 3792)*
- [x] 12. Clinical Trials Certification of Compliance *(Form FDA 3674)*

14. Is any part of the clinical study to be conducted by a contract research organization? [ ] Yes [x] No

If Yes, will any sponsor obligations be transferred to the contract research organization? [ ] Yes [ ] No

If Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred *(use continuation page)*.

Continuation Page for #14

15. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

Kevin G. Ricks, Clinical Research Associate

16. Name(s) and Title(s) of the person(s) responsible for review and evaluation of information relevant to the safety of the drug

Dr. Gregory House, MD, Infectious Disease Researcher

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

17. Name of Sponsor or Sponsor's Authorized Representative

Dr Michael Alan Polis

18. Telephone Number *(Include country code if applicable and area code)*

301-496-8027

19. Facsimile (FAX) Number *(Include country code if applicable and area code)*

301-435-6739

20. Address

Address 1 *(Street address, P.O. box, company name c/o)*

5601 Fishers Ln

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

BG 5601FL RM 4D40

City: Rockville

State/Province/Region: MD

Country: United States

ZIP or Postal Code: 20852

21. Email Address

Not Listed

22. Date of Sponsor's Signature *(mm/dd/yyyy)*

10/13/2014

23. Name of Countersigner

24. Address of Countersigner

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City

State/Province/Region

Country: United States of America

ZIP or Postal Code

WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).

25. Signature of Sponsor or Sponsor's Authorized Representative

Michael Alan Polis, MD, PhD

Digitally signed by Michael Alan Polis, MD, PhD
DN: cn=Michael Alan Polis, MD, PhD, o=National Institute of Allergy and Infectious Disease, ou=Collaborative Clinical Research Branch, email=kricks12@gmail.com, c=US
Date: 2014.10.13 14:53:58 -04'00'

Sign

26. Signature of Countersigner

Sign

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Dr. Henry Walton Jones			
Address 1		Address 2	
1981 Indiana Rd.			
City	State/Province/Region	Country	ZIP or Postal Code
Boston	MA	United States	02115

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — **CONTINUATION PAGE for Item 3**

Name of Medical School, Hospital, or Other Research Facility			
Boston Children's Hospital			
Address 1		Address 2	
300 Longwood Ave.			
City	State/Province/Region	Country	ZIP or Postal Code
Boston	MA	United States	02115

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — **CONTINUATION PAGE for Item 4**

Name of Clinical Laboratory Facility			
Laboratory of the Lost Arc			
Address 1		Address 2	
310 Longwood Ave.			
City	State/Province/Region	Country	ZIP or Postal Code
Boston	MA	United States	02115

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — **CONTINUATION PAGE for Item 5**

Name of IRB			
Temple of Doom			
Address 1		Address 2	
320 Longwood Ave.			
City	State/Province/Region	Country	ZIP or Postal Code
Boston	MA	United States	02115

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

None

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

None

PSC Publishing Services (301) 443-6740 EF

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☒ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
10/12/2014	Sign Henry Walton Jone, PhD Digitally signed by Henry Walton Jone, PhD DN: cn=Henry Walton Jone, PhD, o, ou, email=kricks12@gmail.com, c=US Date: 2014.10.13 09:32:40 -04'00'

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Dr. Emmett Brown			
Address 1		Address 2	
1640 Riverside Drive			
City	State/Province/Region	Country	ZIP or Postal Code
Hill Valley	OH	United States	45229

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — **CONTINUATION PAGE for Item 3**

Name of Medical School, Hospital, or Other Research Facility			
Cincinnati Childen's Hospital			
Address 1		Address 2	
3333 Burnet Avenue			
City	State/Province/Region	Country	ZIP or Postal Code
Cincinnati	OH	United States	45229

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — **CONTINUATION PAGE for Item 4**

Name of Clinical Laboratory Facility			
Flux Capacitor Centers			
Address 1		Address 2	
3636 Burnet Avenue			
City	State/Province/Region	Country	ZIP or Postal Code
Cincinnati	OH	United States	45229

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — **CONTINUATION PAGE for Item 5**

Name of IRB			
Twin Pine Labs			
Address 1		Address 2	
6363 Burnet Avenue			
City	State/Province/Region	Country	ZIP or Postal Code
Cincinnati	OH	United States	45229

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

None

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

None

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8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

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9. COMMITMENTS

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I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
10/12/2014	Sign Emmett Brown, PhD Digitally signed by Emmett Brown, PhD DN: cn=Emmett Brown, PhD, o, ou, email=kricks12@gmail.com, c=US Date: 2014.10.13 09:08:51 -04'00'

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

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1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator
Dr. Leonard McCoy

Address 1		Address 2	
505 Bones Cirlce			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Philadelphia	PA	United States	19104

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — **CONTINUATION PAGE for Item 3**

Name of Medical School, Hospital, or Other Research Facility
The Children's Hospital of Philadelphia

Address 1		Address 2	
3401 Civic Center Boulevard			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Philadelphia	PA	United States	19104

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — **CONTINUATION PAGE for Item 4**

Name of Clinical Laboratory Facility
Enterprise Laboratories of the United Federation of Planets

Address 1		Address 2	
1950 Starfleet Rd.			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Philadelphia	PA	United States	19104

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — **CONTINUATION PAGE for Item 5**

Name of IRB
Klingon Empire

Address 1		Address 2	
3423 Vulcan Pl.			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Philadelphia	PA	United States	19104

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

None

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

None

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8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

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I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

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STATEMENT OF INVESTIGATOR

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10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
10/12/2014	Sign Leonard McCoy, MD Digitally signed by Leonard McCoy, MD DN: cn=Leonard McCoy, MD, o, ou, email=krick12@gmail.com, c=US Date: 2014.10.13 09:08:30 -04'00'

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Dr. Heathcliff Huxtable			
Address 1		Address 2	
10 Stigwood Avenue			
City	State/Province/Region	Country	ZIP or Postal Code
Chicago	IL	United States	60611

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — **CONTINUATION PAGE for Item 3**

Name of Medical School, Hospital, or Other Research Facility			
Ann and Robert H. Lurie Children's Hospital of Chicago			
Address 1		Address 2	
225 E Chicago Ave			
City	State/Province/Region	Country	ZIP or Postal Code
Chicago	IL	United States	60611

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — **CONTINUATION PAGE for Item 4**

Name of Clinical Laboratory Facility			
Cosby Clinical Laboratory			
Address 1		Address 2	
300 E Chicago Ave			
City	State/Province/Region	Country	ZIP or Postal Code
Chicago	IL	United States	60611

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — **CONTINUATION PAGE for Item 5**

Name of IRB			
Fat Albert and the Cosby Kids			
Address 1		Address 2	
400 E Chicago Ave			
City	State/Province/Region	Country	ZIP or Postal Code
Chicago	IL	United States	60611

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

None

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

None

PSC Publishing Services (301) 443-6740 EF

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☒ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
10/12/2014	Sign HeathCliff Huxtable, MD Digitally signed by HeathCliff Huxtable, MD DN: cn=HeathCliff Huxtable, MD, o, ou, email=kricks12@gmail.com, c=US Date: 2014.10.13 09:07:36 -04'00'

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

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1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Dr. Hunter Adams			
Address 1		Address 2	
982 Patches Rd.			
City	State/Province/Region	Country	ZIP or Postal Code
Baltimore	MD	United States	21287

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

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Name of Medical School, Hospital, or Other Research Facility			
Johns Hopkins Children's Center			
Address 1		Address 2	
1800 Orleans Street			
City	State/Province/Region	Country	ZIP or Postal Code
Baltimore	MD	United States	21287

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — **CONTINUATION PAGE for Item 4**

Name of Clinical Laboratory Facility			
Gesundheit! Institute			
Address 1		Address 2	
1900 Orleans Street			
City	State/Province/Region	Country	ZIP or Postal Code
Baltimore	MD	United States	21287

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — **CONTINUATION PAGE for Item 5**

Name of IRB			
Humanitarian Clowning			
Address 1		Address 2	
2000 Orleans Street			
City	State/Province/Region	Country	ZIP or Postal Code
Baltimore	MD	United States	21287

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

None

CONTINUATION PAGE – for Item 6

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PSC Publishing Services (301) 443-6740 EF

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10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
10/12/2014	Sign Hunter Adams, MD Digitally signed by Hunter Adams, MD DN: cn=Hunter Adams, MD, o, ou, email=kricks12@gmail.com, c=US Date: 2014.10.13 09:08:09 -04'00'

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Appended Documents to FDA Form 1572

All investigators must submit the following documents along with their completed 1572 Form:

1. CV or other statement of qualification

2. Study protocol or detailed description to be used (required for all phase 2 and 3 clinical trials)

The investigator should also include:

1. Documented IRB/EC approval

2. Verification of training on study protocol

3. Finalized contractual arrangement (in some cases)

IRB approval and consent form

On 01January2014, Temple of Doom Institutional Review Board has approved this study pending IND approval.

On 01April2014, Twin Pine Labs Institutional Review Board has approved this study after IND approval.

On 01June2014, Klingon Empire Institutional Review Board has approved this study after IND approval.

On 01August2014, Fat Albert and the Cosby Kids Institutional Review Board has approved this study after IND approval.

On 01October2014, Humanitarian Clowning Institutional Review Board has approved this study after IND approval.

Regulatory Oversight Plan

Throughout the study, we will utilize both on-site monitoring and centralized monitoring. This will increase study accountability, validity, and compliance with FDA regulation. Furthermore, extensive oversight ensures patient safety, which being children classifies them as a potential vulnerable population.

Each site will be subject to an on-site monitoring audit by sponsor representative once a month for the first 3 months of the study. This will ensure that the sponsor and investigator are interpreting and implementing the study protocol correctly. Following the initial three months, on-site audits will be conducted every three to six months. In between the on-site audits, centralized monitoring will be utilized each month an on-site audit isn't conducted. As the society grows further into a paperless world of documentation, centralized monitoring can be

conducted anytime and anywhere and is the most efficient, least time consuming method of oversight.

During all monitoring activities, sponsor representatives should review data for significant deviations, obtain an update on staff training and competency, and perform quality assurance tasks to confirm study validity. The results of these audits allow the sponsor and the investigator to respond immediately to protocol deviations or audit findings. During on-site monitoring audits, the sponsor representative has an opportunity to check facility cleanliness and patient care, as well as personal interaction with the investigator and staff.

Per CFR, serious adverse reactions (SAEs) should be reported immediately to the sponsor and IRB. However, there will be incidences were SAEs go unreported for a few days or maybe even a week. A simple, weekly call to study sites as a quality check may decrease the risk and length of unreported SAEs.

Prepared by:

Kevin G. Ricks
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Columbus, OH 43229
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kricks12@gmail.com