



Hong Kong Diabetes Health Association



Wuhan Changer Medical Group Ltd.

Jointly Organized

Glycated Hemoglobin (HbA1c) Clinical Trial Study Project

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Independent Monitoring Committee Introduction

Contents :

1. Glycated Hemoglobin (HbA1c) Clinical Trial Study Project Introduction....	2
2. Structure of Independent Monitoring Committee	3
3. Functions of Independent Monitoring Committee.....	4-5
4. Duties of Independent Monitoring Committee Members.....	5-6
5. Workflow and records of Independent Monitoring Committee’s Work....	7
6. Introduction of Monitoring Members.....	8-14

Diagram 1 : 2017 Global Diabetes Growth Profile

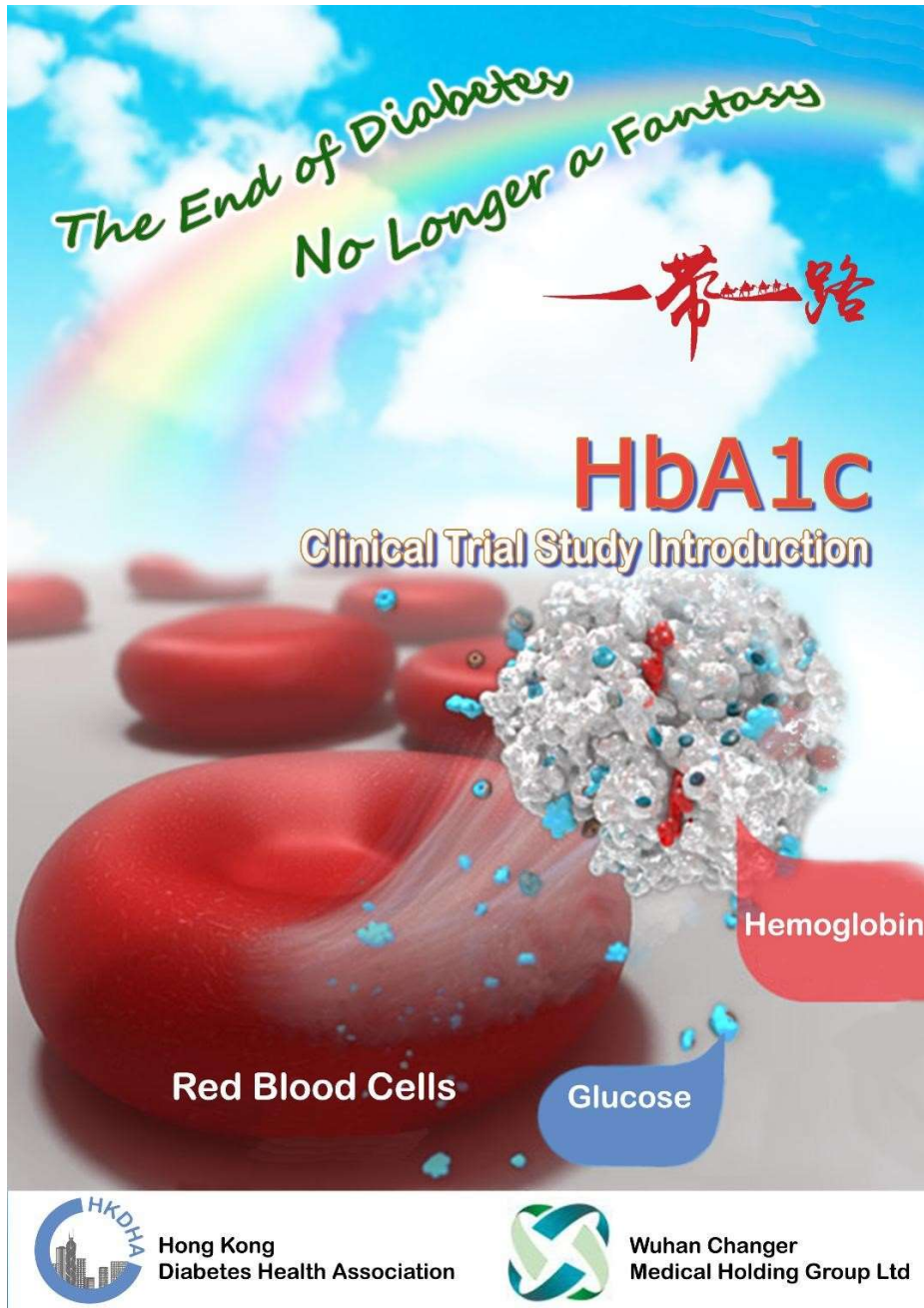
Diagram 2 : Methods of Monitoring

Diagram 3 : Monitoring Committee work flow and records

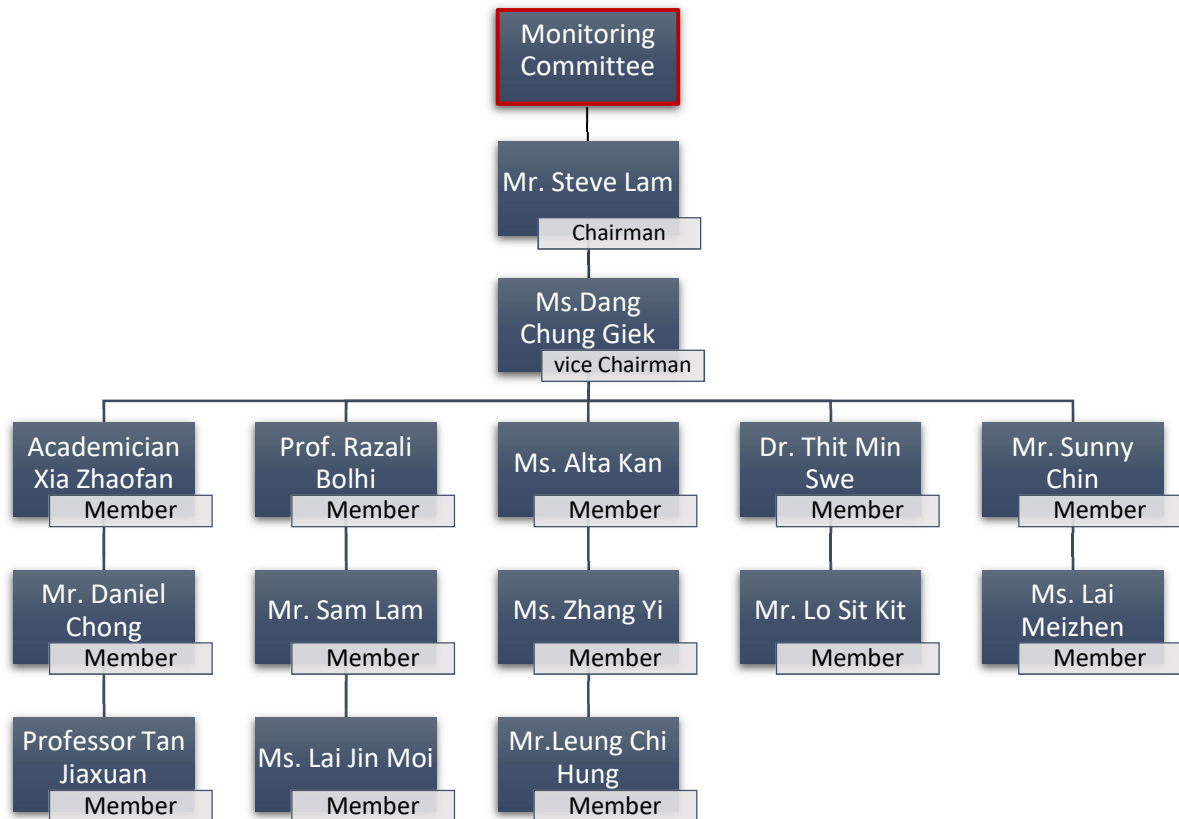
Attachment 1 : Sample of Monitoring Checklist

1. Glycated Hemoglobin (HbA1c) Clinical Trial Study Project Introduction

Please refer to the attached “Glycated Hemoglobin (HbA1c) Clinical Trial Study Project” Introduction



2. Structure of Independent Monitoring Committee



(names) listed in no particular order

3. Functions of Independent Monitoring Committee

Hong Kong Diabetes Health Association (HKDHA) invites professionals and celebrities from various sectors all over the world to be voluntary Monitoring Officers of Independent Monitoring Committee participating in the “Glycated Hemoglobin (HbA1c) Clinical Trial Study Project”. This independently operated committee plays an active external monitoring effect to enhance the credibility of the clinical evidence to be published upon completion of the Research Project.

The Monitoring Officers have full authority to exercise their power of supervision without the interference from the administration of HKDHA, individuals or social organizations. Its function is to ensure the reliability and trustworthiness of the operation of the "Glycated Hemoglobin (HbA1c) Clinical Trial Study Project"; such as project arrangement, resources, data collection, preparation of nature herbal tea and patient management which include:

- a. Patient Management
 - a1. Set up recruitment process for Type II diabetes patients
 - a2. Schedule 20 day therapy arrangement and implementation
 - a3. Assess patient health status
 - a4. Patients receive the same standard of treatment
 - a5. Monitor medical staff performance and follow up treatment progress
 - a6. Employ critical contingency measures
- b. Clinical Trial Study Site Quality and Supporting Facilities
 - b1. Assure on-site medical quality
 - b2. Examine on-site medical supporting facilities
 - b3. Ascertain on-site hygienic standards
- c. Natural Herbal Tea and Chenpi Tea Quality Control
 - c1. Monitor herbal tea preparation process.
 - c2. Evaluate Natural Herbal Tea and Chengpi Tea quality by random spot checks.
- d. Dietary Quality Assurance
 - d1. Ascertain dietary preparation process.
 - d2. Evaluate meal quality by random spot checks.

- e. Information and Data Collection Process
 - e1. Patient data collection and security management.
 - e2. Data collection from all categories and accuracy assurance.
 - f. Work arrangements and quality of implementation in each category
4. Duties of Independent Monitoring Committee Members

In order to meet the monitoring requirements of the above-mentioned functions, the independent monitoring committee will supervise the work in different fields randomly and in the form of “Diagram 2” below.

Diagram 2 : Methods of Monitoring



The Monitoring Officers are to be provided with identification vests as soon as they are on site. Every officer is indiscriminately assigned to different fields to perform surveillance by using following methods:

A. [Interview]

Monitoring Officers randomly visit patients, management personnel and frontline staff to understand the detailed arrangements and implementation status of the work in different fields. The findings are to be recorded down on the provided checklist and verified with authorized signatures.

B. [Inquiry]

Through inquiry about the job arrangement and its effect on the research project is to be carried out to fully understand its practicability and effectiveness about the research project. The findings are to be recorded down on the provided checklist and verified with authorized signatures.

C. [Observation]

Monitoring Officers conduct independent observations in various fields of work, and understand the detailed arrangements and implementation status of work in different fields during the observation process, and select the work that has been observed or write down after observing the matter in the relevant inspection list and verified with authorized signatures.

D. [Sampling]

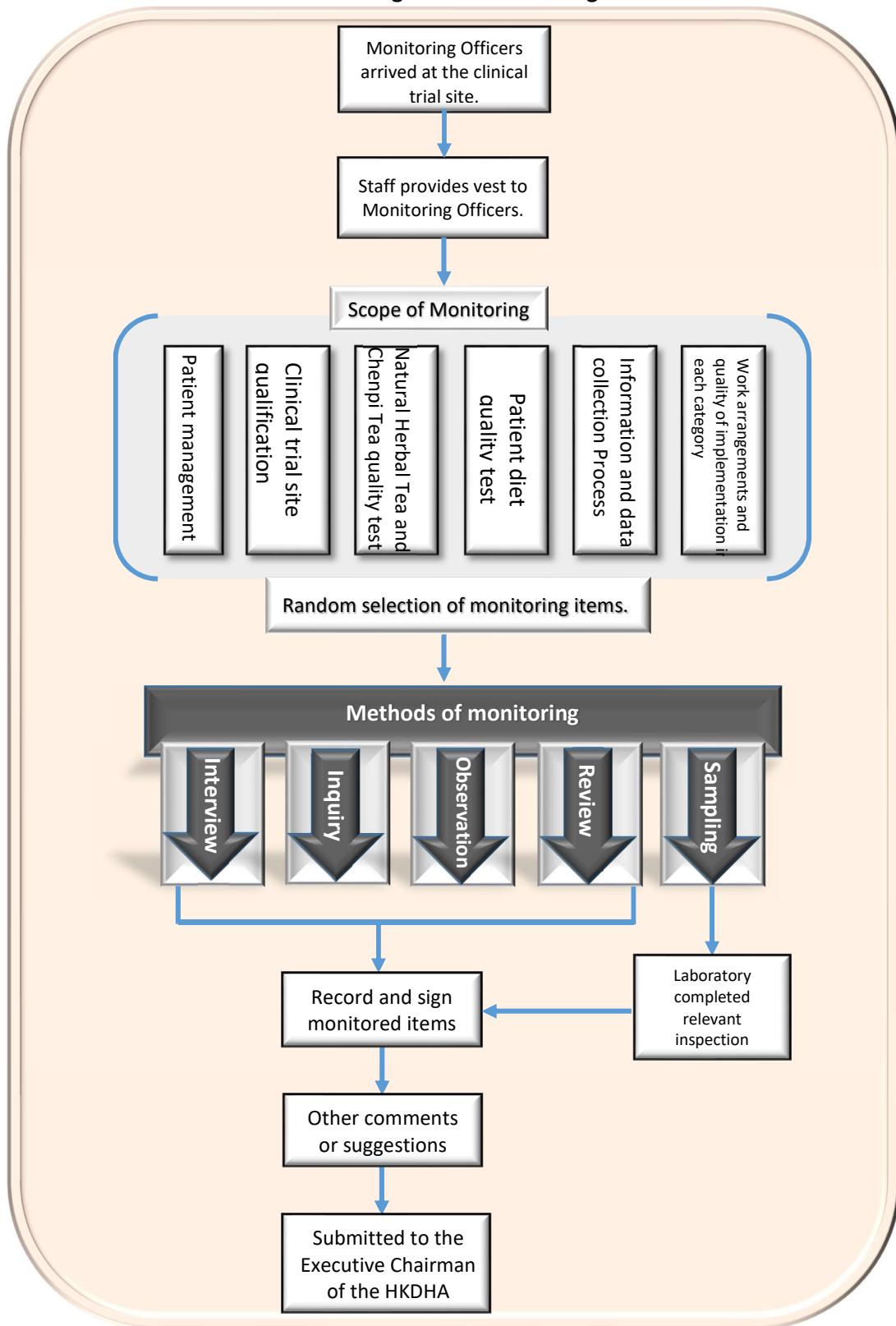
Monitoring Officers shall make random sampling requirements in all areas of work. Relevant inspection items shall be submitted to an accredited inspection agency for professional analysis. The returned inspection reports shall be submitted to the staff of Hong Kong Diabetes Health Association for records.

E. [Review]

Monitoring Officers may randomly make relevant work review requests to personnel in different fields of work. After completing the review, fill in the relevant inspection list of the monitoring committee and verified with authorized signatures.

5. Workflow and records of Independent Monitoring Committee's Work

Diagram 3 : Monitoring Committee work flow and records



6. Introduction of Monitoring Members (Names not in Particular order)

Mr. LAM Chun Ming, Steve

Chairman



Mr. LAM Chun Ming, Steve is a retired Chief Superintendent of Police. He joined the Hong Kong Police Force in 1989 and holds a MBA qualification. In the early stage of his police career, he mainly worked in the criminal investigation department, in particular developing the professional skills in intelligence gathering and analysis. He had received training in strategic intelligence analysis by Australian Federal Police. In 2008, he took the challenges of moving to the uniform branch and working in the frontline for members of the public. He had worked as a Divisional Commander, District Commander, staff officer in Operational policy unit and the Deputy Commandant of Police Tactical Unit Headquarters. During the period, he developed professional strength in the planning, organising and executing large scale public order and security operations. He also took part in the planning and execution of a number of large scale operations. Mr. LAM was promoted to Chief Superintendent in 2015 and worked as the District Commander of Central Police District and Deputy Regional Commander of Hong Kong Island Region. He has an overall service of almost 29 years in the Police Force.

Ms. DANG Chung Giek

Vice Chairman



- State Registered Nurse from Lewisham Hospital London
- Bachelor of Nursing International (Australia)
- Certificate of Diabetes Clinic Management (University Hospital K.L. Malaysia)
- 12 years diabetic educator work experience at General Hospital Kuching, Sarawak
- Research assistant work experience at General Hospital Kuching, Sarawak
- Part time lecture to Unimas (Univeristy of Sarawak) medical students
- Actively involved in Diabetic Association activities since 1988 in health screening for the general public counseling, organizing and assist in diabetic camps

Academician XIA Zhaofan

Monitoring Officer



Department of Medicine and Health, Academician Xia Zhaofan is the Chief Burn Surgical Doctor of the Second Military Medical University (SMMU) Changhai Hospital. Professor Xia is the authority in the field of burns in China. She is mainly engaged in rehabilitation study after burns which includes systemic inflammatory response syndrome after burn 、sepsis and burn

wound repair technology. It is the application of plastic surgery such as flap and microsurgery to special parts for deep burn treatment. In China, she underwent psychological rehabilitation and functional rehabilitation after burns, and was elected as an academician of the Chinese Academy of Engineering in 2013. °

Prof. Dr. Razali Bolhi, PHom

Monitoring Officer



- Doctor of Philosophy in Homeopathy
- Doctor of Philosophy in Sociology
- President, Malaysian United Dayak Islamic Brotherhood Association(PEDI) Sarawak
- President, PANGGAU La Via Campesina Malaysia Council
- Public Relation Bureau Chief Homeopathy Malaysia Council
- Member of Malaysia Homeopathic Medical & Practitioner Council

- Member of Malaysia Society for Complementary Therapists
- Member Indian Board of Alternative Medicine, Calcutta India
- Committee Member of Standard & Criteria of Traditional and Complementary Medicine Division Ministry of Health Malaysia
- Permanent Member of A Working Group for Standard and Criteria for Traditional and Complementary Medicine of MQA
- Member International Association of Education For World Peace
- Member of Global Health Activism Network-Western Reserve University, Canada
- Member of Malaysian Homeopathic Practitioner Association

Ms. KAN Sin Ting Alta, RN, RM, BN

Monitoring Officer



Ms. Kan joined Queen Mary Hospital in 1980 and became a Registered Nurse. Subsequently, she acquired the qualification of Registered Midwife and Bachelor of Nursing. After registration, she had served different departments including medicine, surgery, gynaecology, ear, nose and throat, dermatology, ophthalmology and oncology. In 1990, she specified her works in Bone Marrow Transplantation nursing. Thus, she participated in the establishment and development of the Hong Kong Bone Marrow

Transplant services. She not only expertized in clinical care, but also advocated healthcare promotion, worked hand in hand with various healthcare teams, took part in people development and supported studies and researches. Later on, her duties and responsibilities expanded to management and administration. In 2008, she was promoted to Ward Manager and had been in charge of different specialities, namely neurology, cardiology and Haematopoietic Stem Cells Transplantation Centre. Altogether, she had contributed in nursing for 37 years. °

Dr. THIT Min Swe

Monitoring Officer



1. M.B.,B.S (Yangon)
Bachelor of Medicine & Bachelor of Surgery
2. MPHMM
Master of Primary Health Care Management
25th Batch Mahidol University Thailand
3. Certificate in Intellectual Property
Management by Young Leadership Program of
JACA(Japan)

After he graduated from University of Medicine (1) Yangon, he was working as a House Surgeon for 1 year at Government Hospitals around Yagon Division and Ayarwaddy Division.

Then he was doing Master Degree of Primary Health Care Management at Mahidol University of Bangkok. During his Intensive 2 years of doing MPHMM, he visited many hospitals, clinics and primary health care centers of Thailand for knowledge sharing/ training and studying health care management programs to meet the need of the credits requirement for my Master Degree. He graduated after 2 year by finishing and publishing his thesis regarding Factors influencing HIV/AIDS preventive Behaviors among medical students in Myanmar. Once after he graduated from Mahidol, he was working for 6 months as medical coordinator in Yangon International medical Service of Bumrungrad International Hospital, Bangkok.

Mr. CHIN Tai Ying, Sunny

Monitoring Officer



As an aluminium supplier as his foundation, Mr. Chin had exerted himself in construction industry for more than 30 years. Now Mr. Chin is well aware of the importance of “Big Health” to everyone. Hence, he starts to work his way into medical and healthcare industry, aiming to help others and promoting human wellness and regenerative medication.

Mr. Chin, as the advisor of Association of Bau Sern Ta Ti, he had been making an all-out effort to provide free medication and medicine for the poor and sick citizens of Kuala Lumpur and Selangor. Since 2009 until now, Bau Sern Ta Ti’s free medication and medicine campaign had served more than 25,000 people in need. During the campaign, Mr. Chin and his team of traditional Chinese physicians had helped countless diabetes and high blood pressure patients.

Mr. CHONG Yoke Chu, Daniel

Monitoring Officer



- Degree in Business Administration from Edith Cowan, Australia
- Exclusive Distributor medical equipment for Operating Theatre, min 8 years
- Venture into offering Stem Cell Treatment for almost 5 years
- Co-founded Bio Genx Solution Sdn Bhd year 2016, specializes in medical and healthcare solution and providing alternative regenerative treatments
- A Committee Member of a NGO “Great Commission” social welfare programme for 5 years
- Currently an Advisor Member for “Bau Sern Ta Ti Free Medication and Medicine Campaign”

Mr. LO Siu Kit MH

Monitoring Officer



- 2017 The Government of HKSAR Medal of Honour
- 2012 The Government of HKSAR Chief Executive's Commendation for Community Service
- 2008-2019 Tsuen Wan District Council – Elected Member
- 2012-2022 Election of representatives of the 12th National People's Congress of the HKSAR of the People's Republic of China
- 2013-2021 Member of the 8th Committee of

Huicheng District, Huizhou City, China People's Political Consultative Conference

- 2008 Academician of Hong Kong Business Professional Accreditation Centre
- Member of the Rehabilitation Advisory Committee of the Labour and Welfare Bureau
- Member of the New Territories South Regional Traffic Accident Coordination Committee
- Transport and Housing Bureau Appeal Board (Housing) Committee
- Member of the Yan Chai Hospital Governance Committee

Ms. ZHANG Yi

Monitoring Officer



- Former Director of the Nursing Department of the Affiliated Tumor Hospital of Guangzhou Medical University
- Director of the Pension Care Professional Committee of the Guangdong Provincial Pension Service Association
- Director of the Office of the Guangzhou Nursing Association
- Quality Director of Family Care Guangzhou Pension Service Co., Ltd.

Focus on oncology surgical care research and fruitful clinical care experience. She published several specialist nursing and nursing management papers on Chinese Journal of Nursing, Chinese Journal of Practical Nursing, Zhongshan Medical Care Magazine and Southern Care Journal.

Ms. LAI Meizhen

Monitoring Officer



- Head Nurse of the Department of Endocrinology, Guangzhou Red Cross Hospital, Guangdong Province
 - Guangdong Province Diabetes Specialist Nurse, Deputy Director of Nursing and Master of Nursing
 - Deputy Director of the Diabetes Special Committee of the Guangdong Province Nursing Association
 - Vice President of the Diabetes Nurses Branch of the Guangdong Province Nurses Association
 - Deputy Director and Secretary of the Diabetes Professional Committee of the Guangzhou Nursing Association
- Ms. Lai has abundant clinical experience in the field of diabetes care. Specializes in the education management, diabetic foot care and wound management of diabetic patients. Hosted and participated in two provincial research projects, three research projects at municipal level and four research projects at the hospital level.

Mr. LAM Sum Lim, Sam

Monitoring Officer



- Eastern District Council member
- Eastern District Council Chairman, District Facilities Management Committee
- Eastern of Districts Youth Programme Committee
- Vice Chairman of the Eastern Border Branch of the DAB
- President of Cihui Women's Association
- Executive President of Hong Kong Huiqingshe
- Vice President of the HK Youth Association
- Deputy Director of Shau Kei Wan & Chai Wan Fangzhong's Club
- Vice Chairman of Juxianshe
- Member of the Youth Committee of the HK Chinese Enterprises Association
- Honorary President of Huidong Association
- Honorary President of Hong Kong Taishan Association (HK Island Branch)
- Honorary Advisor of Jianyi Society

Professor TAN Jiaxuan

Monitoring Officer



- Special allowance from the State Council
- Former Vice Chairman of the Foshan Municipal Political Consultative Conference
- Former Vice Chairman of the Foshan Municipal Science & Technology Commission
- Former Dean of Foshan First People's Hospital
- Chief Physician of cardiothoracic surgery
- Graduate tutor of Sun Yat-sen University and Guangdong Medical College
- Visiting Professor of Medicine and Health Management at Sun Yat-Sen University
- Honorary President of Foshan Medical Association
- Chairman of the Foshan Medical Association Surgery Society
- Director of the Guangdong Medical Association
- Member of the Standing Committee of the Institute of Cardiovascular Surgery, Guangdong Medical Association
- Vice Chairman of the Guangdong Institute of Trace Elements Science

Ms. Lai Jin Moi

Monitoring Officer



- State Enrolled Assistant Nurse at SGH Sarawak.
- State Registered Nurse at GH K L.
- Midwifery at SGH Sarawak.
- Diabetes Clinic Management at University Malaya K L.
- Advanced Diploma in Diabetes Education at University Malaya K L.
- Working experience
- 13 years general nursing , 5 years midwife

16 years outpatient clinic experience include 14years as Diabetes Educator & Diabetes Clinic Management

- Initiated 1st Diabetes Registry in Sarawak at KK JM Kuching, Sarawak
- As Diabetes Clinics Supervisor & Monitor in Sarawak for 2 years

Attachment 1_Sample of Monitoring Checklist_P1.

HbA1c_CTFarm006-1

監察委員會檢查項目清單 (Monitoring committee check list)

相關流程/Related flow	項目內容 (Items)	已檢查(是否合格?) Checked (Pass/Fail?)	備註 (Remark)
	A. 病人檢測項目及護理管理 (Checking items and patient's management)		
Flow 3	A1. 體重 (每天早上空腹) Weight (Every morning fasting)		
Flow 3	A2. 體溫 (每天早上空腹) Body temperature (Every morning fasting)		
Flow 3	A3. 血壓 (每天早上空腹) Blood pressure (Every morning fasting)		
Flow 3	A4. 空腹血糖 (每天早上空腹) Blood glucose (Every morning fasting)		
Flow 3	A5. 糖化血紅蛋白 (每天早上空腹) HbA1c (Every morning fasting)		
Flow 3	A6. 早餐後兩小時血糖值 Blood glucose level 2hr after breakfast		
Flow 3	A7. 午餐後兩小時血糖值 Blood glucose level 2 hr after lunch		
Flow 3	A8. 晚餐後兩小時血糖值 Blood glucose level 2 hr after dinner		
Flow 3	A9. 檢測用設備 Equipments		
Flow 3	A10. 病人紀錄(類別、數據紀錄、表格資料) Patient's record (Identity, data, record)		
Flow 3	A11. 特殊狀況紀錄及跟進 Record of special situation and follow up		
Flow 4	A12. 病人藥量調整過程及紀錄 Adjustment of drug dosage and record		
Flow 5, 6	A13. 抽血送化驗所 (早上空腹, 星期四及HbA1c值下降) Exsanguinate (Morning fasting, day 1, 20 and when HbA1c level dropped)		
Flow 9	A14. 顯微鏡血液檢視 (9/10, 19-20/10, 28-29/10) Microscopic blood analysis		

整體意見 (Overall comments):

監察委員姓名
Name of Monitoring Officer _____
所屬機構
Organization _____

監察委員簽署
Signature of Monitoring Officer _____
日期
Date _____

Attachment 1_Sample of Monitoring Checklist_P2.

監察委員會檢查項目清單 (Monitoring committee check list)

HbA1c_CTForm006-2

項目內容 (Items)	已檢查(是否合格?) Checked (Pass/Fail?)	備註 (Remarks)
B. 天然草本茶 (Natural Herbal Tea)		
B1. 包裝 Packaging		
B2. 儲存 Storage		
B3. 設備 Equipment		
B4. 煎藥情況 Preparation of herbal tea		
B5. 人員 Staff		
B6. 運送 Transport		
B7. 入樽 Bottling		
B8. 草本茶抽樣檢測 (藥茶房) Sampling (after bottling)		
B9. 草本茶抽樣檢測 (運送中) Sampling (transport)		
B10. 草本茶抽樣檢測 (病人領取後) Sampling (from patient)		
B11. 隨機訪問病人服用情況 Randomly visit patients about drinking natural herbal tea		
C. 陳皮茶 (Chenpi Tea)		
C1. 包裝 Packaging		
C2. 儲存 Storage		
C3. 設備 Equipment		
C4. 煎藥情況 Preparation of Chenpi tea		
C5. 人員 Staff		
C6. 運送 Transport		
C7. 入樽 Bottling		
C8. 陳皮茶抽樣檢測 (藥茶房) Sampling (after bottling)		
C9. 陳皮茶抽樣檢測 (運送中) Sampling (transport)		
C10. 陳皮茶抽樣檢測 (病人領取後) Sampling (from patient)		
C11. 服用時間、份量 (早、晚) Time of consumption (Morning, night)		
C12. 隨機訪問病人服用情況 Randomly visit patients about drinking Chenpi tea		

整體意見 (Overall comments):

監察委員會姓名 _____ 監察委員會簽署 _____

Name of Monitoring Officer _____ Signature of Monitoring Officer _____

所屬機構 _____ 日期 _____

Organization _____ Date _____

Attachment 1_Sample of Monitoring Checklist_P3.

HbA1c_CTForm006-3

監察委員會檢查項目清單 (Monitoring committee check list)

D. 飲食 (Food)	
D1. 廚房 (環境) Kitchen (Environment)	
D2. 廚房 (員工) Kitchen (staff)	
D3. 廚房 (設備) Kitchen (equipment)	
D4. 廚房 (衛生) Kitchen (hygiene)	
D5. 隨機抽取食物化驗是否有降血糖藥物 Randomly take food sample for hypoglycaemic drugs test	
D6. 隨機訪問病人對飲食的滿意度 Randomly visit patients about their satisfaction on food provided	
E. 運動及活動 Exercise & afternoon activities	
E1. 早餐後一小時運動 (40 分鐘) 40 minutes exercise, 1 hr after breakfast	
E2. 午餐後一小時運動 (40 分鐘) 40 minutes exercise, 1 hr after lunch	
E3. 晚餐後一小時運動 (40 分鐘) 40 minutes exercise, 1 hr after dinner	
E4. 下午活動 (講座或景點觀光) Afternoon activities (Health related talk or sightseeing)	
F. 文件、記錄檢查 Documents, Records	
Flow 3 F1. 工作人員數據輸入 Data input by operational staff	
Flow 3 F2. 管理人員審核 Data checking by management staff	
F3. 資料儲存 Document filing and storage	
整體意見 (Overall comments):	

監察委員姓名
Name of Monitoring Officer _____
所屬機構
Organization _____

監察委員簽署
Signature of Monitoring Officer _____
日期
Date _____