**9.3 LEGAL, ETHICAL AND PROFESSIONAL ISSUES**

**9.3.1 LEGAL**

In order to create machine learning models for the analysis, data is of utmost importance. It was required to get voice recordings from patients who are diagnosed with Parkinson’s disease and also healthy patients and some patients who have vocal issues similar to Parkinson’s but are not diagnosed with Parkinson’s. Since, there are no public datasets available in Sri Lanka that gives speech recordings of the Parkinson’s patients, data collection had to be done manually. **National Hospital of Sri Lanka**, in Colombo, was chosen, as it has the highest number of Parkinson’s patients admitted in Sri Lanka.

Initiating the data collection part was not a straightforward task as it required many legal and ethical permissions from the Hospital, as it is a Government-controlled institution, and also the safety of the patient is of utmost importance. Therefore, to initiate the data collection process, an official letter from the Informatics Institute of Technology was requested from our team, which states the nature of the project and the guarantee that the data obtained would not be misused and would be sorely used in order to build the project. Around the end of November 2019, our team visited the Ministry of Health in order to obtain permission in order to conduct tests in the National Hospital of Sri Lanka, and an official letter was provided to us, validating our project. Then, our team contacted the Deputy Director General of the National Hospital of Sri Lanka with the letter from IIT, the permission provided by the Ministry of Health, and an early draft of our project proposal.

The Deputy Director General forwarded our request along with the project proposal to Dr. Pradeep De Silva, a reputed physician at the NHSL, in order to validate the proposal. Dr Pradeep proposed some changes to the proposal that would make the project effective, and then around the starting week of December, the proposal was corrected and was submitted to Dr. Pradeep, who validated the proposal. Our team also acquired the services from Ms. Aberame Thevapalan, a medical student at the Faculty of Medicine, University of Colombo, in order to help us in the problem domain, and her help was useful in getting approval from Dr. Pradeep. Then the validated proposal was forwarded to the Deputy Director General, who informed that he would submit the proposal to the committee board meeting. The approval was delayed because of the Christmas and the New Year holidays.

In the early week of January, our proposal got approved by the committee board, and we were forwarded to visit the Neurological Department of the National Hospital of Sri Lanka in order to collect the data. Dr. Sunethra Senanayake, one of the administrative heads of the Neurological Department and the specialist in the neuro-related diseases, was contacted and as she was intrigued about our project, she guaranteed that she would extend her full support to the project. She directed us to the doctors related to the Parkinson’s disease channeling and also informed us the dates in which we can meet the patients: that is on each Thursdays, Parkinson’s patients would visit the hospital and on the second Thursday of each month, there would be a special clinic for the Parkinson’s patients. From February to the mid of March, our team regularly visited the Neurological Department on Thursdays, from morning to noon, and collected the speech data from the patients, and our process of collecting data was halted by the spread of COVID-19.

**All the documents and the permissions that was obtained/submitted can be viewed at the Appendix section of the document.**

**9.3.2 ETHICAL ISSUES**

A research project like our one poses a lots of ethical issues, that needs to be solved before collecting data from the patients. We assured the Deputy Director General of National Hospital of Sri Lanka, and Dr. Sunethra, one of the heads of the Neurological Department, that we would adhere strict rules when collecting data (i.e. the voice recordings) of the patients and also the data obtained would not be used publicly for financial gain.

Before recording the voices of the patients, consent forms were created in order to assure the patient that he or she would not be put through physical or emotional stress and only if the patient willingly participates in the session that we would be collecting the data. Consent forms were prepared in all three main languages of Sri Lanka (Sinhala, Tamil and English), therefore it ensures that the patient would get a clear understanding of why the test is being performed and would be able to clearly understand the measures that are being taken to protect the data. Only the patient’s name, age, the severity rating of Parkinson’s and the recordings were obtained from each patient, and sensitive information was not obtained.

The recordings were stored securely in the local storage of the computer and was only used in order to extract the acoustic features using Praat and was stored in the csv file.

Implementing the web application faced ethical issues that needed to be resolved. Since the main user is the doctor, the details of the doctors need to be stored, so the user can log in, perform analysis, and so on. Therefore, in order to store the data securely, such as email and password, Firebase was used and also Google Sign In was implemented, which minimizes privacy issues. And, when the user inserts the recording of the patient, as soon as the acoustic features are extracted, the audio file would be removed, ensuring that the audio obtained from the patients would not be used for purposes other than the research.

**All the consent forms and other necessary documents are attached in the appendix.**

**9.3 PROFESSIONAL ISSUES**

One of the main concerns the doctors had was whether our project would replace the role of doctors in detecting Parkinson’s Disease. But our project is far from that, it is just a useful tool that would inform the user whether the patient has a chance of being diagnosed with Parkinson’s, and the user (in this case, a doctor), would use this as just one of the analysis value and conduct other measures (scans, physical test) that would ensure the patient is diagnosed with Parkinson’s. Therefore, our product does not explicitly state that the patient is 100% diagnosed with Parkinson’s but provides information that the patient might have Parkinson’s or not, based on the results that are being obtained and recommends the user to perform additional tests.