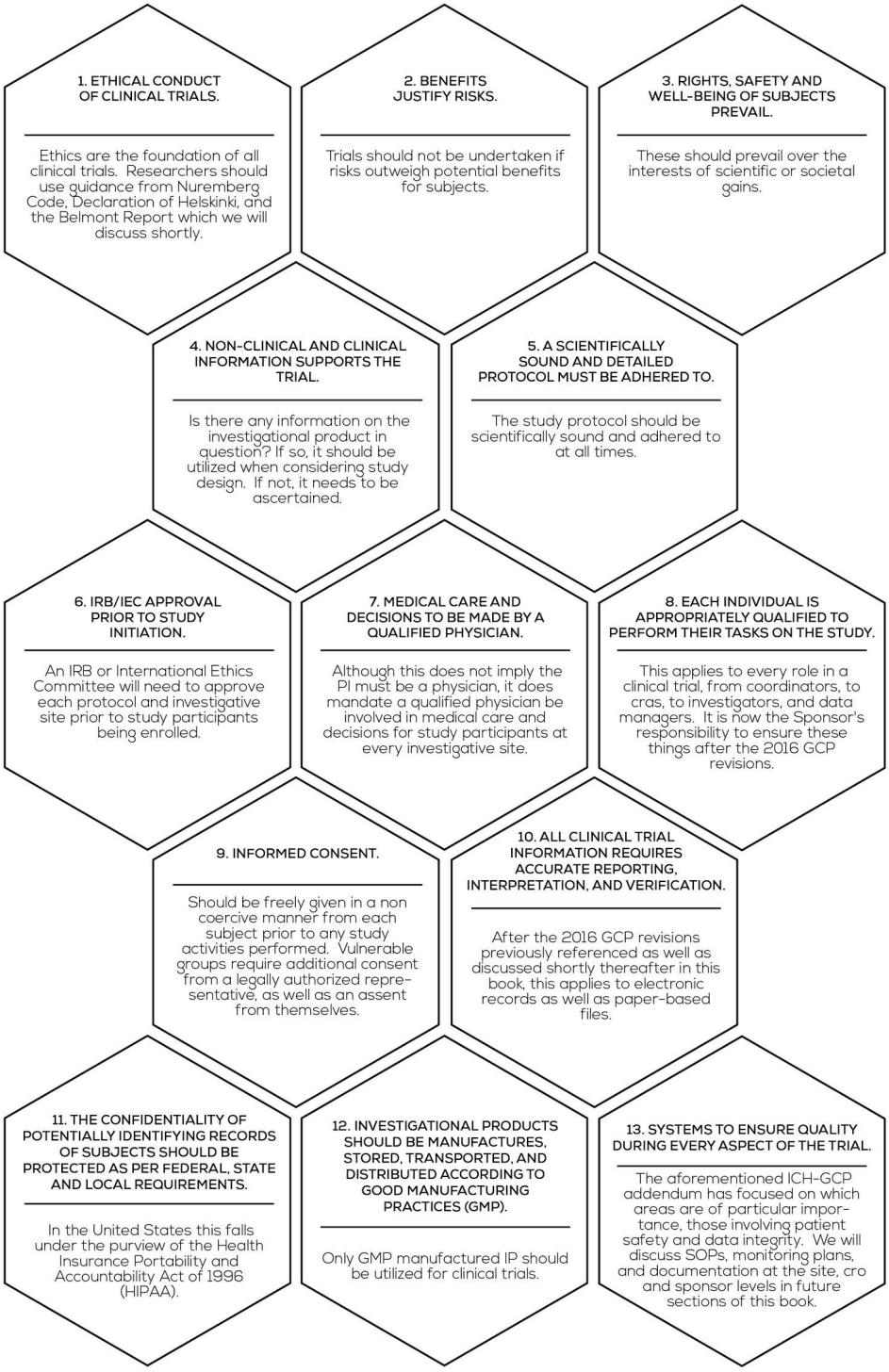
THIRTEEN BASIC PRINCIPLES OF ICH-GCP



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: February 28, 2019
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 Clinical Investigator			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

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			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "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

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 Sign

(**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 Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: March 31, 2019

TO BE COMPLETED BY APPLICANT

The following information concerning _____ , who participated
Name of clinical investigator

as a clinical investigator in the submitted study _____
Name of

_____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
FIRM/ORGANIZATION	
SIGNATURE	Date *(mm/dd/yyyy)*


Basic Equipment Needed To Open A Clinical Research Site:
Steel Cabinet
Blood draw chair
Conference table chairs
Waiting room chairs
ECG
Centrifuge
Thermo-meter for stored items
Exam table
ECG Cart
Stethos-cope
BP Cuff manual
Scale
Conference table
-20c Freezer
Printer/ Copier/ Fax
Phone system
Thermometer for humans
Writing / Library Table for exam room
Locking Refrigerator
Toner

AEs collected from time ICF signed through last study visit and must be followed until resolved or stabilized.

AE number	Event diagnosis (name)	Intermittent?	Onset date / time (if known)	Resolution date / time (if known)	Severity[1]	Serious?	Expected?	Attribution[2]	If not attributable to study drug, alternate etiology	Action taken[3]	Outcome[4]	PI/Sub-I Initials	Date of Initials
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						
						Yes No	Yes No						

	Acute Treatment Phase											Non-Remitter Combination Treatment								Extension for Remitters & Combo Responders					
	Scr	BI	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 8	Wk 10	Wk 12	Wk 13	Wk 14	Wk 15	Wk 16	Wk 17	Wk 18	Wk 20	Wk 22	Wk 24	Mo 9	Mo 12	Mo 15	Mo 18	Mo 21	Mo 24
Informed Consent	X										X														
Demographics	X																								
SCID	X																								
Med Hist. & PE	X																								
Screening labs	X																								
DNA	X																								
Inflammatory markers & mRNA		X		X Med	X CBT						X		X Med	X CBT					X						
CTQ/EHEI	X																								
PABS		X																							
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
HDRS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MADRS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
HARS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BDI		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
QIDS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CGI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Q-LES-Q		X				X			X		X	X			X			X		X	X	X	X	X	X
SDS		X				X			X		X	X			X			X		X	X	X	X	X	X
DHUS		X				X			X		X				X			X		X	X	X	X	X	X
LIFE											X									X	X	X	X	X	X
LES		X									X									X	X	X	X	X	X
Hope Scale		X									X									X	X	X	X	X	X
SWAP-200		X																							
IPDE		X																						X	
MRI		X		X Med	X CBT						X														
Dex/CRH test		X									X														

Training Log

Investigator Name:	Protocol:	Site Number:

Printed Name	Signature	Title of Training	Date of Training

Check if final page of log: ☐

Delegation of Authority Log

STUDY NAME

Site Number:____

The purpose of this form is to: a) serve as the Delegation of Authority Log and b) ensure that the individuals performing study-related tasks/procedures are appropriately trained and authorized by the investigator to perform the tasks/procedures. This form should be completed prior to the initiation of any study-related tasks/procedures. The original form should be maintained at your site in the study regulatory/study binder. This form should be updated during the course of the study as needed.

Please Print	Obtain Informed Consent	Source Document Completion	Case Report Form (CRF) Completion	Assess Inclusion and Exclusion Criteria	Physical Examination	Medical History	Medication History / Concomitant Medication	Collect Vital Signs	Review Vital Signs and Labs for Clinical Significance	Laboratory Specimen Collection/Shipping	AE Inquiry and Reporting	AE/SAE interpretation (severity/relationship to IP)	Administration of Investigational Product (IP)	IP Accountability	Regulatory Document Maintenance	Administrative	
NAME:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:		DATES OF STUDY INVOLVEMENT:
NAME:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:		DATES OF STUDY INVOLVEMENT:
NAME:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:		DATES OF STUDY INVOLVEMENT:
NAME:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:		DATES OF STUDY INVOLVEMENT:
NAME:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:		DATES OF STUDY INVOLVEMENT:

I certify that the above individuals are appropriately trained, have read the Protocol and pertinent sections of 21CFR 50 and 56 and ICH GCPs, and are authorized to perform the above study-related tasks/procedures. Although I have delegated significant trial-related duties, as the principal investigator, I still maintain full responsibility for this trial.

Investigator Signature: ______________________________________ **Date:** __________________________________

Did this participant have any protocol deviations? Yes No

Description of protocol deviation	Date deviation occurred)	Meets IRB notification criteria?	If yes, date IRB notified	PI Initials*	Date of Initials
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			
		Yes No			

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

SITE CONTACT INFORMATION	
Principal Investigator Name:	**Visit performed by/Title:**
Principal Investigator/Institution Address: Tel: Fax: Email:	**Study Coordinator Address (if different from Investigator):** Tel: Fax: Email:
Laboratory Address (if different from above): Tel: Fax: Email:	**Pharmacy Address (if different from above):** Tel: Fax: Email:
Other address (i.e. satellite site): Tel: Fax: Email:	**Other address (i.e. satellite site):** Tel: Fax: Email:

INVESTIGATOR AND STAFF				
Site personnel in Attendance				
Name	**Role/Responsibilities**	**Present at Visit?**		
		Yes	**No**	**Telephone Contact**

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

***General Instructions**: Provide a brief explanation in the comment field for all shaded boxes that are marked with an 'X' and for all required follow-up actions. Indicate item number.*

REVIEW OF STUDY DOCUMENTS	Yes	No	N/A
1. Was the protocol synopsis reviewed?			
a. Study objective and design			
b. Visit schedule and procedures			
c. Inclusion and Exclusion criteria			
d. Enrollment/randomization process			
e. Investigational product administration procedures			
2. Was the Investigator's Brochure reviewed?			
3. Was the Informed Consent process discussed?			
4. Was the process for data capture in the case report form reviewed?			
5. Does the PI or staff have previous experience in using electronic data capture (EDC)?			
6. Was the process for capture and storage of source documents reviewed?			
7. Does the site use Electronic Medical Records (EMR)?			
a. If yes, does the monitor have access to the EMRs?			
b. If yes, is training required prior to use of the EMR system?			
8. Was the process of retaining and archiving study records reviewed?			
9. Are translations required?			

COMMENTS: *The following are the minimum comments that should be inserted.*
Q1.

- *Does the PI show protocol understanding*
- *Did the PI accept the investigator responsibilities?*
- *Does the PI have any concerns with completing the study?*

Q3. Describe process
Q5. Describe previous EDC experience
Q6. Describe process
Q8. Describe process

- *Who is responsible for archiving of records?*
- *Once archived, what is the turnaround time for retrieving documents?*

PATIENT RECRUITMENT	Yes	No	N/A
10. Were the estimated study start and completion dates reviewed?			
11. Does the PI have the potential to recruit the required number of suitable patients within the agreed timelines?			
12. Does the site have recruitment strategies planned for the study?			
13. Is there potential conflict with other studies?			
14. Will the site require any advertising to assist in patient recruitment?			

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

PATIENT RECRUITMENT	Yes	No	N/A
COMMENTS: *The following are the minimum comments that should be inserted.* *Q12.* • *Total number of patients in practice?* • *Number of patients in practice with indication under study?* • *Number of patients expected to be enrolled in the study in a given timeline (indicate Stage)?* • *Describe standard of care used for indication under study?* • *What if any inclusion/exclusion criteria will most impact ability to enroll patients?* • *What if any study procedures will most impact your ability to enroll patients?* *Q14.* • *If DSCS or sponsor will deploy a social media campaign (Facebook, websites, etc). How can social media assist with advertisement?* • *Has site any experience with* o *Advertising: ☐ Yes, ☐ No, If "YES" rate experience and type:* o *Local Physician referrals: ☐ Yes, ☐ No, If "YES" rate experience:* o *Educational Physician dinners: ☐ Yes, ☐ No, If "YES" rate experience:* o *Patient advocacy groups: ☐ Yes, ☐ No, If "YES" rate experience:* o *Education patient dinners/sessions: ☐ Yes, ☐ No, If "YES" rate experience:* o *posters/patient educational material:* o *Other (specify):*			

PRINCIPAL INVESTIGATOR AND STAFF	Yes	No	N/A
15. Have obligations of the PI, stated in the Form 1572, as well as obligations of the staff been discussed?			
16. Has the PI provided adequate evidence of his qualifications (CV and current medical license)?			
17. Does the PI have previous experience in clinical trials, GCPs and the appropriate therapeutic area of indication?			
18. Does the PI have sufficient time to conduct the study?			
19. Does staff have sufficient time to conduct the study?			
20. Has the PI identified a clinical study coordinator (CRC)?			
21. Will the PI require any additional personnel to conduct the trial?			
22. Are any members of the staff IATA certified?			
23. Do all applicable staff have documented GCP and human research protection?			

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

PRINCIPAL INVESTIGATOR AND STAFF	Yes	No	N/A
COMMENTS: *The following are the minimum comments that should be inserted.* *Q18.* • *If yes, how many years of experience does the PI have?* • *If yes, how many trials (total and in therapeutic area indicated) have they worked on?* • *If yes, how many other trials does the PI work on?* *Q20.* • *If yes, how many years of experience does the CRC have?* • *If yes, how many trials (total and in therapeutic area indicated) have they worked on?* • *If yes, how many other trials does the CRC work on?* *Q21.* • *List staff who is IATA certified.*			

FACILITIES	Yes	No	N/A
24. Are the facilities adequate to perform the procedures detailed in the protcol?			
25. Is the storage for source documents, case report forms and administrative files adequate and secure?			
26. Is the storage for any devices adequate and secure?			
27. Does the PI anticipate using satellite site(s)?			
28. Does the site have equipment that adequately meets the requirements of the protocol?			
29. Does the site require any additional equipment?			
30. Is the site using a central laboratory?			
31. Has a local laboratory been identified and found to be suitable?			
32. Have onsite laboratory requirements and procedures been discussed with the appropriate staff?			
33. Does the site have emergency equipment on site?			
34. How far is the nearest hospital from the site?			
35. Is the monitoring space adequate?			
36. Does the site provide necessary tools to monitors, e.g. internet access and copy machine access?			

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

FACILITIES	Yes	No	N/A
COMMENTS: *The following are the minimum comments that should be inserted.* *Q24.* • *How many exam rooms are on site?* • *Is there a separate room for the consenting process?* *Q25* • *Who has access to this area?* *Q28* • *If yes, does the site have maintenance records or logs for required equipment?* • *Are inspection stickers present and current on required equipment?* *Q31* • *If yes, provide details including contact names(s) in comments section.* • *If yes, please list and describe equipment used for processing, including maintenance schedule, expiration dates, responsible personel, etc.* • *If yes, does the laboratory have a back-up generator?* *Q33* • *If yes, please list and describe emergency equipment, including maintenance schedule, expiration dates, responsible personel, etc.*			

PHARMACY AND INVESTIGATIONAL PRODUCT STORAGE	Yes	No	N/A
37. Is there a locked storage area with limited access for investigational product?			
38. Does the site have an adequate refrigerator and/or freezer? *Please comment below*			
39. Is there routine temperature monitoring of the refrigerator and/or freezer?			
40. Does the site have the refrigerator and/or freezer's calibrated and inspected regularly?			
41. Is there an alarm system for power outages?			
42. Does the site have a back-up generator?			
43. Does the site have a system in place for dispensing and storing investigational product?			
COMMENTS: *The following are the minimum comments that should be inserted.* *Q37* • *Who has primary and secondary access to the locked storage area?* *Q38* • *Comment on the number of -20 and 2-4 degree –whatever is applicable to the study.* *Q39* • *If yes, is temperature monitored daily or 24/7 continuous basis?* *Q40* • *When was the most recent maintenance and calibration?* *Q41* • *Who is notified in the event of a brief outage, and also a long term outage, i.e. due to a hurricane?*			

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

INSITUUTIONAL REVIEW BOARD/ INSTUTIONAL ETHICS COMMITTEE	Yes	No	N/A
44. Will a central IRB be used?			
45. Will a local IRB be used?			
46. Have the identity and requirements of the IRB/IEC been requested?			
47. Has the adverse event reporting requirements for the IRB/IEC been identified?			
48. Has the date of the next IRB/IEC meeting and frequency of meetings been requested?			
49. Does the IRB utilize expedited review?			
50. Has a general assurance statement that IEC/IRB is organized and operates according to GCP been requested?			

COMMENTS: *The following are the minimum comments that should be inserted.*

Q44.

- *Identify the central IRB.*

Q45.

- *Can a waiver be used in order to utilize a central IRB?*
- *If yes, will the study go through additional sub-committees (e.g. radiation, biosafety, etc) for review and approval? If yes, will this review be in parallel to main IRB/IEC review?*

Q48

- *What are the dates/days and average turnaround time for local IRB and ethics review.*

REGULATORY	Yes	No	N/A
51. Have all necessary documents been collected?			
52. Has the site ever been audited by a regulatory agency (i.e. FDA, IRB)?			
53. Does the site have written SOPs?			
54. Does the site have a dedicated regulatory submissions person?			

COMMENTS: *The following are the minimum comments that should be inserted.*

Q52.

- *Curriculum vitae for PI, Sub-I's*

Q53

- *Please collect documentation of audit findings and response, if available.*

Q54

- *If yes, are they available for review?*

Q55

- *If no, who is responsible for regulatory submissions?*

MONITORING	Yes	No	N/A
55. Has the monitoring visit frequency been discussed?			
56. Has the direct access to, and the review of, source documents been discussed?			
57. Have the relevant source documents to be maintained been specified and discussed?			

COMMENTS:

SITE QUALIFICATION VISIT REPORT

Sponsor	Protocol No.	Investigational Product	Visit Date(s)

CLINICAL AGREEMENT/FINANCES	Yes	No	N/A
58. Has the confidentiality agreement been executed?			
59. Have the site's reimbursement and other financial implications for the study been discussed?			
60. Was the publication policy discussed?			
COMMENTS:			

OUTSTANDING FINDINGS/ ACTION ITEMS

Are there any action items from this visit? ☐ Yes (Please list below.) ☐No

Date Identified	Action Item and Plan for Resolution	Target Completion Date	Actual Completion Date	Assigned to

STUDY FORECASTS	
Total number of patients planned for this site.	
Projected patient accrual per month.	
Project IRB/IEC meeting date(s).	
Project IRB/IEC approval date	
Projected first patient screening date	

As per the Qualification Visit made to this Investigator/Site, and according to the discussions and findings described in the present report, my assessment is that this site should be considered:

☐ Qualified to perform this clinical trial

☐ Not qualified to perform this clinical trial

COMMENTS: *If not qualified is checked, discuss reason(s) why.*
Discuss any factors that may delay the start of the study for the site.
Any other issues for site should be recorded here.

Monitor's Name (Print):		
Monitor's Signature:		Date:
Approved by: Name/Title: (Print):		
Approved by Signature:		Date:

DSCS CRO
1830 Commercenter East
San Bernardino, CA 92408

[Date]

[Principal Investigator Name]
[Site Name]
[Street Address]
[City, State ZIP]

Re: [Protocol Title] Protocol No. [XXX]

Dear [PI Name]:

This letter is to confirm my visit to your site for the above-referenced study on [Day], [Date]. I will plan to arrive at your site at [HH:MM] and depart at [HH:MM]. During the last visit, the following items were outstanding*: (OR if no issues-skip this section)*

- [List visit objectives]

I will work together with [Name of study lead at site] in order to complete monitoring and outstanding issues for your site. At the conclusion of my visit, I would like to meet with you briefly to discuss any findings, answer any questions you may have, and provide you with an overall study status update.

If you have any questions, please feel free to contact me at [Phone Number] or, or via e-mail at [Email].

Kind regards,

[Name of Person Completing Letter]
[Title]
DSCS CRO
cc: CRC, Trial Master File

IATA
http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html

GCP
https://gcp.nidatraining.org/

NIH
https://phrptraining.com

CLIA Waiver
https://www.cdc.gov/hiv/testing/nonclinical/clia.html

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCertificateofWaiver.pdf