# PATIENT INFORMATION SHEET

**Study Title: WORKPLACE SMOKING CESSATION: SMOKING RELAPSE, SUSTAINED CESSATION AND BEHAVIOURAL ATTRIBUTES FOLLOWING A QUIT ATTEMPT**

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**Please read the following information carefully**

We are happy to inform you that you have been invited to take part in a smoking cessation study. This consent form may contain words that you do not fully understand. Hence, before you give consent to volunteer for this research, you should read the following carefully and ask as many questions as necessary to be sure that you comprehend what your participation involves and the procedures to be followed.

**Introduction**

Tobacco use is considered the single most preventable cause of premature morbidity and mortality. It is a major cause of lung cancer, cardiovascular diseases, COPD, resulting in 1.2 million deaths annually according to WHO.

As up to now, according to NHMS 3 (National Health Morbidity Survey, 2006), the prevalence of smoking among adults in Malaysia over the age of 18 years is very high totaling up to 21.5%, of which constitute 46.4% of male the male population overall.

**What is the purpose of this study?**

The main purpose of this study is to look at reasons and factors to relapse among smokers. This is a smoking cessation project, thus, participants will receive smoking cessation therapy which will consist of behavioural therapy and pharmacotherapy, as an aid to their quit smoking attempts.

**What are the procedures to be followed?**

There are certain procedures that participants are required to follow. Each participant will be *followed up for a total of 6 months.* During this study, participants will be asked to:

1) *Attend all 3 individual sessions with the investigator* Participants will be given a set of new medication and counseling advices on how to stop smoking during each session. Each session will last approximately 10-20 minutes, on a fixed given date. Other measurements will also take place include peak flow measurements, weight and Co expired breath.
   Attendance in smoking cessation is very important and is highly associated with successful outcome. Participants who are unable to attend the sessions will need to inform the examiner in advance by giving name and a new preference date within the same week.

2) After the treatment phase, participants will be *contacted by phone calls at least 2 times*, lasting 10 minutes each call. The phone calls will be 1-3 months apart.

3) There are a few sets of *questionnaires* that participants are required to answer, as honest as possible.

4) Keep tract of smoking cessation activity via a *quit smoking diary*, which will be given.

**Release of Research Records and Confidentiality**

All information obtained during the study will remain ***confidential.*** As part of the interview process you might be asked some sensitive questions, which you are required to answer. All aspects of the information is completely confidential. The only individuals who will have access to this data are Dr Siti Munira, supervisor(s), independent ethics committee, to the extent permitted and applicable by law, and the research assistant (s) conducting the project. The nature of this study and the information provided by your participation will not be revealed.

**Who should not enter the study?**

This study is open to all University of Malaya staff. If you have the following criteria you are welcomed to join:

1) Age 20 years and above
2) Smoke at least 5 cigarettes per day for 12 months.
3) Have a desire to quit
4) Willing to adhere to protocol including attendance and follow-up sessions.

However, patients with the following conditions are not advised to enroll, and will be excluded:

1) Major psychiatric disorders. (on medication or/and psychiatric follow-up)
2) History of myocardial infarction, cardiac arrhythmia and unstable angina pectoris.

**What will be benefits of the study:**

**(a) To you as the subject?**

Investigators will aid participants to *quit smoking* as early as 1 month and up to 12 months. Participants will understand the process of smoking cessation and techniques used to abstain from smoking via counseling sessions. Medications will also be given as an adjunct.

**(b) Costs*:***

Participation in this study will not result in any additional costs to you. All costs are paid for.

**(c) To the investigator?**

There are many benefits that are expected from this study, not only to investigator but also to University Malaya and the Ministry of Health.

- To reduce number of smokers in the population of study, in this case among Wellness Program participants.
- To reduce financial burden of smoking related diseases in population of study.
- As an academic research to produce a Dr PH (Doctor of Public Health) student.
- Publications on the result of this study would be expected to contribute new knowledge to smoking research, in Malaysia and worldwide.

**What are the possible drawbacks?**

Possible drawbacks from this study:

1. Participants are not being promised that they will discontinue smoking by end of

treatment/follow-up as it is also dependent upon internal factors as well, e.g. individual motivation and desire to quit.

2. Drug Information :

- *Precautions of medication.*

Nicotine replacement therapy is an established drug for smoking cessation since 10 years ago and has gained FDA approval. It has been reported by studies to be well tolerated and effective as an aid to smoking cessation. However, it is important that you take the medication exactly as your trial doctor has instructed. Never increase the dosage unless your doctor tells you to.

This NRT gums is not suitable for pregnant ladies, and those who have history of myocardial infarction, serious arrhythmia and unstable angina pectoris (heart diseases).

- *Adverse Effects of Medication*

As any other medications, minimal side effects may be experienced in certain (5%) patients. Common side effects of nicotine chewing gum include mouth soreness, hiccups, dyspepsia and jaw ache. In case of you experiencing any of the above, do not hesitate to contact the researcher (Dr Siti Munira) for advice and assistance.

**Can I refuse to take part in the study?**

This study is voluntary, as there is no penalty for refusal to participate. Participants are also free to withdraw consent and participation in this project anytime without penalty after notifying the project director. However, participants whom withdraw from the study will not be promised to be given continuation of medication. This is subject to availability.

**Who should I contact if:**

- I have additional questions during the course of the study? /If I develop any side effects from the study?

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