

# Essential Documents (ED) Activity

## ESSENTIAL DOCUMENTS RUBRIC

### Protocol Signature Page

Protocol/amendment identifiers (protocol title or number, and version number and/or version date) are present	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Name, signature and date of signature of the PI are present	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

### FDA 1572 (For IND studies and can be client specific if non-IND)

Is the most updated version of the form (paper or electronic format) available at the time of signature	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
If a paper form is used, is acceptable printed as a single-sided or a double-sided document	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Any additional pages (of the form in paper format) are clearly identified (e.g., page 2 of 3, with name of investigator and section number(s))	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Is completed in English (names and addresses of institutions, departments and ethics committee may be written in local language)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
All sections are completed (“none” or “not applicable” entered where necessary)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Information is repeated in full each time it is requested (i.e., “ditto” or “see above” are not used)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 1:</b> Indicates full legal name and address where the investigator can be reached by mail or in person (must correspond to the CV - identical address match is not required)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 2:</b> Appropriate box is checked	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 3:</b> Indicates name and address of all facilities where study activities will be conducted (study data generation and collection, shipment of test article) - at least one of the addresses must be referenced in the PI CV	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 4:</b> Indicates the names and addresses of central and/or local laboratories	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 5:</b> Indicates the name and address of the ethics committee responsible for review and approval of the study and site	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 6:</b> Indicates the names of sub investigator(s) authorized by the PI to make key assessments and/or decisions on subject care; and includes names of other study personnel as requested by the Client Company	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## FDA 1572 continued

<b>Section 7:</b> Complete protocol name and protocol number, if any, is present	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Section 8:</b> Appropriate box is checked	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
<b>Sections 10 and 11:</b> Signature of PI is present (valid e-signatures are acceptable) and the date of PI signature is present (typed or handwritten)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## IRB/EC Approval

Clearly identifies the documents that were reviewed:			
Protocol and any amendments and revisions, including protocol number/title and version number and/or date	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
CRF, if applicable, and revisions	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
ICF (for each language used at a site) and revisions, including version number and/or date	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Other written information provided to subjects (for each language used at a site) and revisions	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Advertisement for subject recruitment and revisions	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Other documents (e.g., Investigator's Brochure, safety report) given review or review and approval/favourable opinion, and revisions	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
States the name of the investigator or site for which approval/initial opinion was given (unless documents that are submitted are not site-specific)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Date of approval is present (meeting date or letter date or signature date)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Clearly identifies the ethics committee that approved the documentation	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Is initialed or signed by the Chairperson/Designee (e-signature or a web portal printout is acceptable if approval documentation is issued in electronic format)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
If modifications/revisions are required prior to approval, documentation is present to indicate the conditions were met and final approval is granted	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
If documentation does not contain all details of approved documents, the following documentation is present to provide clarification: <input type="checkbox"/> Documented clarification provided by the ethics committee or, <input type="checkbox"/> A fully-detailed submission letter is referenced in the approval documentation from the ethics committee	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## Ethics Committee List of Members

Indicates ethics committee is organized as required by GCP principles, and applicable national/local regulations	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Allows identification of the non-scientific/independent member (e.g., occupation/affiliation of members are included)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
If a member of the investigator site staff is a member of the ethics committee, there is documentation to confirm that this member did not vote on the proposed study (if not specifically addressed in the membership list, compliance statement, approval documentation or other specific correspondence with the ethics committee)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
If names of members are not included, sufficient information is provided to allow identification of proper constitution	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## Curriculum Vitae (Principal Investigator)

Investigator name is present (at least the first and last name) and is spelled correctly	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the present position/current employment with work address or indicates an affiliation with a location (i.e. Institution name) where the study will be conducted	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the registration number/medical license number required to practice medicine in that country, if required (if the number is not indicated on a separate document such as a copy of a medical license)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows relevant education, training, and experience to conduct the trial (e.g., medical degree, professional qualification, clinical trial experience)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Information is current (i.e., dates of publication, positions are within 2 years before site activation, or CV is signed and dated within 2 years before site activation)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
For IND studies or at the request of the Client Company, CV is in English	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## Screening and Enrollment Log

Investigator name is present (at least the first and last name) and is spelled correctly	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the present position/current employment with work address or indicates an affiliation with a location (i.e. Institution name) where the study will be conducted	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the registration number/medical license number required to practice medicine in that country, if required (if the number is not indicated on a separate document such as a copy of a medical license)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## Site Monitoring Report

Investigator name is present (at least the first and last name) and is spelled correctly	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the present position/current employment with work address or indicates an affiliation with a location (i.e. Institution name) where the study will be conducted	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the registration number/medical license number required to practice medicine in that country, if required (if the number is not indicated on a separate document such as a copy of a medical license)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>

## Final Study Accountability Log

Investigator name is present (at least the first and last name) and is spelled correctly	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the present position/current employment with work address or indicates an affiliation with a location (i.e. Institution name) where the study will be conducted	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>
Shows the registration number/medical license number required to practice medicine in that country, if required (if the number is not indicated on a separate document such as a copy of a medical license)	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>