# Project Protocol

## HANDETECT Project

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# List of Abbreviations

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| MD | Movement Disorders |
| PD | Parkinson’s Disease |
| HD | Huntington’s Disease |
| AI | Artificial Intelligence |
| ML | Machine Learning |

# Research Synopsis

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| Study Title | An AI-based Algorithm to Analyze Handwriting Patterns for Early Detection of Movement Disorder Diseases |
| Study Population | The project population consists of individuals diagnosed with various movement disorders. Both male and female participants are eligible for inclusion in the study. The age range of the participants may vary, covering individuals from different age groups. The health status of the participants will reflect their specific neurological condition. Participants may come from diverse backgrounds and may have different levels of experience with handwriting tasks. |
| Study Design | A prospective cross-sectional study. Patients diagnosed with various movement disorders will be recruited. Handwriting samples and demographic information will be collected through a standardized assessment. The samples will be analyzed using AI-powered handwriting analysis to identify potential early markers of movement disorders. |
| General Objective | To utilize advanced AI-powered handwriting analysis as a non-invasive and objective tool to identify early markers of movement disorders in patients with various neurological conditions. |
| Specific Objectives | ● Develop an algorithm to analyze handwriting to detect movement disorder diseases<br>● Enable continuous monitoring of movement disorders through regular handwriting assessments to provide valuable insights into disease progression and treatment efficacy |

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| Study Endpoints/Outcome | ● Diagnostic Accuracy: Determining the sensitivity and specificity of the AI-powered handwriting analysis in correctly identifying movement disorders compared to traditional diagnostic methods.<br>● Early Detection Rate: Measuring the percentage of participants who are identified with movement disorders at an early stage using the handwriting analysis approach |
| Sample Size | 260 |
| Study Duration | 39 weeks |

# Table of Contents

# 1.0 Background of Project

## 1.1 Introduction

Movement disorders are a range of neurological illnesses that disrupt normal motor and muscular function, resulting in either excessive or reduced movement. Examples of movement disorders include Parkinson's disease, Huntington's disease, Cerebral Palsy, and Wilson's disease. These conditions are characterized by alterations in brain function, affecting areas responsible for balance, coordination, and muscle control. Individuals afflicted by movement disorders often experience symptoms such as tremors, muscle spasms, speech difficulties, and other challenges that significantly impact their daily lives.

Movement disorder diseases are growing concerns on a global scale. For example, Parkinson's disease, one of the most common movement disorders, presently affects approximately 6.2 million individuals worldwide. Predictive models estimate a staggering increase to 12.9 to 14.2 million cases by the year 2040 [7]. Similarly, research suggests that Huntington's disease affects approximately 2.71 individuals per 100,000 people globally [8]. Cerebral Palsy is reported to be around 2-3 cases per 1,000 live births [9].

Fortunately, with early detection, appropriate treatment, and expert care, individuals with movement disorders can lead fulfilling lives [14]. Timely identification of these conditions is crucial for initiating interventions that alleviate symptoms, slow disease progression, and improve overall quality of life. However, early detection remains a significant challenge due to the complexity and diversity of movement disorder symptoms.

To address this gap, our project aims to harness the power of machine learning in the early detection of movement disorders. By utilizing advanced AI models, we intend to analyze handwriting patterns as a potential diagnostic tool. Handwriting analysis offers a non-invasive, easily accessible means of assessing motor function, as the act of writing engages various motor and cognitive processes. Through this innovative approach, we aim to develop a reliable, objective, and user-friendly system that can assist in the early detection, continuous monitoring, and personalized management of movement disorder diseases.

By empowering healthcare professionals with an efficient tool for early identification, our project seeks to improve patient outcomes, enable proactive interventions, and ultimately enhance the lives of individuals living with movement disorders.

## 1.2 Problem Statement

Accurate and timely diagnosis of movement disorder diseases is crucial to achieving a high rate of recovery through early treatment. However, the current clinical diagnostic accuracy of neurologists is limited. Studies indicate that up to 20% of movement disorder cases may be misdiagnosed or late-diagnosed [10]. This can lead to delayed or incorrect treatment plans, negatively impacting the patient's life quality.

The late detection of movement disorder diseases before the first clinical diagnosis has also been associated with increased mortality rates. Delayed identification of movement disorders prevents individuals from receiving timely treatment, which could potentially reduce symptoms and slow disease progression.

It is noteworthy that early detection of movement disorder diseases, such as Parkinson's disease (PD), is vital for applying rapid treatment. However, approximately 37% of PD patients miss the optimal window for early detection and monitoring [13]. This delay in detection not only extends the suffering of individuals but also affects the effectiveness of treatment strategies.

Besides, current detection of movement disorders using handwriting patterns is mostly through the eye of neurologists, which causes misdiagnosis and leads the patient to late treatment and reduces the possibility of recovery from the movement disorders.

By developing an intelligent handwriting analysis approach, we aim to leverage the unique characteristics of handwriting as effective diagnostic criteria. This approach has the potential to provide an objective and quantifiable method for early detection and continuous monitoring of movement disorder diseases.

By addressing the aforementioned challenges and improving early detection rates, our project seeks to enhance patient outcomes, facilitate timely interventions, and ultimately improve the overall prognosis for individuals with movement disorders.

# 2.0 Objectives

- Develop an algorithm to analyze handwriting to detect movement disorder diseases
- Enable continuous monitoring of movement disorders through regular handwriting assessments to provide valuable insights into disease progression and treatment efficacy

The primary objectives of this research project are to develop an innovative algorithm capable of analyzing handwriting patterns with high accuracy, aiming to detect various movement disorder diseases at their early stages. By harnessing the power of machine learning and artificial intelligence, the algorithm will be trained on a diverse dataset of handwriting samples collected from individuals with confirmed movement disorders. This approach seeks to identify specific patterns or markers within the handwriting that may indicate the presence of a movement disorder, enabling swift and reliable diagnosis.

Furthermore, this project seeks to establish a method for continuous monitoring of movement disorders through regular handwriting assessments. By implementing a longitudinal approach, participants will be encouraged to undergo periodic handwriting assessments over time, allowing researchers to track disease progression and evaluate the efficacy of various treatment interventions. This continuous monitoring aspect is crucial for gaining valuable insights into the dynamic nature of movement disorders and understanding how they evolve over the course of the disease.

By achieving these objectives, our research aims to revolutionize the early detection and monitoring of movement disorder diseases, empowering healthcare professionals with a non-invasive and efficient tool for improving patient outcomes. Ultimately, the development of an accurate and user-friendly handwriting analysis system has the potential to significantly impact the lives of individuals living with movement disorders, fostering proactive interventions and enhancing their overall quality of life.

# 3.0 Methodology

## 3.1 Study Type and Design

This research project adopts an observational study design, specifically a cross-sectional study, which includes a survey component. The study aims to analyze handwriting patterns to detect movement disorder diseases. The choice of this design is based on the proposed objectives, which involve assessing handwriting samples from participants to identify potential markers for movement disorders.

The study endpoints will focus on the accuracy of the algorithm in detecting movement disorders through handwriting analysis. The primary endpoint will be the algorithm's sensitivity and specificity in correctly identifying individuals with movement disorders based on their handwriting patterns. Secondary endpoints will include measures of disease progression and treatment efficacy, such as changes in handwriting patterns over time and the correlation between handwriting analysis results and clinical assessments.

The study will have two study groups, a healthy control group comprising individuals without movement disorders and a treatment group comprising individuals with confirmed movement disorder diagnoses.

The study will collect handwriting samples as biospecimens at regular intervals during the treatment period. These samples will be stored securely and processed for analysis. The collected specimens will not be used for genetic studies, and their use for future studies will be limited to this specific research project.

Questionnaires will be used as instruments during the study to gather supplementary data about participants' demographics, disease severity, and other relevant information.

## 3.2 Study Population

The target population for this study comprises individuals diagnosed with movement disorders. Our target movement disorders are:

- Parkinson's Disease (PD)
- Essential Tremor (ET)
- Huntington's Disease (HD)
- Dystonia
- Tourette Syndrome (TS)
- Cerebral Palsy (CP)
- Ataxia
- Wilson's Disease
- Multiple System Atrophy (MSA)
- Progressive Supranuclear Palsy (PSP)
- Amyotrophic Lateral Sclerosis (ALS)
- Spinal Muscular Atrophy (SMA)

Participants will be recruited from hospitals, patient organizations and disease study groups from all over the world.

- **Hospitals**: Collaborate with neurologists, movement disorder specialists and other relevant healthcare providers who treat patients with specific movement disorders.

- **Patient Organizations**: Reach out to patient organizations dedicated to supporting individuals with the movement disorder being studied. Inform them about the research project and request their assistance in disseminating information about the study to their members who may be eligible and interested in participating.

- **Disease Study Groups**: Contact the research coordinators or relevant departments of the specific disease study group and request their assistance in recruiting eligible participants.

## 3.3 Inclusion Criteria

To be eligible for participation, individuals must meet the following criteria:

- Confirmed diagnosis of our target movement disorders.
- Willingness to provide informed consent for participation.
- Ability to understand the assessment requirements.

## 3.4 Exclusion Criteria

Individuals meeting any of the following criteria will be excluded from the study:

- Presence of severe cognitive impairment that may hinder understanding the study requirements.
- Inability to provide informed consent.
- Total inability to perform handwriting tasks due to physical limitations or any other factors.

## 3.5 Withdrawal Criteria

Participants may choose to withdraw from the study at any point, and their decision to do so will be respected without any negative consequences. The withdrawal criteria for this project are as follows:

- **Participant Consent**
  If a participant decides to withdraw their consent for participation, they can inform the research team and their data will be excluded from the analysis.

- **Incomplete Data**
  If a participant does not provide complete or sufficient data for analysis, the research team may consider their data incomplete, and they will have the option to withdraw their participation.

- **Personal Reasons**
  Participants may withdraw from the study due to personal reasons or unforeseen circumstances, and their decision will be honoured.

- **Health Concerns**

  If a participant experiences any adverse effects or discomfort during the handwriting assessment process, they have the right to withdraw from the study.

- **Study Termination**

  In the event that the research team determines it is necessary to terminate the study for any reason, participants will be notified, and their data will be treated with confidentiality and not used in any future analyses or studies or shared with any other third parties.

It is important to emphasize that withdrawal from the study will not affect the participants' rights or medical care in any way. Participants will not be penalized or face any consequences for choosing to withdraw, and they are free to participate in other research projects or seek alternative treatments if they wish. The research team is committed to maintaining the confidentiality of all participants' data, and withdrawal will not result in any breach of privacy or confidentiality.

## 3.6 Sample Size

For our study, we have 13 study groups, consisting of 12 disease groups and 1 healthy control group. To determine the sample size for each group, we consider the power of the study (80%), the level of significance (alpha = 0.05), the expected outcome difference between the interventions (16%), and the standard deviation (s.d.) of the data (8%).

The formula to calculate the sample size is as follows.

$$n = ((Z\_\alpha/2 + Z\_\beta)\text{^}2 * s.d.\text{^}2) / difference\text{^}2$$

Where:

- ***Z_α/2*** is the critical value of the standard normal distribution corresponding to the level of significance (alpha/2), approximately 1.96.

- ***Z_β*** is the critical value of the standard normal distribution corresponding to the power (1 - beta), approximately 0.84.
- ***s.d.*** is the estimated standard deviation of the data, approximately 0.08.
- ***difference*** is the expected outcome difference between the two interventions, approximately 0.16.

Using the values provided:

$$n = ((1.96 + 0.84)\text{^}2 * 0.08\text{^}2) / 0.16\text{^}2 \approx 19.67$$

Allowing for a 10% dropout rate, we will use a final sample size of approximately 20 participants per group.

Therefore, each study group will have a sample size of 20 participants to ensure sufficient statistical power and reliable results.

## 3.7 Study Duration and Timeline

The study duration and timeline for our project are as follows:

- Projected Start Date: 5th July 2023
- Projected End Date: 14th May 2024

**Stage 1 - Preparation and Protocol Development: July 2023 to August 2023**
During this stage, we will finalize the study protocol, develop the data collection tools, and obtain necessary approvals and ethical clearance.

**Stage 2 - Participant Recruitment and Data Collection: August 2023 to May 2024**
In this stage, we will actively recruit study participants from hospitals, patient organizations, and disease study groups. Data collection will involve conducting handwriting assessments and gathering supplementary information. Data collection will be conducted throughout our research to get more comprehensive data.

**Stage 3 - Data Analysis: October 2023 to December 2023**
After completing data collection, we will analyze the collected data using advanced algorithms and statistical methods to detect movement disorder diseases based on handwriting patterns.

**Stage 4 - Interpretation and Reporting: December 2023 to May 2024**
The final stage involves presenting the research findings at competitions, publishing scientific papers, and sharing the results with the scientific community.

The participation duration for each subject will be approximately 10 minutes. During this time, participants will be asked to complete the handwriting assessment tasks and provide supplementary information, contributing to the overall study data.

Please note that the timeline provided is an estimate and may be subject to adjustments based on the progress of the study and other external factors. We are committed to conducting the research with utmost diligence and efficiency to achieve meaningful outcomes for the benefit of individuals with movement disorders.

## 3.8 Data Collection Process

Participants in the research project will be asked to complete a series of handwriting assessment tasks. These tasks have been carefully designed to evaluate various motor and cognitive functions related to movement disorders. The assessment tasks include:

- **Archimedes Spiral**: Participants will be instructed to draw an Archimedes spiral freehand using their dominant hand. This task assesses fine motor control and hand-eye coordination.

- **Simple House**: Participants will draw a simple house with a roof, windows, and a door. This task evaluates gross motor skills and spatial awareness.

- **Running Stickman**: Participants will be asked to draw a stickman figure running. This task assesses coordination and fluidity of movement.

- **Simple Wave Curves**: Participants will draw a series of wave-like curves. This task evaluates hand steadiness and smoothness of movement.

- **L-Loops**: Participants will be instructed to draw loops in the shape of the letter 'L.' This task assesses the precision and control of hand movements.

- **Straight Lines**: Participants will draw straight lines in different directions. This task evaluates the accuracy and steadiness of hand movements.

- **Simple Car**: Participants will draw a simple car with wheels and basic features. This task assesses fine motor control and attention to detail.

The handwriting assessment tasks will be provided to participants in a standardized template format. Participants will have the flexibility to complete the tasks at their comfort and pace.
In addition to the handwriting assessment tasks, supplementary data will be collected from participants to gather relevant demographic and clinical information. The supplementary data will include:

- **Age**
- **Gender**
- **Disease Name**
- **Disease Severity**
- **Duration of Symptoms**
- **Handedness**
- **Family History of the Disease**

The data collection process will briefly involve the following steps:

1. **Participant Recruitment**: Participants will be recruited from hospitals, patient organizations, and disease study groups. Collaboration with healthcare providers and relevant organizations will ensure the identification of eligible participants.

2. **Informed Consent**: Before participating in the study, eligible individuals will be provided with detailed information about the research objectives, procedures, potential risks, and benefits. Participants will be required to provide informed consent before proceeding with the study.

3. **Handwriting Assessment**: Participants will be given access to the handwriting assessment tasks and templates. They will be instructed to complete the tasks using their dominant hand.

4. **Supplementary Data Collection**: Participants will be asked to provide supplementary demographic and clinical information through a structured questionnaire.

5. **Data Submission**: Participants will submit their completed handwriting assessment tasks and supplementary data through various methods, such as Google Drive, email, WhatsApp, or physical mail, based on their convenience.

6. **Data Management**: All collected data will be stored securely on a designated computer accessible only to authorized research team members. Data backups will be performed regularly to prevent data loss.

Eligible participants will be given access to the handwriting assessment materials and instructions and can perform the assessment at their convenience and submit their results using the following method:

- **Direct Collection by Research Team**
  If the assessment is conducted locally in Penang, Malaysia, the research team members are available to collect the assessment results physically.

- **Google Drive**
  We created a Google Drive folder, which participants may conveniently take photos or scan their assessment results sheet and upload there, in a separate sub-folder for each assessment. We will download the results sheet and delete the online copy as soon as possible when we notice the upload. The folder is configured so that the edit history of the folder won't be visible to others.

- **Email**
  Participants or your organization may send the assessment results sheet through our email: m-9389033@moe-dl.edu.my.

- **WhatsApp**
  Participants may also conveniently take photos of their assessment results sheet and send us through WhatsApp.

- **Physical Mail**
  Participants or the respective organizations can send the assessment results sheet to the following address:
  **Chung Ling High School**
  **23, Kampung Baharu,**
  **11400 Ayer Itam,**
  **Penang, Malaysia.**

## 3.9 Risk and Benefits to Research Participants

During the course of this study, there are minimal risks involved for the participants. The study procedures involve routine and non-invasive handwriting assessments and the collection of relevant medical information. As stated in the literature, there are no serious side effects known to be caused by investigational procedures. The participants' safety and well-being will be closely monitored throughout the study to ensure any potential risks are promptly addressed.

While there are no direct benefits to the individual participants, this research project aims to contribute to the field of movement disorders and neurology. By developing an algorithm for handwriting analysis to detect movement disorder diseases, this study has the potential to improve the early detection and monitoring of these conditions. This, in turn, may lead to more timely interventions and better disease management, ultimately enhancing the quality of life for individuals affected by movement disorders.

Additionally, the study will provide valuable insights into disease progression and treatment efficacy, contributing to a better understanding of the disease/condition studied. The findings from this research may help to inform future medical advancements and interventions in the field of movement disorders.

## 3.10 Ethics of Study

This study will be conducted in strict compliance with ethical principles as outlined in the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline. The welfare and rights of all study participants will be prioritized throughout the research process.

As part of this study, potentially vulnerable subjects, such as pregnant and lactating women, children, prisoners, cognitively impaired individuals, and critically ill subjects, may be enrolled. The inclusion of these vulnerable populations is essential for gaining a comprehensive understanding of movement disorder diseases and ensuring the applicability of the findings to diverse patient groups.

To protect the rights and well-being of these vulnerable subjects, specific measures will be implemented. Informed consent will be obtained from all adult participants and the parents or legal guardians of minors. For cognitively impaired individuals, appropriate consent procedures will be employed based on their capacity to understand and decide. In the case of critically ill subjects, decisions will be made in accordance with relevant laws and regulations, always with their best interests in mind.

Throughout the study, continuous monitoring and close supervision will be carried out to ensure the safety and ethical treatment of all participants. Any adverse events or risks will be promptly addressed, and appropriate actions will be taken to minimize potential harm.

The ethical considerations and protection of vulnerable subjects are of paramount importance to this research project. By adhering to ethical guidelines and ensuring the safety and dignity of all participants, this study aims to contribute valuable knowledge to the field of movement disorder diseases while upholding the highest ethical standards.

## 3.11 Informed Consent

Informed consent will be obtained from all study participants in a clear, transparent, and respectful manner. The process will follow these steps:

1. **Information Provision**: Potential participants will be informed about the study during their usual clinic visits or other appropriate settings. The information will be explained in a language and format that is easily understandable to the participants.

2. **Consent/Assent Discussion**: The participants will have an opportunity to discuss the study with the investigators and ask any questions they may have. The researchers will provide clarifications and address any concerns raised by the participants.

3. **Voluntary Participation**: Participants will be informed that their participation is voluntary, and they have the right to decline or withdraw from the study at any time without facing any consequences or loss of benefits. They will be encouraged to take their time in making a decision and may take the information sheet home to discuss it with their family members or support network if needed.

4. **Written Consent/Assent**: If the participants decide to participate, they will be asked to sign and date the informed consent form or provide assent if they are minors or lack decision-making capacity. For vulnerable subjects, such as cognitively impaired individuals or critically ill patients, alternative consent procedures will be employed in accordance with relevant guidelines and regulations to ensure their rights and interests are protected.

5. **Retaining Consent Forms**: The signed informed consent forms will be securely retained with the handwriting assessment forms, ensuring that participant information is kept confidential and accessible only to authorized research team members.

The informed consent/assent process will be overseen by trained personnel such as patient organizations staff or doctors who will ensure that participants fully understand the study details and can make an informed decision regarding their involvement. The study team is committed to upholding the principles of autonomy, respect, and dignity throughout the informed consent process, ensuring the ethical conduct of the research.

## 3.12 Data Management and Confidentiality

Data management is a crucial aspect of our research project and we will implement a comprehensive system to ensure the security and confidentiality of all collected data. The following measures will be put in place for effective data management:

- **Secure Storage**

  All data collected during the study, including participants' handwriting assessments and supplementary information, will be stored securely on a computer. Access to this computer will be restricted to authorized research team members only. The physical copy of the assessments will be stored securely in a cabinet which is only accessible to research team members.

- **Data Backups**

  Regular data backups will be performed to prevent data loss. Backed-up data will be stored securely in a separate location to ensure redundancy and safeguard against potential technical failures. Data backups are also restricted to authorized research team members only.

- **Anonymization**

  We will never collect or store any identical private information of research participants, such as names, addresses, contact numbers, etc.

- **Data Disposal**

  All data will be securely disposed of after the research has been done. We won’t store any copies or backups of the collected data, including the handwriting samples and supplementary data.

- **Data Sharing Restrictions**

  Under no circumstances will participants' data be shared with third parties outside the research team. The data will be used solely for this research project and will not be utilized for commercial purposes.

## 3.13 Conflict of Interest

The principal and co-investigators of this study declare that they have no conflict of interest that could influence the impartiality or integrity of the research process or the study's outcomes. There are no consultative relationships with any entity related to the protocol that might be considered an apparent conflict of interest.

## 3.14 Publication Policy

In adherence to ethical principles and data confidentiality, this study's publication policy ensures that no personal information or identifying details of study participants will be disclosed in any research publication, presentation, or dissemination of study findings.

All research reports or any other form of publication arising from this study will use aggregated data, ensuring that individual participants cannot be identified. Any information presented will be on a group level, providing an overview of the collective data without compromising the privacy of individual subjects.

Protecting the confidentiality and privacy of our participants is of utmost importance, and all efforts will be made to maintain the anonymity and confidentiality of their private information throughout the publication process. This policy is integral to upholding the ethical standards of the study and maintaining the trust and confidence of the study participants and the wider research community.

## 3.15 Termination of Project

The study may be terminated at any time by the sponsor or principal investigator for various reasons, including but not limited to ethical concerns, safety considerations, lack of feasibility, or inadequate recruitment. In the event of study termination, all enrolled participants will be promptly informed about the decision.

Participants will be notified of the study termination and provided with any relevant information or guidance concerning their ongoing care, if applicable. The termination decision will be made with the utmost consideration for the well-being and safety of the participants.

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