Form 20.1 Notice of Site Visit to Members of the Site Visit Team



<dd/mm/yyyy>

**<NAME OF ERC MEMBER>**

EVHRDC Member

**Re: <STUDY PROTOCOL TITLE> <EVHRDC ERC CODE>**

Dear **<TITLE OF VISITING TEAM MEMBER> <SURNAME>**:

We wish to inform you that the EVHRDC-ERC has appointed you to be a member of the Site Visit Team responsible for verifying compliance of the study site with EVHRDC-ERC approved protocol and related documents, such as, contents of the informed consent form, etc.This site visit is being organized because of: \_\_\_\_\_\_\_\_. As part of the team, your responsibilities include the following:

1. Review the study protocol and the ICF (note: make sure that the site is using the most recent version)
2. Review the submitted Form 9.1 Progress Report (note: make sure that the site is using the most recent version)
3. Ask the PI or staff to explain the informed consent process
4. Ensure security, privacy, and confidentiality of the documents at the study site
5. Discuss the findings with the research team
6. Solicit feedback from the study site

The details of the Site Visit are as follows:

| **Study Site** |  |
| --- | --- |
| **Address** |  |
| **Date** | <dd/mm/yyyy> |
| **Time** | <hh:mm> |

To facilitate the intended site visit, please signify your confirmation by signing in the space provided below, date your signature, and return one copy of this letter to the EVHRDC-ERC Staff Secretary.

Thank you and best regards.

Very truly yours,

Name and Signature



Chair, EVHRDC-ERC

Name and Signature



CONFORME of ERC Member

DATE SIGNED: <dd/mm/yyyy>