

Form 442 Question 6: Description of Research Project

A description of the nature of the research project being conducted.

In this research project we want to perform a pilot study to analyze and compare the data captured by the Byteflies NV sensor dots with a clinical standard measurement device. This in order to validate that the solution has medical value. This project is carried out together with the “University Hospitals Cleveland Medical Center”.

A summary of the procedure is given below:

CF Patients of the UHCMC’s CF center will be asked to enroll when they come in for a routine clinic or study visit. They will be assigned randomly to GROUP 1 (no MIC) or GROUP 2 (w/ MIC). After the informed consent procedure, the participant will be given instructions on how to affix the wearable device. Next, they will continue with the normal visit protocol as indicated. No changes will be made to any of the standard protocols. At the end of the visit, the participant will be asked to remove the device and fill out a brief user experience survey. The research nurse will download the data from the wearable device and attach pertinent summary results from clinical tests to the REDCap entry.

A showing that the communications facilities requested are necessary for the research project involved.

The Sensor Dot needs to be configured while it is attached to the patient. Since it is required to be small to be comfortable for the patient it was not possible to add a local user interface to the Sensor Dot. Therefore, a wireless interface has been added that allows configuration via the 2.4GHz band. This is paired with a computer that allows updating the configuration and validating the captured vital signals.

A showing that existing communications facilities are inadequate.

Existing infrastructure that can communicate with and configure the Sensor Dot is not available at this location and thus needs to be deployed.