Introduction process, statement of the study, purpose,

INTRODUCTION Informedconsent is a relevant aspect of the process where the participant of a studyunderstands and agree for participate in a study. The informed consent processneed to fulfill main objectives which namely the ethical and moral right ofautonomy, freedom of choice and legal authorization for a study.

Itis not only a legal and ethical concern but a core factorin decisional process. Humans need to be treated as autonomous entities, whoare carefree to conduct theirlives without other party controlling their life. Subjects aretreated as autonomous agents in a study if researcher hasinformed them about the study, giving them choice to choose whetherto take part and allow them to refuse fromtaking part in the study, any time with no penalty(Levine, 1986). Informedconsent is an important tool before begin a studyusing human as their subjects.

Taking consent involves process ofnotify the subject about important things such as introduction ofstudy process, statement of the study, purpose, description of riskand discomforts, selection of research subjects, explanationof procedures, description of benefits, disclosure of alternatives, assurance of an anonymity and confidentiality, offer to answer question, voluntary involved in the study, option to retreat and consent toincomplete disclosure for some studies.

By doing so, takingpart and involvement of the subjects in the study isvoluntary.

There areseveral issues related to informed consent regarding research involvinghuman subjects. 1. Diminishedautonomy

There

is an issue with subjects that having diminished autonomy wherethey are vulnerable because of legal or mental incompetence, terminally ill or confinement to an institution such as prisoners(Levigne, 1986). These subjects require additional protection of their right to self–determination because of their inability to give informedconsent. Furthermore, these people are exposed to coercion which happenwhen someone intentionally present an overt threatof harm or an excessive reward to another to obtaincompliance.

2. Children When a studyinvolved younger generation under the age of 18, consent has tobe obtained from parents or caretaker. Often a child’scompetence to give consent is operationalized by age, withincompetence being irrefutable up to age 7 (Broome, 1999). TheU. S Department of Health and Human Services (DHHS) regulation require” soliciting the assent of the children and thepermission of their parents orcaretakers.

During a study, the children need to be given a choice toask questions and to withdraw from study if he orshe desires. 3. Languagebarrier Language barrier is anotherissue involving informed consent. Misunderstandings and misinterpret ofinformation can happen because of incorrect or inadequate languagetranslations. According to Department of Health and Human Services regulationsof US, to protect the human rights, itis mandatory that informed consent information be presented” in language understandable to the subject” and, in most situations, that informed consent be documented in writing. Subjectswho cannot speak English must be

presented with a consentdocument, written in a language that they understand. Theaim of clinical study is to gain and develop knowledge in order to improvehealth for society.

Ethics of clinical study in the contact of clinicalresearch are all about values, norms, correct and wrong, good and bad and whichis must be done and must not be done. Investigators are responsible forresearch ethics to ensure that there is no potential for exploitation and orabuse of human research subjects. Two significant events that have contributedto the development of research ethics; a. Nazi experiments and Nuremberg Trial1946, b. Tuskegee Syphilis study. TheBelmont Report (1979), had come out with three important ethical principlesthat had been accepted and used by worldwide. These 3 fundamental ethicalprinciples are; Respect for person, beneficence and non-malfeasance and lastlyis justice. 1.

Respect for personStartingfrom the participation, in the middle of the participation and until theparticipation have ended, the person should be treated with respect andequally. Respect for person who involve in the research means; the researchershould inform the participants regarding all of the aspects related to thestudy and participant’s decision to participate which means taking consent fromthe participants. Other than that, researcher must protect participant’sconfidentiality and privacy and provide opportunity of early withdrawal withoutpenalty. Besides that, participants need to be monitored during and after thetrails, participants need to be informed regarding new information and detailsand to re-take the consent if necessary. At the end of the study, theparticipants should be informed the result of the study, compensateparticipants to research injury, all of the

information regarding clinicaltrial should be recorded, handled and keep properly. The researcher must makesure the medical records and data of subjects must be keep confidentially.

2. Beneficenceand non-malfeasanceExperiments need to be started and only canbe continued if the advantages are expected to justify the risk. Anassessment of risks and benefits of the research lies on the responsibility ofInternational Review Board (IRB) Independent Ethics Committee and before theresearcher embarking on that particular research. In order to gain interest of science and society, there are some important things to consider which are on the correct, safetyand well-being of the participants.

Medical physicians or qualified medicalpersonnel should hold the responsibilities in giving medical care and medicaldecisions made on behalf on the trial subjects. All trials must havescientifically protocols to ensure research outcomes are accurate andreproducible, researcher should provide adequate information regarding pre –clinical and clinical, research conducted following and IRB approved protocolsand the products of investigational should be manufactured and used based onGood Manufacturing Practice (GMP). 3.

JusticeTrialsubjects should be fairly selected. The selection of subject must be considerof inclusion and exclusion criteria, target group as well as how to approachthem. Furthermore, the selection requires a clear scientific objectivesregarding the study, and not vulnerability, privilege, efficiency or otherfactors unrelated to research purposes. Groups of trial subjects should beaimed especially for risky study or study without advantages, which they

areconvenient or vulnerable. Conclusion Byhaving an insight and awareness regarding these type of issues involve in humansubjects, it is so important to both parties, subjects and researcher. Anymisunderstanding of information eventually will end up with subjects to involvein the study that they not approve of and the three major ethical principlesare the great tool use on the best ethical practices that involved in researchand to bring ethical awareness to their thinking and decision – making.

Researcher need to instillin their mind and heart to treat the subjects accordingly.