<table>
<thead>
<tr>
<th>Item</th>
<th>Authority and Administration for Studies Involving Human Drugs, Biologics and Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Compare the Investigator Agreement with the information provided by the assigning Center.</td>
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</table>
| 2.   | **Obtain** a list of all studies performed by the investigator. Include:  
Protocol Number  
Protocol title  
Name of sponsor  
Study dates |
| 3.   | **Document** the following in the EIR:  
   a. Address of all locations which study subjects were seen.  
   b. How the sponsor provided information to the investigator about the test article, protocol and obligations of the investigator.  
   c. Whether the authority for the conduct of the various aspects of the study was contracted and/or delegated properly so that the investigator retained control and knowledge of the study. Include a list of delegated tasks.  
   d. The following dates:  
      i. IRB approvals including initial review, all amendments, the IC documented and all revised IC documents.  
      ii. When was the Investigator Agreement signed by the clinical investigator  
      iii. When the first subject was screened.  
      iv. When the first subject signed the IC  
      v. First administration of test article  
      vi. Last follow-up for any study subject.  
   e. If investigator discontinued his/her participation in the study and **describe** the reason(s). |
<p>| 4.   | <strong>List</strong> the name and address of the |</p>
<table>
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<tr>
<th>Facility(ies) performing laboratory or diagnostic tests required by the protocol. <strong>Describe</strong> the investigator’s documentation of the laboratory or diagnostic testing facility’s qualifications (e.g. certification under CLIA)</th>
</tr>
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</table>

5. **Determine** the process used to recruit subjects. If recruitment materials or phone recruitment scripts were employed, **document** their review and approval by the IRB. **Document** instances in which the investigator utilized methods or distributed information that appeared to be coercive in nature, any promotion material representing the test article as safe and effective for the purpose which it is under investigation or implied favorable outcomes or other benefits beyond what is outlined in the IC and protocol.

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**PROTOCOL FOR HUMAN DRUG, BIOLOGIC OR DEVICE STUDY**

1. Compare the copy of the protocol provided with the assignment to the Investigator’s copy of the protocol and amendments

2. Did the investigator follow the protocol with respect to:
   a. Subject selection (inclusion/exclusion criteria) □ Yes □ No □ NA
   b. Number of subjects enrolled
   c. Randomization scheme (where applicable)
   d. Required procedures and evaluations (e.g. blinding procedures)
   e. Administration of the investigational product:
      i. For devices- used according IFU (where applicable)
     a. Identify the circumstances resulting in termination.

3. **Verify** that the investigator followed the protocol approved by the IRB. Review any changes to and deviations from the
**BIMO SITE AUDIT CHECKLIST**

[insert name] Clinical Trial

<table>
<thead>
<tr>
<th>Determine whether deviations to the protocol were:</th>
</tr>
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<tr>
<td>i. Documented, showing dates of and reason for each deviation.</td>
</tr>
<tr>
<td>ii. Documented, with prior approval from the sponsor for deviations if the investigational plan except if emergency use.</td>
</tr>
<tr>
<td>iii. Documented, with prior approval from the reviewing IRB and FA for deviations from the investigational plan that may affect the scientific soundness of the plan or the rights, safety or welfare of human subjects, except in an emergency.</td>
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</table>

**Collect** correspondence or other documentation that supports adverse inspectional observations.

### INSTITUTIONAL REVIEW BOARD FOR DRUG, BIOLOGIC OR DEVICE STUDY

1. **Identify** name, address and chairperson for the IRB for the study.

2. **Determine and describe** if the investigator obtained IRB approval of the items listed below before initiation of study-specific procedures on subjects:
   - a. The protocol and any amendments;
   - b. The informed consent documents; and
   - c. Advertisements and other information provided to study subjects.

3. **Describe** the nature and frequency of communication with the IRB. Determine whether the investigator submitted information promptly to the IRB, in compliance with the protocol and applicable regulations, of all deaths, SAEs, and unanticipated problems involving risk to human subjects.

4. If there is a question as to whether the correct consent document was used, obtain a copy of each version of the IC approved by the IRB.

5. **Collect** correspondence or other documentation that supports adverse inspectional observations.

### HUMAN SUBJECT'S RECORDS
1. Informed Consent

a. **Describe** the informed consent process. For the study being inspected, include the following information:

i. Who (SC, investigator, nurse, etc.) explained the study and consent document to prospective study subjects and was it provided in a language understandable to each subject?

ii. How did the IC process take place? (e.g. was this explanation given orally, by video, through a translator, etc)?

iii. Was consent obtained prior to enrollment in the study (prior to performance of any study related tests and administration of test article)?

iv. After signed and dating the IC, was each subject or the authorized representative given a copy of the IC?

v. Was the appropriate IRB-approved consent document used for all subjects?

vi. If the short form was used (21 CFR 50.27 (b)(2), was the IC process appropriately documented?

a. Did the subject or the subject’s representative sign the short form?  

b. Was a witness present, who signed the short form and the copy of the summary?

c. Did the person actually obtaining the consent sign a copy of the summary?

d. Is the case history documented to show whether a copy of the summary and short form were given to the subject or the subject’s representative?

vii. **Review** the IRB approval letter for the study. Did the IRB stipulate any conditions for the IC process and, if so, did the investigator follow those stipulations?

b. **Review** the IC documents signed by the subjects. If number is small (e.g. 25 or fewer) review 100% of the IC documents. **Determine** the following:
### i. Did the subject or the subject’s legal representative sign the IC document prior to entry into the study? If subject did not sign the IC, determine who signed it and that person’s relationship to the subject. Describe how the investigator determined that the person signing the IC was the subject’s legally authorized representative.

### ii. Determine whether subjects signed the version of the IC that was current at the time of entry into the study.

### iii. For pediatric studies, was assent obtained from the subjects in addition to the permission of the parents? ☐ NA

### iv. Determine whether the written consent document or oral consent complies with the 8 required elements in 21 CFR 50.25(a)

#### 2. Source Documents

**a. Describe** the investigator’s source documents in terms of their organization, condition, completeness and legibility.

**b. Determine** whether there is adequate documentation to ensure that all subjects were alive and available for the duration of their stated participation in the study.

**c. Determine** whether the records contain:

1. Observations, information and data on the condition of the subject at the time of entry into the clinical study, as required by the protocol;

2. Documentation of the subjects exposure to the test article as required by the protocol;

3. Observations an data on the condition of the subject throughout participation in the investigation, including results of lab tests, development of unrelated illness and other factors which might alter the effects of the test article;

4. Identification of key personnel involved in collecting and analyzing data at the site.
### 3. Case Report Forms

**a. Describe** the process for obtaining and recording information in CRFs.

- **i.** Who obtained and recorded the information;
- **ii.** The source of the information (e.g., were data transcribed from another document or were data recorded directly onto the CRF); and
- **iii.** Whether corrections were made to the CRF data entries. If corrections were made, **determine** who made them, the reason(s) for the changes, and whether the investigator was aware of these changes.

**b.** Compare the source documents with the CRFs and any background information provided (e.g. data tabulations provided by the sponsor) per the assignment memorandum and sampling plan (if applicable). **Determine** whether:

- **i.** The study subjects the eligibility requirements (inclusion/exclusion);
- **ii.** Protocol specified clinical laboratory testing (EKGs, x-rays, etc.) was documented by laboratory records;
- **iii.** All AEs were documented and appropriately reported;
- **iv.** The investigator assessed the severity of the AE and documented the relationship of the event to the test article including any AE that was previously anticipated and documented by written information from the sponsor; and
- **v.** All concomitant therapies and intercurrent illness were documented and reported.

**Determine** whether the investigator reported all dropouts and the reasons to the sponsor.

### OTHER STUDY RECORDS

Study-related information may also be recorded in other documents. **Determine** if the investigator maintains other records pertinent to the study, e.g., administrative study files, correspondence files, master subject list appointment books, sign-in logs, screening lists and MedWatch forms. Review these records to ensure that all pertinent information has been reported to sponsor. **Document** any discrepancies.

**a.** Obtain a list of all clinical studies
# BIMO SITE AUDIT CHECKLIST

[insert name] Clinical Trial

## FINANCIAL DISCLOSURE

1. Ask the investigator if and when he disclosed information about his financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children. (21 CFR 54.4(b))

2. Ask the clinical investigator if and when he updated the information about such financial interests, to report changes that occurred in the value of the financial interests during the course of the clinical investigation or within one year following completion of the study (21 CRF 54.4(b)).

## ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES

Refer to the guidance manual

**Test Article Control**

1. Accountability 812.140(a)(2)
   
   - **Determine** who is authorized to administer or dispense the test article.
   
   - **Determine** whether the test article was supplied to a person not authorized to receive it.
   
   - **Compare** the amount of test article shipped, received, used and returned or destroyed. **Verify** the following:
     
     - Receipt date(s), quantity received, and the condition upon receipt;
     
     - Date(s), subject number, and quantity dispensed; and
     
     - Date(s) and quantity returned to sponsor. **IF** not returned to sponsor, **describe** the disposition of the test article.
   
   - **Determine** where the test article is stored, whether it was stored under appropriate conditions as specified in the study protocol, and who had access to it.

   - **If** the test article is a controlled substance: □ NA

   - **Determine** how it is secured; and □ NA
## BIMO SITE AUDIT CHECKLIST

[insert name] Clinical Trial

### RECORDS CUSTODY AND RETENTION

**Determine** whether study records are retained according to the protocol and 21 CFR 812.140(d) and (e)

### REPORTS TO SPONSOR

Determine if required reports (including CRFs) are submitted to the sponsor in accordance with the study protocol and 21 CFR 812.150.

### MONITORING

1. **Determine** if the sponsor monitored the progress of the study to assure that the investigator compiled with the protocol and regulations.

2. Describe the monitoring activities.

   **Examples:**
   a. Pre-study contacts with the investigator (e.g. meetings, visits, correspondence);
   b. Frequency and nature of monitoring (e.g., on-site visits, telephone calls, fax, email);
   c. **Determine** if the study records include a log of on-site monitoring visits, written reports or other communication provided to the investigator. Obtain a copy of the log (if any) and examples of monitor reports and communications; and
   d. Follow-Up activities performed by the investigator when the monitor found deficiencies or recommended changes, for example, in the conduct of the study or records associated with the study.

3. **For sponsor-investigators, determine** if any monitoring was done for the study and, if so, **describe**.

   □ NA

Clinical Research Associate (print name)

Clinical Research Associate Signature: Date:

### SUMMARY OF FINDINGS: