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**RESEARCH PROPOSAL**

**TITLE:**

**FACTORS ASSOCIATED WITH VACCINE HESITANCY AMONG PARENTS OF CHILDREN WITH AUTISM SPECTRUM DISORDER (ASD) IN MALAYSIA**

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**CHAPTER ONE**

# **INTRODUCTION**

## **Background of the Study**

Autism Spectrum Disorder (ASD) is a complex neurodevelopmental disorder characterized by a spectrum of communication, behaviour and social impairments that begins in early childhood and persist throughout life (Howe & Eggett, 2018). The global prevalence rate of autism has increased tremendously from prevalence rate of 1 in 2,500 children to 1-2 in 100 children by the early 2000 (CDC, 2018). In a recent study done by the Autism and Developmental Disabilities Monitoring (ADDM) Network funded by CDC estimates 168 per 10,000 children (or one in 59 children) is diagnosed with ASD (Redfield et al., 2014) . In Asia, a systematic review in six Asian countries that excluded South Asian countries reported that ASD prevalence was 14.8 per 10,000 from 1980 to current (Sun & Allison, 2010). In China, a meta-analysis found that the pooled prevalence of ASD based on clinical diagnostic criteria was 39.23 per 10,000 children (Wang et al., 2018). Only one available study in South East Asia, namely Indonesia estimates the ASD prevalence rate at 11.7 per 10,000 (Elsabbagh et al., 2012). At present, there is no local epidemiological data available on the prevalence of autism in Malaysia. However, a minor scale study on children aged 18 to 26 months conducted by the Ministry of Health of Malaysia demonstrated a prevalence rate of 16 in 10,000 children, or approximately 1 in 62512 (Family Health Division 2006).

The aetiology of ASD is still uncertain but it is known that genetic and environmental factors may play a role. The diagnosis of ASD can be made clinically based on comprehensive history taking and behaviour evaluation. According to DSM V criteria, diagnosis of ASD can be establish if there are persistent deficits in social communication and social interaction, restricted, repetitive patterns of behaviour, interests, or activities and symptoms must be present in the early developmental period in which symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning. Diagnostic tools may be used to assist in the clinical diagnosis.

The epitome controversy regarding ASD and vaccine occurred in 1995. Dr Andrew Wakefield, a British surgeon attracted professional attention when he published an article in The Lancet proposing a link between measles, mumps and rubella (MMR) vaccine with bowel disease and pervasive developmental disorder which term later as autism. Later, Wakefield was charged due committing scientific fraud by fabricating data and his article was formally withdrawn (Battistella, Carlino, Dugo, Ponzo, & Franco, 2013).

Despite a Cochrane systematic review (Demicheli, Rivetti, Debalini, & Di Pietrantonj, 2013) reporting no association between childhood vaccination and autism, there remain concerns about such a connection in certain groups of the population identified nowadays as the vaccine hesitancy (VH).

VH is defined by WHO as a “delay in acceptance or refusal of vaccines despite availability of vaccination services” (Macdonald & Group, 2015). It differentiates vaccine acceptance and vaccine refusal and change previous characterization of individuals and groups as either anti-vaccine or pro-vaccine. In recent years, countries that were near to eliminating the disease have seen a resurgence of the vaccine-preventable diseases (VPDs) due to the VH parents (VHP).

The MMR ‘vaccine scare’ led to a drop in MMR vaccine coverage from 91.8% prior to the scare to 79.9% in 2004 resulting in measle outbreaks in England(Cacciatore, Nowak, & Evans, 2018). In the USA (Hill, Elam-Evans, Yankey, Singleton, & Kang, 2018), the percentage of children aged 19–35 months who received the MMR vaccine slightly decreased from 91·6% in 2011, to 91·5% in 2017. Similar trends elsewhere have resulted in a 30% rise in measles cases worldwide (CDC, 2016)—even in countries such as the USA, where measles had been eradicated in 2000. The Strategic Advisory Group of Experts (SAGE) on Immunization recognized the global importance of vaccine hesitancy as an emerging issue prompting WHO to declare vaccine hesitancy as one of the ten biggest threats to global health in 2019(The SAGE Working Group, 2014). At the November 2011 meeting, SAGE welcomed the decision to create a working group to address this issue. The SAGE Working Group on Vaccine Hesitancy was established in March 2012 with the mandate to prepare for a SAGE review and advice on how to address vaccine hesitancy and its determinants(The SAGE Working Group, 2014). Few models for vaccine hesitancy and determinant matrix was developed by the SAGE Working Group.

From the current research, the prevalence of VH is ranging from 6% - 30% in USA (Gilkey et al., 2014) (Opel, Mangione-smith, et al., 2011) (Opel, Taylor, et al., 2011). In Malaysia, the prevalence rate is 11.6% according to a study done in urban health clinic in Kuala Lumpur (Mohd Azizi et al., 2017). However, rates of vaccine VHP among the subpopulation of children with ASD have not been fully investigated. According to a study (Zerbo et al., 2018) conducted in USA, researchers found that vaccine uptake was high, but following an ASD diagnosis, children including siblings of those with ASD were less likely to be vaccinated.

## **Research tool and instrument**

The study tool is the Malay version of the Parent Attitudes about Childhood Vaccines (PACV) questionnaire. It is developed in 2011 by Douglas J Opel et al (Opel, Mangione-smith, et al., 2011). It is translated and validated in Malay version by Haizlene et al (Halim, Abdul-razak, Yasin, & Isa, 2019). It contains 12-items questionnaire with three factor domains – “Behavior”, “Safety and efficacy”, and “Schedule and immunity”. The aim of this questionnaire is to identify vaccine-hesitant parents, and assess their behaviour and concerns about childhood vaccines. The details regarding the development of this questionnaire will be described in section 3.7.

## **Problem Statement**

1. ASD is a growing concern especially among parents. The estimated worldwide prevalence is 1 in 59 children (or 16.8 per 1,000 8-year-olds) based on recent study by CDC (CDC, 2018). In Malaysia, a prevalence rate of 1.6 in 1000 children, or approximately 1 in 62512 children are suspected to have ASD from a minor scale study on children aged 18 to 26 months (Family Health Division 2006). However, there is no local epidemiological data available on the true prevalence of ASD in Malaysia.
2. ASD was proposed to be related with MMR vaccination causing ‘vaccine scare’ leading to vaccine hesitancy globally. The impact of VH among parents has led to outbreak of vaccine-preventable diseases worldwide.
3. VH is an emerging term in the literature. They comprise a much larger group than those who reject vaccines completely. VHPs are also potentially more likely to change their attitude on vaccination. Thus, VHPs are important for understanding and counteracting growing vaccine resistance. In order to put the scientific benefits of vaccines into practice, a better understanding of VHPs and their concern is vital.
4. Studies conducted from other countries regarding vaccine hesitancy in parents of a child with ASD is scarce. In Malaysia the study regarding VHP of a child with ASD is still lacking. In order to achieve this, it is novel to explore the prevalence vaccine hesitancy in parents of a child with ASD and to identify its associated factors in Malaysia.

## **Research Questions**

1. What is the prevalence of vaccine hesitancyamong parents of children with Autism Spectrum Disorder (ASD)?
2. What are the factors associated with vaccine hesitancy among parents of children with ASD?

## **Objectives**

**1.5.1 General Objectives**

This study aims to determine the factors associated with vaccine hesitancy among parents of children with ASD in Malaysia.

**1.5.2 Specific Objectives**

1. To determine the prevalence of vaccine hesitancy among parents of children with ASD
2. To identify the factors associated with vaccine hesitancy among parents of children with ASD

## **Research Hypothesis**

There is high prevalence of vaccine hesitancy among parents of children with ASD in Malaysia.

Alternative hypothesis

There is low prevalence of vaccine hesitancy among parents of children with ASD in Malaysia.

## **Significance and Novelty of the Study**

This study is the first study in Malaysia to establish the factors associated with vaccine hesitancy among parents of children with ASD. Assessing the prevalence of VHP of a child with ASD will provide an insight on the current VH in special groups in line with the WHO recommendation. It is also can provide objective evidence on how to deal with this group to increase the uptake of vaccination among them. The evidence will be useful for healthcare provider and the government in order to implement a stricter policy for VHP to reduce the public health risks associated with vaccine hesitancy. Furthermore, intervention strategies can be developed to address vaccine hesitancy among this subpopulation.

**CHAPTER TWO**

# **LITERATURE REVIEW**

## **2.1 Definition of terms**

According to CDC, the definition of terms is as below:

1. Vaccine: A product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease. Is a product that stimulates an immune response to protect the person against specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose
2. Vaccination: The act of introducing a vaccine into the body to produce immunity to a specific disease.
3. Immunization: Process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.
4. Immunity: Protection from an infectious disease

Other definition of terms:

1. Childhood vaccines: Childhood vaccine stated in this study refer to basic primary immunization for children aged 0 - 24 months in line with Ministry of Health’s (MOH) national vaccination schedule recommendations.
2. Vaccine hesitancy: Delay in acceptance or refusal of vaccination despite availability of vaccination services (Macdonald & Group, 2015)

## **2.2 Vaccine hesitancy globally**

Vaccine attitude is a continuum ranging from vaccine acceptance to complete rejection. Vaccine-hesitant individuals are a heterogeneous group in the middle this vaccine continuum. Vaccine hesitancy is an expression of concern or doubt about value or safety of vaccination. They may refuse some vaccines, but agree to others; delay vaccines or accept vaccines but are unsure in doing so.

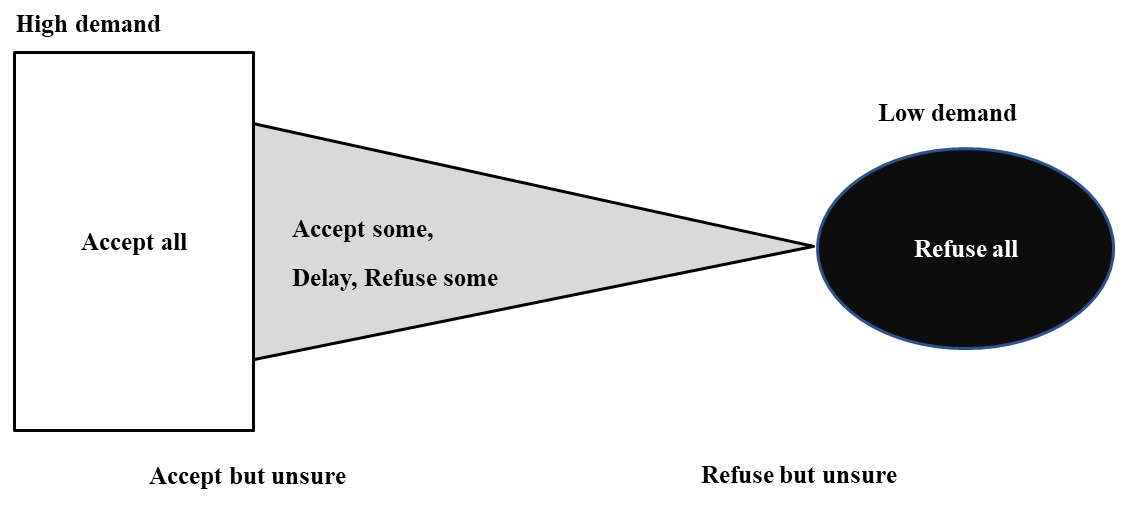


Figure 2.4: Vaccine Hesitancy Continuum

VH has become a global challenge as the number of countries reporting data on hesitancy has progressively increased, reaching 83% in 2017 (Lane, MacDonald, Marti, & Dumolard, 2018). The prevalence of VH in USA ranging from 6% to 30%.

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| --- | --- | --- | --- | --- |
| No | Year / Authors | Country | Sample | Results |
|  | Vaccine hesitancy among parents in a multi-ethnic country, Malaysia  Shaheera et al., 2017 | Malaysia | Cross sectional  Convenience sampling,  545 | Prevalence VH 11.6% of parents  Associated with unemployed parents, parents who were younger, had fewer children and non-Muslim |
|  | Vaccine hesitancy among parents in Kuala Lumpur: a single center study  Musa, Soni, Cheong, & Nordin, 2019 | Malaysia | Cross sectional  Sampling not mentioned (include all)  314 parents  From December 2016 to May 2017 | Prevalence of VH of 14.5%  Univariate analysis found no link between sociodemographic factors and VH in parents.  Only five of these determinants were included in the final model as statistically significant (p< 0.05) predictors of VH among parents in KL. The five factors were introduction to a new vaccine, negative past experiences of vaccinations, distrust of the pharmaceutical industry, distrust of health systems and providers and being male. |
|  | Vaccine Hesitancy toward Childhood Immunisation among  Antenatal Mothers at National University Hospital Kuala  Lumpur  Kalok et al., 2017 | Malaysia | Cross-sectional study of 1081 antenatal mother | Eighty-five (7.9%) antenatal mothers were vaccine hesitant  Non-Muslim antenatal mothers were 7 times more likely to be vaccine hesitant compared to Muslims  Antenatal mothers with lower education levels (primary and secondary school) were 4 times more likely to be vaccine hesitant  Employed mothers were less likely to be vaccine hesitant  The fear of adverse side effects of vaccines was the predominant reason given for those who were vaccine-hesitant |
|  | Validity and reliability of a survey to identify vaccine-hesitant parents, 2011 | US | Cross-sectional ,survey sample was selected by simple random sampling from a birth cohort of 19–35 month old singleton children born  between April 2007 and August 2008 ,  Response rate was 46% (N = 230). | Larger percentage of parents surveyed who had refused (16%) or delayed (27%) recommended immunizations than have been reported previously.  Children were more likely to be under-immunized if they had a parent aged 18–29 years old, who had a high school education or less, had more than one child, and who was white. |

**2.5 VH in Malaysia**

To date, there is no national data on vaccine hesitancy in Malaysia. From extensive literature review, there are three studies specifically measure prevalence of VH in Malaysia. It was found that the prevalence of VH in Malaysia ranging from 11.6% to 14.5%. Further information on the studies are elaborated further in the table below.

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| 3 | Vaccine Hesitancy toward Childhood Immunisation among  Antenatal Mothers at National University Hospital Kuala  Lumpur  Kalok et al., 2017 | Malaysia | Cross-sectional study of 1081 antenatal mother | Eighty-five (7.9%) antenatal mothers were vaccine hesitant  Non-Muslim antenatal mothers were 7 times more likely to be vaccine hesitant compared to Muslims  Antenatal mothers with lower education levels (primary and secondary school) were 4 times more likely to be vaccine hesitant  Employed mothers were less likely to be vaccine hesitant  The fear of adverse side effects of vaccines was the predominant reason given for those who were vaccine-hesitant |
| 4 | Validity and reliability of a survey to identify vaccine-hesitant parents, 2011 | US | Cross-sectional ,survey sample was selected by simple random sampling from a birth cohort of 19–35 month old singleton children born  between April 2007 and August 2008 ,  Response rate was 46% (N = 230). | Larger percentage of parents surveyed who had refused (16%) or delayed (27%) recommended immunizations than have been reported previously.  Children were more likely to be under-immunized if they had a parent aged 18–29 years old, who had a high school education or less, had more than one child, and who was white. |

**2.6 Factors associated with VH in Malaysia**

As mentioned earlier, vaccine hesitancy is a behaviour influenced by a wide range of factors, such as knowledge or past experiences. This refusal is also linked to historical, political and socio-cultural contexts (Fournet et al., 2018)(Leask, Willaby, & Kaufman, 2014)(Nowak et al., 2015). There seems to be a case of low awareness regarding the benefits of child vaccination among Malaysian parents as they perceive that those diseases are no longer in existence. These findings were revealed in a cross-sectional study performed by Awadh et al (Awadh et al., 2014). In another study it was found that mothers and parents with lower education level are more vaccine hesitant (Mohd Azizi et al., 2017)(Kalok et al., 2020).

Furthermore, in a local study in Kinta (Lim et al., 2016), it is note that the three most commonly missed vaccines for both immunization refusal and defaulter were same which was Measles, Mumps and Rubella vaccine (MMR), followed by the third dose of Hepatitis B (HepB) and third dose of Diphteria, Tetanus, Pertusis, Polio and Haemophilus influenzae vaccine (DTaP/IPV/Hib). The three main reasons for refusing vaccines were a preference for alternative treatment, six (75%), assumption that vaccines have no effect, three (37.5%), and doubt regarding vaccine contents two (25%) while the three main reasons for defaulting vaccines were busy with work, 10 (32.3%), long waiting time at the clinic, 7 (22.6%), and child not well, 7 (22.6%) (Lim et al., 2016).

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| --- | --- | --- | --- | --- |
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| 3 | Vaccine Hesitancy toward Childhood Immunisation among  Antenatal Mothers at National University Hospital Kuala  Lumpur  Kalok et al., 2017 | Malaysia | * Cross-sectional study of 1081 antenatal mother | * Eighty-five (7.9%) antenatal mothers were vaccine hesitant * Non-Muslim antenatal mothers were 7 times more likely to be vaccine hesitant compared to Muslims * Antenatal mothers with lower education levels (primary and secondary school) were 4 times more likely to be vaccine hesitant * Employed mothers were less likely to be vaccine hesitant * The fear of adverse side effects of vaccines was the predominant reason given for those who were vaccine-hesitant |
| 4 | Factors affecting timeliness of immunization in Malaysia  Awadh et al., 2014 | Kuantan  Malaysia | Cross-sectional ,survey sample was selected by simple random sampling from a birth cohort of 19–35 month old singleton children born  between April 2007 and August 2008 ,  Response rate was 46% (N = 230). | A total of 479 children immunization records were screened and their parents were interviewed. High immunization coverage (>95%) for each of the recommended vaccine has been found in this study. However, 63.5% (n=304) of the children had overall age appropriate immunization status. Parent’s education, employment status, family size, and place of living were identified as risk factors for not having age appropriate immunization. Born in larger family size and having low educated parent were predictors for not being age appropriately immunized |

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| --- | --- | --- | --- |
| No | Year / Authors | Country | Results |
| 5 | Exploring immunisation refusal by parents in the Malaysian context  Lim, W Y Jeganathan, Netia  Rahmat, H Mustafa, N A | Preak,  Malaysia | Of 10,189 immunisable children, 95 missed primary immunisation. Contact was established with 52 and 44 completed telephone interviews. Of these, 8 (18.2%) refused immunisation, while 31 (70.5%) defaulted immunisation. The immunisation refusal and defaulter rates per 10,000 children immunised per year were 8 and 30, respectively. The main reason for refusing im- munisation was a preference for alternative treatment 6 (75.0). |
| 6 | Refusal towards vaccination: A survey among Malay parents  Nurazzura et al.,2019 | Kuantan  Malaysia | The results indicate that 58% of parents refused to vaccinate their children. Although parents are aware of the importance of vaccines, they refused to adopt them due to the perception that vaccination is unhygienic in nature and is considered unhealthy for their children. They also believed that other preventive methods are better than vaccination. The findings also illustrate significant positive correlation between parents’ educational level and their attitude towards vaccine refusal |
| 7 | Trends in Vaccination Refusal in Children Under 2 Years of Age in Kedah, Malaysia: A 4-Year Review From 2013 to 2016  Huah et al., 2016 | Kedah  Malaysia | Data contributed by 60 public health centers were used to determine the annual incidence rates (per 1000 newborns) of vaccination refusal, and to identify the reasons for refusal among the mothers. The trend analysis revealed a 2.2-times increment in the incidence rates of vaccination refusal from 4.72 in 2013 to 10.51 in 2015, followed by a 52.2% reduction to 5.02 in 2016 (P = .046). Besides, the proportion of mothers who refused vaccination because of religious belief reduced from 78% between 2013 and 2015 to 67.1% in 2016 (P = .005). Overall, the finding confirms the positive impact of the educational and religious interventions introduced by the State Health Department of Kedah since January 2016; nonetheless, efforts to strengthen the existing strategies and thereby to maximize the vaccination coverage in Kedah are warranted. |

**2.6 Vaccine uptake and Autism Spectrum Disorder (ASD)**

Prevalence rate of VH among the subpopulation of children with ASD have not been fully investigated. According to a study conducted in USA, researchers found that vaccine uptake was high, but following an ASD diagnosis, children including siblings of those with ASD were less likely to be vaccinated. A survey conducted among 98 parents of children with ASD and 65 parents of children without ASD in Canada found that a lower proportion of children with ASD received their measles, mumps, and rubella (MMR) or diphtheria and tetanus toxoids and acellular pertussis and inactivated poliovirus (DTaP-IPV) vaccines compared with children without ASD (Kuwaik et al., 2014). Another study reported no significant difference between rates of vaccination of 71 children with ASD and those of 135 children without ASD but, they found that families with children with ASD were less likely to vaccinate subsequent children (Glickman, Harrison, & Dobkins, 2017). In a survey of 197 parents, the researchers found that half of the parents of children with ASD changed vaccination practices for their younger children because of beliefs that vaccines contributed to their child’s ASD (Bazzano, Zeldin, Schuster, Barrett, & Lehrer, 2012). After surveying 486 parents of children with ASD, Rosenberg and colleagues found that almost 20% of parents declined or delayed MMR immunization in the younger siblings of children with ASD (Rosenberg, Law, Anderson, Samango-Sprouse, & Law, 2013).

|  |  |  |  |
| --- | --- | --- | --- |
| No | Year / Authors | Country | Results |
| 1 | Immunization uptake in younger siblings of children with autism spectrum disorder.  Kuwaik et al., 2014 | Canada | A significant group difference emerged for overall immunization status (Fisher's exact test = 62.70, p < .001).  One or more immunizations in 59/98 younger sibs were delayed (47/98; 48%) or declined (12/98; 12.2%); immunizations were delayed in 16/98 probands (16.3%) and declined in only one. All controls were fully immunized, with only 6 (9.2%) delayed.  Within the "younger sibs" group, 25/98 received an autism spectrum disorder diagnosis; 7 of whom (28%) were fully immunized. |
| 2 | Vaccination Rates among Younger Siblings of Children with Autism  Glickman, Harrison, & Dobkins, 2017 | California USA | Families with children who had autism spectrum disorder were less likely to vaccinate subsequent children. Specifically, the rate of vaccination among full biologic infant siblings of children with autism spectrum disorder was 83.1%, as compared with 97.0% among low-risk infants (Pearson chi-square value with one degree of freedom, 12.62; P<0.001) |
| 3 | Vaccine-related beliefs and practices of parents of children with autism spectrum disorders  Bazzano, Zeldin, Schuster, Barrett, & Lehrer, 2012 | Los Angeles  USA | 43% of 460 eligible parents of children under 18 years of age with autism spectrum disorders  Half of the parents discontinued or changed vaccination practices, and this was associated with a belief that vaccines contributed to autism spectrum disorders, indicating a potential subset of undervaccinated children. |
| 4 | Survey of Vaccine Beliefs and Practices Among Families Affected by Autism Spectrum Disorders  Rosenberg, Law, Anderson, Samango-Sprouse, & Law, 2013 | US | The highest proportion of delaying or omitting vaccines occurred for MMR (19.6%; 95% CI = 16.2-23.4), followed by varicella (14.5%) and DTP/DTaP (11.7%)  Odds of delaying or omitting any vaccine in the series, compared with receiving the full series, were much higher among those endorsing a “definitely did” belief in an autism–vaccine link in their older index child (mOR 4.77 and mOR 21.2, respectively).  Being in the youngest cohort of siblings (born between 2003 and 2005) was associated with significantly higher mOR for delayed (mOR 2.9; 95% CI = 1.3-6.5), but not omitted, receipt.  Highest maternal education was significantly correlated with delaying (mOR 3.1; 95% CI = 1.1-8.6) or omitting (mOR 4.4; 95% CI = 1.2-15.5) early-childhood vaccination series in younger siblings, independent of belief in a vaccine– autism link |

**2.7 Theoretical Frameworks of Vaccine Hesitancy**

As mentioned earlier, at its fundamental, VH is an outcome of behaviour that results from a dynamic decision-making process that can theoretically be affected by a wide range of factors. In further refining the definition of VH, few conceptual models are being assessed by the WHO’s Strategic Advisory Group of Experts (SAGE) Working Group of Vaccine Hesitancy (WG) for understanding and grouping VH determinants (Figure 4) (Macdonald & Group, 2015). The conceptual models have been considered and evaluated for flexibility and global applicability. These factors were considered and tested for possible use in facilitating the establishment of vaccine hesitancy indicators survey questions and interventions at both international and local level. For this study only one conceptual model will be highlighted - The “3 Cs” model. This model was chosen because it was considered to be the most readily interpreted, furthermore the aspects have been integrated into the definition of VH. The "3 Cs" model was first developed by the WHO EURO Vaccine Communications Working Group in 2011. It emphasizes three categories: complacency, comfort and trust.

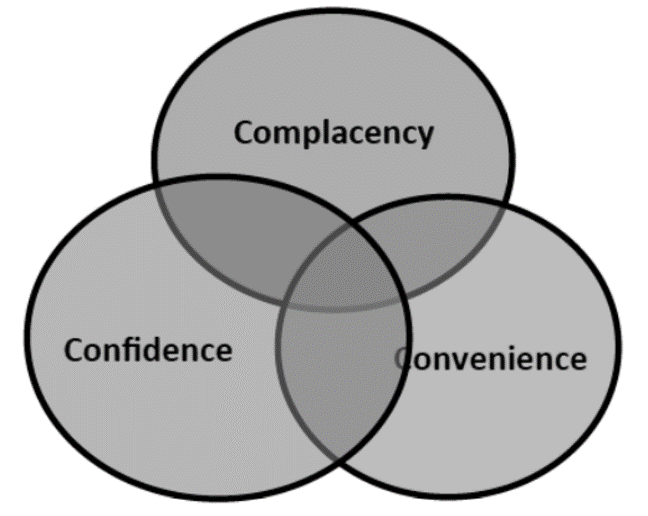


Figure 2.5: Confidence, Complacency, Convenience Model of Vaccine Hesitancy

Further explaination on the “3 Cs” model are described below:

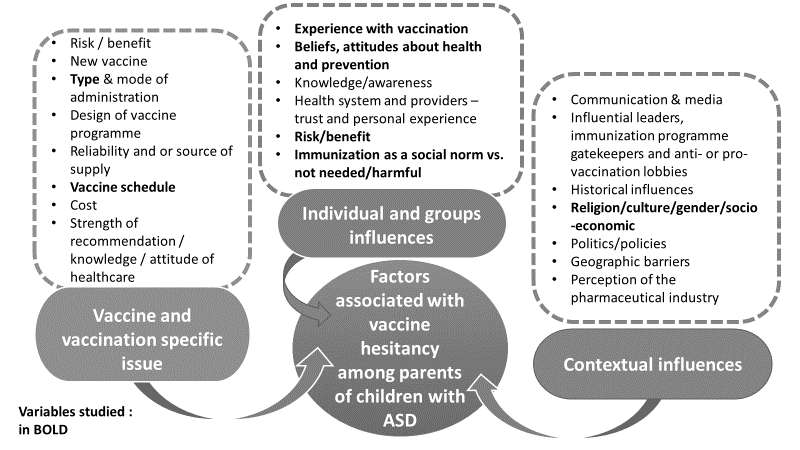
|  |  |
| --- | --- |
| Confidence | Trust in:   * The effectiveness and safety of vaccines * The system that delivers them, including the reliability and competence of the health services and health professionals and * The motivations of policy-makers who decide on the needed vaccines |
| Complacency | * Vaccination is a victim of its own success as individuals weigh risks of vaccines against risks of diseases that are no longer common resulting in complacency and further hesitancy. * Self-efficacy (the self-perceived or real ability of an individual to take action to vaccinate) also influences the degree to which complacency determines hesitancy. |
| Convenience | * Measured by the degree to which physical accessibility, feasibility and willingness to spend, geographical availability, capacity to understand (linguistic and health literacy) and availability of immunization services determine the uptake of vaccines. * The service quality (real and/or perceived) and the magnitude to which vaccination services are provided at a place and time and in a cultural background that is practical and easily accessible often affect the decision to be vaccinated and could lead to vaccine hesitancy. |

Evaluation of these models highlighted the complexity of vaccine hesitancy and is not influenced by a simple set of individual factors.

**2.8 The Conceptual Frameworks of factors associated with vaccine hesitancy among parents of children with autism.**

In summary from literature review above, the main categories of factors associated with vaccine hesitancy among parents of a child with autism can be divided into: three main domains i.e. individual, contextual and vaccine and vaccine specific issue domains. These have formed the conceptual framework of my study as shown in Figure 2.6. For the conceptual framework of this study, the major variables are vaccine hesitancy which will be determine by the scoring of the PACV-Malay questionnaire. Its associated factors including the two important domains relatively identifiable and measurable.

Some of the factors in the domain were not included in the study as these would require translated and validated measurement tools. Therefore, they are beyond the scope of this study



# **CHAPTER THREE**

# **RESEARCH METHODOLOGY**

## **3.1 Study Design**

The study design used in this research will be a cross-sectional design.

## **3.2 Study Population**

This study will be conducted among parents of children with ASD attending National Autism Society of Malaysia*(*NASOM*)* and Community-Based Rehabilitation (CBR) in Selangor.

## **3.3 Sampling Frame**

The sampling frame will be parents of children with ASD attending National Autism Society of Malaysia*(*NASOM*)* and Community-Based Rehabilitation (CBR) in Selangor from July 2020 till January 2021.

## **3.4 Inclusion Criteria and Exclusion Criteria**

* + 1. **Inclusion Criteria**

This study will include parents more than 18 years old who fulfil the following criteria:

* + 1. Has at least one child with confirmed clinical diagnosis ASD
    2. Able to understand written Malay

**3.4.2 Exclusion Criteria**

This study will exclude parents who unable to read and understand Malay language.

## **Sample Size Determination:**

The sample size is calculated using the OpenEpi Version 3.01 for “Sample

size for a Proportion of Descriptive Study’ from

<http://openepi.com/SampleSize/SSPropor.htm>

The calculations are as below:

Sample size, *n = deff x*

where,

*n* = sample size

*deff* = design effect (for cluster surveys)

*N*  = population size (for finite population correction factor or FPC)

*p* = hypothesized % frequency of outcome factor in the population

= confidence interval

*d* = desired precision

The design effect was set at 1 as this was a cross sectional study design. There is no study done in regard to VH in autism locally and even globally thus the sample size determined from VH in general population. The sample size is determined based on the previous study, where the lowest prevalence of VHP is 11.6% (Mohd Azizi et al., 2017) and the highest prevalence of VHP was 14.5% (Musa, Soni, Cheong, & Nordin, 2019). By taking confidence level of 95%, the sample size calculated based on the prevalence are:

|  |  |
| --- | --- |
| **Prevalence** | **Sample size** |
| **11.6%** | **158** |
| **14.5%** | **191** |

The bigger sample size of 191 is chosen. However, adjusting 20% attrition rate, the minimum sample size needed will be 229.

## **3.6 Sampling Method**

**3.6.1 Sampling Frame**

The sampling frame will be among parents with autism child attending National Autism Society of Malaysia (NASOM) and Community-Based Rehabilitation (CBR) in Selangor.

**3.6.2 Sampling Technique**

This study will be conducted using convenience sampling method until the target sample size is achieved. This sampling method is chosen as there will be difficulty to conduct probability sampling due to the limited time allocated for data collection in this study. 🡪 NOT CONFIRM YET

For the patient recruitment, data collection days will be two days per week for three months. During data collection day, all parents who attended will be approached at the centre with consecutive of every two parents and will be screened for eligibility according to the inclusion and exclusion criteria. Those who are excluded, will substituted with the next two parents. Subsequently, those who fulfilled the criteria will be offered to participate in the study. Finally, those who consent will be given a data collection form, sociodemographic form and PACV-Malay version questionnaire. Recruitment period is planned for six months between July 2020 and January 2020.

**3.6.3 Recruitment and data collection procedures**

For the patient recruitment, data collection days will be two days per week for three months. Data collection procedure will be as described below:

1. All parents attending NASOM and CBR in Selangor will be assessed at the assessment room.
2. Everyone in two parents ≥18 years old will be approached and screened for eligibility.
3. The eligible parents will be invited to participate in the study.
4. Those who fulfll the eligibility criteria and are interested to participate will be given the study information sheet containing important information pertaining to the study which includes the background of the study, purpose of the study, benefit of the study, information regarding participation in the study, study procedure, confidentiality status and researcher contact information. Once they have understood and agreed to participate, written informed consent will be obtained.
5. Patients who consent will be recruited into the study.
6. Sociodemographic data (age, gender, ethnicity, religion, marital status, education level, income, occupation, number of child alive in the house, medical history (of the ASD child) and PACV-Malay version through self-administered will be collected.

## **3.7 Study Tool**

Demography collection sheet and the previously translated and validated PACV questionnaire in Malay version (Halim et al., 2019) will be used as study tool. Permission to use the PACV – Malay version questionnaire from the questionnaire developer has been obtained.

The PACV-Malay version consists of 12 items framed within three factor domains - “General attitudes”, “Safety and efficacy”, and a de novo domain “Schedule and immunity”. The PACV-Malay was reliable with total Cronbach alpha of 0.77. Based on previous validation studies, respondents who scored < 50 can be considered as non-hesitant parents, while those who scored ≥ 50 may be considered as vaccine hesitant parents.

## **3.8 Conduct of the Study**

**3.8.1 Data Collection Plan and Study Procedure**

Data Collection Plan and Study Procedure Patient recruitment period is planned for a total of 6 months (3 months in NASOM and 3 months in CBR). The use of convenience sampling will be vulnerable to selection bias. Therefore, to minimize sampling bias, systematic convenience sampling technique of every two consecutive parents will be approached and invited to participate. Those who are interested to participate will be given the study information sheet containing important information pertaining to the study which includes background of the study, purpose of the study, benefit of the study, information regarding participation in the study, study procedure, confidentiality status and contact information. Once they have understood and agreed to participate, written informed consent will be obtained. Demographics of parents and medical history of the ASD child will be obtained through self-administered questionnaire. Patients will be screened for eligibility according to the inclusion and exclusion criteria. Those who are eligible will be recruited for the study. Data collection of factors associated with vaccine hesitancy among parents of children with ASD will be obtained by the researcher using demographic collection sheet and the Parents Attitude in Childhood Vaccination (PACV)-Malay questionnaire. Clear verbal instructions will be given on how to fill up the questionnaire. Participants will be reminded to complete the questionnaire in approximately 15 minutes without referring to notes or family members. Participants will be free to ask for clarification from the researcher at any time should any query arise. Pen or pencil will be provided to the participants. Once the questionnaire is completed, participants will be requested to return it directly to the researcher. The questionnaire will then be checked for completeness and the participant will be kindly reminded to complete it only if they agree. Patient recruitment period is planned for a total of six months (three months months in NASOM, remaining three months in CBR Selangor). The same researcher will be assigned for the data collection task throughout this period.

## **Statistical Analysis**

Data entry and statistical analysis will be performed using the latest IBM Statistical Package for Social Sciences (SPSS) program.

Descriptive analysis will be used to describe the socio-demographic characteristic, clinical factors and prevalence of vaccine hesitancy. Mean +/- Standard Deviations (SD) will be used to describe continuous data, while frequencies and percentages will be used to describe categorical data.

Inferential analysis will be conducted to determine the associated factors for VH among parents of child with ASD. Odds ratios (OR) and its 95% confidence intervals (CI) will be calculated using logistic regression. Univariate analysis will be conducted by using simple logistic regression to identify factors with p-value of <0.05. These factors will then be analyzed using multiple logistic regression to control for vaccine hesitancy among parents with child of ASD.

## **Operational variables definition**

The study variables that would be studied are factors associated with vaccine hesitancy among parents of children with ASD. It will be described in the Table 3.

Table 3: Operational Variable Definition

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Term** | **Variable in SPSS** | **Definition** | **Operational definition** |
| 1. | Respondent | Respondent | Respondent of the questionnaire | Father  Mother |
| 2. | Age | Age group | Age group of respondents | 1. 18 - 29 years old  2. 30 - 39 years old  3. 40 - 49 years old  4. 50 - 59 years old  5. ≥60 years old |
| 3. | Gender | Gender | Gender of respondent | Male  Female |
| 4. | Ethnicity | Ethnicity group | Ethnicity of respondent | Malay  Chinese  Indian  Others |
| 5. | Religion | Religion | Religion of the respondent | Islam  Buddha  Hindu  Others |
| 6. | Marital status | Marital | Current marital status of respondent | Married  Unmarried  Separated/ Divorced/ Widowed |
| 7. | Education of the parents | Highest education level | Highest education level attained by respondent | No formal education  Primary education  Secondary education  Tertiary education |
| 8. | Occupation | Occupation | Current occupation of respondent | Public Sector  Private Sector  Self-employed  Housewife/ unemployed |
| 9. | Household income | Household income | Household income | Less than RM1000  RM1000 – RM1999  RM2000 – RM2999  RM3000 – RM3999  RM4000 – RM4999  RM5000 – RM 10000  More than RM 10000 |
| 10. | Number of children alive in household | No of children in the house | Number of children in the house | One  Two  Three  Four or more |
| 11. | Past experienced with vaccine? |  |  |  |
| 12. | Which vaccine concern you the most?  And why | Type of vaccine | Type of vaccine most concerned about | BCG  Hepatitis B  DTaP  Hib  IPV  MMR  Why ? |

## **Study variables**

Table 3.1 will show the dependent and independent variables in the study.

Table 3.1: Dependent and independent variables

|  |  |
| --- | --- |
| **Dependent variable** | **Independent variable** |
| Vaccine hesitancy | Sociodemographic factors are;  Respondent  Age  Gender  Ethnicity  Religion  Marital status  Education level  Occupation  Income  Number of children  Vaccine specific issues:  Type of vaccine  Past experienced with vaccine |

**Dependent variable**

Table 3.1.1: Dependent and independent variables

|  |  |  |
| --- | --- | --- |
| **Variables** | **Definition** | **Measurement scale** |
| Vaccine hesitancy | Vaccine hesitancy score  More than 50  Less than 50 | Categorical (nominal) |

**Independent variable**

Table 3.1.2: Dependent and independent variables

|  |  |  |
| --- | --- | --- |
| **Variables** | **Definition** | **Measurement scale** |
| Respondent | The respondent who answer the questionnaire. Being either:  Father  Mother | Categorical (nominal) |
| Age | As stated by the respondent, as actual age in years for the current year | Numerical (continuous) |
| Gender | Male  Female | Categorical (nominal) |
| Ethnicity | As stated by the respondent. Being either:  Malay  Chinese  Indian  Other | Categorical (nominal) |
| Religion | As stated by the respondent. Being either:  Islam  Buddha  Hindu  Other | Categorical (nominal) |
| Marital status | As stated by the respondent, the current marital status either  Married: currently married  Unmarried: not married  Separated/ Divorced/ Widowed: was married before but already separated with the partner | Categorical (nominal) |
| Education | The highest formal educational level obtained by the respondent according to Malaysian Education system:  No formal education  Primary Level: standard 1 to standard 6  Secondary Level: Form 1 to Form 6  Tertiary Level: Form 6/ College/ University | Categorical (nominal) |
| Occupation | As stated by the respondent, the current employment status either:  Public Sector  Private Sector  Self-employed  Housewife/ unemployed | Categorical (nominal) |
| Household income | As stated by the respondent, based on the total household income:  Less than RM1000  RM1000 – RM1999  RM2000 – RM2999  RM3000 – RM3999  RM4000 – RM4999  RM5000 – RM 10000  More than RM 10000 | Categorical (nominal) |
| Number of children in the house | Total number of children in the house  One  Two  Three  Four or more | Categorical (nominal) |
| Past experienced with vaccine |  |  |
| Which vaccine concern you the most? And why | Type of vaccine most concerned about  BCG  Hepatitis B  DTaP  Hib  IPV  MMR  Why ? | Categorical (nominal) |

Proposed study variables

Table 3.2: Demographic distribution of study population (n=196)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **General** | **No VHP (Score less than 50)** | **VHP (Score more than 50)** | **P value** |
| Respondent  Father  Mother |  |  |  |  |
| Age (Mean ± SD) |  |  |  |  |
| Gender (%)  Male  Female |  |  |  |  |
| Ethnicity (%)  Malay  Chinese  India  Others |  |  |  |  |
| Religion  Islam  Buddha  Hindu  Other |  |  |  |  |
| Marital status (%)  Married  Not married  Separated/ Divorced/ Widowed |  |  |  |  |
| Education level (%)  None  Primary  Secondary  Tertiary |  |  |  |  |
| Occupation (%)  Public Sector  Private Sector  Self-employed  Housewife/ unemployed |  |  |  |  |
| Household income  Less than RM1000  RM1000 – RM1999  RM2000 – RM2999  RM3000 – RM3999  RM4000 – RM4999  RM5000 – RM 10000  More than RM 10000 |  |  |  |  |
| Medical problem?? |  |  |  |  |
| Number of children in the house  One  Two  Three  Four or more |  |  |  |  |
| Which vaccine concern you the most? And why  BCG  Hepatitis B  DTaP  Hib  IPV  MMR  Why ? |  |  |  |  |

\*Statistically significant relation (P value < 0.05)

## **3.9 Flow Chart of the Conduct of the Study**

Obtained consent for permission from

1) NASOM

2) JKM for CBR

Parents attending above mentioned center will be approached.

Patients who are interested to participate will be given the study information sheet.

Written informed consent will be obtained from those who agree to participate.

Screening for eligibility will be done according to the inclusion and exclusion criteria.

Sociodemographic data will be obtained through face to face interview.

The PACV Malay version questionnaire will be given to the participants for self-administration.

Data will be analyze using IBM SPSS programme.

Data interpretations and report writing.

## **3.10 Study Limitations**

This study has several limitations. Firstly, the population in this study is limited to parents of child with ASD therefore, the findings may not be generalizable to the population in Malaysia. Second, the study is conducted in Selangor only and as mentioned above it is also may not re-presenting the other population in Malaysia.

## **3.11 Expected Outcomes**

This study will determine the factors associated with vaccine hesitancy among parents of children with ASD. These findings can be used for the healthcare provider for future research to assess the outcome of VH in subpopulation in Malaysia. From this study, we would be able to identify factors associated of VH among parents of child with ASD. Intervention can then be developed and directed in particular towards the ASD population to those associated with vaccine hesitant parents.

# ETHICAL CONSIDERATION

Ethical approval will be obtained from the Research Ethics Committee, Research Management Institute, UiTM before the study is conducted. Patient information sheet will be given to the participants who are interested to participate. Once they have understood and agreed to participate, written informed consent will then be obtained. Confidentiality will be reassured to participants. Information obtained from the questionnaire will only be used for research and educational purpose.

# FUNDING AND BUDGET

This study will be self-funded.

Proposed budget for this study is as followed:

|  |  |  |  |
| --- | --- | --- | --- |
| Budget items | Cost per items (RM) | Number of items | Total cash cost (RM) |
| Paper A4 size | 15 | 6 | 90 |
| Printing | 0.10 per paper | 5 | 115 |
| Stationary (files/pen) | 10 | 10 | 100 |
| Research total | | RM 305 | |

# **GANTT CHART**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Year | 2019 | | 2020 | | | | | | | | | | | | 2021 | | | | | | | |
| Months | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Literature Review |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Proposal preparation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Research proposal defense |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Ethics application |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data collection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exam Part 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thesis writing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mock thesis presentation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thesis submission and defense |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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# **APPENDICES**

**Borang Maklumat untuk Subjek**

**SIKAP IBU BAPA TENTANG VAKSIN (SUNTIKAN IMMUNISASI) DI KALANGAN KANAK - KANAK AUTISME DAN FAKTOR-FAKTOR BERKAITAN DI MALAYSIA**

**Pengenalan Kajian**

Anda telah dijemput untuk mengambil bahagian dalam soal selidik yang bertajuk ”SIKAP RAGU IBU BAPA TENTANG VAKSIN (SUNTIKAN IMMUNISASI) DI KALANGAN KANAK - KANAK AUTISME DAN FAKTOR-FAKTOR BERKAITAN DI MALAYSIA’.

Sikap ragu atau ”*Vaccine hesitancy’* ibu bapa kepada vaksin semakin meningkat bukan sahaja di Malaysia bahkan di dunia. Baru-baru ini, negara kita telah mengalami kemunculan semula penyakit yang boleh dicegah vaksin. Terdapat lonjakan kes penyakit yang boleh dicegah vaksin seperti Penyakit Campak, Difteria dan juga Poliomeilitis. Malahan, kes kematian kanak-kanak akibat daripada lonjakan penyakit yang boleh dicegah vaksin juga dicatatkan. Kebanyakan kes-kes yang berlaku ini adalah di kalangan kanak-kanak yang tidak lengkap vaksin atau tidak di vaksinkan langsung.

Pada tahun 1998, seorang doktor pakar iaitu Dr Andrew Wakefield berserta pasukannya telah membuat satu kajian berkenaan kaitan antara Vaksin 3 serangkai (MMR) dengan masalah usus serta perkembangan kanak-kanak iaitu autisme. Di dalam kajian tersebut, ia melibatkan jumlah sampel yang sedikit iaitu 12 orang kanak-kanak sahaja. Kesemua kanak-kanak itu telah mengalami perkembangan mental yang berkurangan atau dikenali sebagai ‘regression of behaviour’. Kajian ini tidak dilakukan secara berterusan. Ia dilakukan sekejap sahaja dan kajian tersebut tidak dapat membuktikan kaitan vaksin 3 serangkai dengan autisme secara saintifik. Terdapat elemen penipuan yang di buat oleh doktor tersebut. Kemudian, kajian ini telah ditarik balik secara legal dan lesen amalan perubatan doktor tersebut telah diberhentikan. Akan tetapi, masih ada di kalangan ibu-bapa yang masih mempercayai kata-kata pakar perubatan tersebut. Maka daripada saat itu muncul beberapa golongan yang di label sebagai golongan anti-vaksin dan ”pro-choice’. Akan tetapi masih ramai lagi ibu bapa yang di dalam kalangan ragu-ragu terhadap vaksin tetapi tidak di kaji secara menyeluruh di Malaysia.

Tujuan Kajian

Tujuan kajian ini dijalankan adalah untuk mengetahui dan memahami hubung kait sikap ragu terhadap vaksin di kalangan ibu bapa yang mempunyai anak autisme.

**Prosedur Kajian**

Kajian ini memerlukan peserta untuk mengisi borang soal selidik latar belakang, demografi dan soalan kaji selidik tentang sikap ibu-bapa terhadap vaksin (suntikan imunisasi) kanak-kanak.

**Penyertaan dalam Kajian**

Penyertaan anda di dalam kajian ini adalah secara sukarela. Anda berhak menolak tawaran penyertaan ini atau menarik diri daripada kajian ini pada bila-bila masa tanpa sebarang penalti.

**Manfaat Kajian**

Dengan menagmbil bahagian dalam kajian ini, anda memberi peluang kepada para pengkaji untuk mengetahui dan memahami hubung kait sikap ragu terhadap vaksin di kalangan ibu bapa yang mempunyai anak autisme. Sekiranya terdapat perkaitan, kajian ini akan dijadikan bahan rujukan kepada perancang polisi dan kerajaan untuk mengambil langkah pencegahan supaya pendedahan terhadap keraguan vaksin di kalangan ibu-bapa yang mempunyai kanak-kanak autisme dapat di elakkan.

**Risiko Kajian**

Tiada risiko kajian yang akan di alami kerana kajian ini tidak memerlukan anda untuk memberi sampel atau tidak berkait dengan ubatan.

**Kerahsiaan**

Maklumat perubatan anda akan dirahsiakan oleh penyelidik dan tidak akan didedahkan melainkan jika ia dikehendaki oleh undang-undang.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penganalisaan dan penggunaan data hasil dari kajian ini.

Sekiranya anda mempunyai sebarang pertanyaan mengenai kajian ini atau hak-hak anda, sila hubungi penyelidik di talian (012-6871487)

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**Borang Izin**

Untuk menyertai kajian ini, anda diperlukan menandatangani Borang Izin ini.

Saya dengan ini mengesahkan yang saya telah memenuhi syarat umur dan dalam keadaan yang berkeupayaan untuk bertindak untuk diri sendiri/ \*sebagai penjaga yang sah dalam perkara-perkara yang berikut:

Saya memahami ciri-ciri dan skop kajian ini.

Saya telah membaca dan memahami semua syarat penyertaan kajian ini.

Saya berpuas hati dengan jawapan pada kemusykilan saya tentang kajian ini.

Saya secara sukarela bersetuju menyertai kajian ini dan mengikuti segala atur cara dan memberi maklumat yang diperlukan kepada penyelidik seperti yang dikehendaki.

Saya boleh menarik diri daripada kajian ini pada bila-bila masa tanpa memberi sebab.

Saya telah pun menerima satu salinan Borang Maklumat dan Borang Izin.

Kecuali kecederaan yang disebabkan kelalaian dan kecuaian oleh penyelidik, saya dengan ini melepaskan dan menggugurkan UiTM dan semua penyelidik dari semua laibiliti berhubung dengan, wujud dari atau berkaitan dengan penyertaan saya dan bersetuju untuk menjadikan mereka tidak bertanggunggan terhadap apa-apa kerugian atau kecederaan yang mungkin akan saya tanggung disebabkan penyertaan saya.

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Nama Subjek/Penjaga Sah Tandatangan

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No. Kad Pengenalan Tarikh

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Nama Saksi Tandatangan

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No. Kad Pengenalan Tarikh

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Nama Pengambil Izin Tandatangan

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No. Kad Pengenalan Tarikh

**APPENDIX C**

**SIKAP RAGU IBU BAPA TENTANG VAKSIN (SUNTIKAN IMMUNISASI) DI LANGAN KANAK - KANAK AUTISME DAN FAKTOR-FAKTOR BERKAITAN DI MALAYSIA OR**

**FAKTOR – FAKTOR BERKAITAN SIKAP RAGU IBU BAPA TENTANG VAKSIN (SUNTIKAN IMMUNISASI) DI LANGAN KANAK - KANAK AUTISME**

**(FACTORS ASSOCIATED WITH VACCINE HESITANCY AMONG PARENT OF CHILDREN WITH AUTISM SPECTURM DISORDER (ASD) IN MALAYSIA**

**(Fail Rujukan Klinikal)**

Nama Ibu / bapa:

No Kad Pengenalan:

Nama Anak:

No Kad Pengenalan:

Nombor kajian :

Tarikh maklumat dan borang kebenaran ditandatangani:

Lokasi:

Telefon :