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| Subject : \* | Developing Informed Consent Document, and Obtaining and Documenting Informed Consent in Research Involving Human Subjects |
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| **1. Objectives**http://bmc.bdms.co.th/_layouts/images/blank.gif |
| In the conduct of research studies involving human subjects, written informed consent is an important process to ensure that research subjects are fully informed about the study; that they understand it and their right to refuse to participate or to withdraw consent to participate at any time without repercussions. In obtaining informed consent, the investigator should comply with the applicable regulatory requirement(s) and should adhere to Good Clinical Practice (GCP) and to the ethical principles that have their origin in the Declaration of Helsinki. The purposes of this W/P are as following.1. To describe the procedures for preparing, obtaining and documenting initial and ongoing informed consent.
2. To describe steps for fulfilling the requirements of GCP, the ethical principles, and applicable regulations.
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| **2. Scope** http://bmc.bdms.co.th/_layouts/images/blank.gif |
| This WP covers the procedures for developing and revising the informed consent document (ICD) consent and obtaining and documenting initial and ongoing informed consent in research studies which are conducted in the Bangkok Hospital Medical Center (BHMC) involving competent human subjects. This WP does not include obtaining informed consent in research studies where the research subject/participant is incompetent, minor or vulnerable; and usual written consent is impossible or impractical. |

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| **3. Definition**http://bmc.bdms.co.th/_layouts/images/blank.gif |
| 1. Informed consent is a process by which a research subject/participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
2. The investigator is the person responsible for the conduct of the research study at a study site. If a team of individuals at a study site conducts a study, the investigator is the responsible leader of the team and may be called the principal investigator.
3. The sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a research study.
4. The institutional review board (IRB) or independent ethics committee (IEC) is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a study, by among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the study subjects/participants.
5. The legally acceptable representative (LAR) is an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject/participant, to the subject/participant's participation in the research study.
6. The impartial witness is a person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject or the subject’s LAR cannot read, and who reads the informed consent form and any other written information supplied to the subject.
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| **4. Roles and Responsibilities**http://bmc.bdms.co.th/_layouts/images/blank.gif |
| This W/P applies to all BMC personnel who are involved in developing and revising ICDs and in obtaining and documenting informed consent in medical research involving human subjects. This may include personnel who are taking the role of principal investigator, sub-investigator, study/research coordinator, study/research nurse, study/research manager or study monitor, and sponsor and IRB/IEC.* The principal investigator is responsible for preparing, obtaining and documenting the informed consent. The investigator may delegate those responsibilities to other hospital personnel. However, the investigator should make sure that they are appropriately qualified by education and training to assume the assigned responsibilities, and the informed consent process complies with this W/P, GCP and applicable regulations.
* IRB/IEC is responsible for initial and continuing review and approval of a study protocol, ICD and other materials or method that will be used in obtaining and documenting informed consent from research subjects/participants in a research study. IRB/IEC may provide advice on the informed consent process for a research study where the research subject/participant is incompetent, minor or vulnerable, and written consent is impossible or impractical.
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| **5. Procedure/Work Process** http://bmc.bdms.co.th/_layouts/images/blank.gif |
| 1. General Requirements
	1. The informed consent document (ICD), comprises the research subject/participant information sheet and consent form, is a written information tool used for conducting  consent discussions with potential research study subjects. In addition, the ICD serves as an ongoing reference for the participating subjects and provides written confirmation that informed consent was appropriately obtained.
	2. Freely-given informed consent should be obtained from every research subject/participant prior to the initiation of any study-related procedures. The consent must be voluntary and without coercion or inducement. Adequate documentation of the consent is required to verify that consent was obtained appropriately.
	3. Informed consent is an interactive process that is ongoing throughout the participant’s involvement in the study.
	4. The person who conducts a process of informed consent should be appropriately qualified by education and training. The assignment and qualification of that person should be documented.
	5. In preparing, obtaining and documenting informed consent, the investigator and the sponsor should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
	6. Prior to the beginning of the trial, the investigator should have the IRB’s written approval of the written ICD and any other written information to be provided to subjects.
	7. For a research study where the subject/participant is incompetent, minor or vulnerable or where written consent is impossible, the research should be done only after consideration and approval of IRB/IEC. Consent should be obtained and documented as advised by the IRB/IEC in accordance with applicable regulations.
	8. For a research study where  a physician is an investigator, the physician should be particularly cautious if the potential research subject/participant is in a dependent relationship with the physician or may be at risk of consenting under duress. In such situations the informed consent process should be conducted by an appropriately qualified person who is completely independent of this relationship.
2. Preparing the Informed Consent Document (ICD)
3. Prepare a draft ICD based on the final study protocol and information about the investigational medicinal product.
4. The research subject/participant information sheet must contain all the applicable elements listed in the Checklist of Required Elements in an ICD (F/M-04-RSD-008).
5. Use language that is non-technical and understandable to the research participant, and with respect to their culture of research.
6. Use a consistent, clear font that is easy to read.
7. Use simple/concise sentences and paragraphs with clear subheadings. If information is complicated, bulleted lists, tables, charts or diagrams may help to make the information more comprehensible.
8. An example checklist of headings and subheadings for the information sheet is provided in F/M-04-RSD-004.
9. Write the ICD as though the person who conducts the informed consent process is speaking to the potential research subject/participant; therefore use you and your, we and our, rather than third person, and use active voice rather than passive voice.
10. If acronyms are used, they must be spelled out in full the first time they appear.
11. Do not use exculpatory language through which the research subject/participant or the legally acceptable representative is made to waive or appear to waive any of his/her legal rights.
12. Do not use language, which releases or appears to release the investigator, the hospital or the sponsor for liability from negligence.
13. Include references to the protocol, the name of the study site/hospital, the version number and date of version, page number and total number of pages (Page X of Y) in the footer of each page of the ICD.
14. If the information sheet is lengthy, a summary of the information or key facts section at the beginning of the information sheet is recommended; however make sure that the potential research subject/participant will read the full information before considering consent.
15. For the informed consent form, use the Research Subject/Participant Consent Form (F/M-03-BHMC-070) as the template.
16. Proofread the ICD for spelling and grammar.
17. The principal investigator should make the final review and approval by using the Informed Consent Document (ICD) Review and Approval Form (Attachment 3). The signed and dated approval form should be filed in the study folder.
18. If the original ICD has to be translated to another language, forward  and backward translations should be performed by qualified translators. The Certificate of Translation should be issued by the translator and filed in the study folder.
19. Obtaining and Documenting Informed Consent
20. Before the conduct of informed consent, review the version and page of the ICD to ensure that the most recent version of the IRB/IEC-approved ICD is used and all pages are present.
21. Fully inform the potential research subject/participant or subject/participant’s LAR of all pertinent aspects of the research study as described in the ICD, in non-technical language that is easy for him/her to understand.
22. Provide the potential subject/participant or subject/participant’s LAR with a copy of the ICD to read and comprehend the essential information described in the ICD.
23. Allow the potential subject/participant or subject/participant’s LAR ample time to read the ICD and ask questions; all questions must be answered. If requested, allow him/her to take the ICD home to review with his/her family members or other trusted person.
24. Ensure that the potential subject/participant or subject/participant’s LAR has understood the information. It is recommended to ask questions of the potential subject/participant or subject/participant’s LAR to assess his/her comprehension of the information.
25. If the potential subject/participant or subject/participant’s LAR agrees to participate in the research study, he/she must sign and personally date two copies of the ICD.
26. The investigator/designee who conducted the informed consent must also sign and personally date the ICDs. An ICD must not be signed or dated by a person  not involved in the informed consent process.
27. If required, the impartial witness can sign and personally date the ICDs.
28. Provide the subject/participant or subject/participant’s LAR with a copy of the signed and dated ICD; the other copy will be retained in the investigator file.
29. Document the informed consent process in the source document (e.g., medical record) including the study name or protocol identifier, consent obtained date, and name of the person who conducted the informed consent.
30. Consent Renewal
31. Revise the ICD whenever important new information becomes available, which may be relevant to a research subject/participant’s willingness to participate in the research study or to continue his/her participation. The revision to ICD may be based on safety reports, update of information of the investigational medicinal product, amendments to the study protocol, or recommendation from IRB/IEC or the Data and Safety Monitoring Board.
32. Revise the version number and date of version in the footer of ICD.
33. Submit the revised ICD to IRB/IEC with reason(s) for review and [seek?] approval.
34. Use the IRB/IEC-approved revised ICD in obtaining and documenting consent for the ongoing research subject/participants and for a new potential research subject/participant.v.      Maintain all related documents for audit trail.
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| **6. Workflow** http://bmc.bdms.co.th/_layouts/images/blank.gif |
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| **7. Communication Channel & Training** http://bmc.bdms.co.th/_layouts/images/blank.gif |
| To be conduct : the document tracking system for use the renewal ICD (update; version date) and other related document such as Protocol, Participant Information sheet: PIS .  |

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| **8. Monitoring and Measuring** http://bmc.bdms.co.th/_layouts/images/blank.gif |
| All research studies involving human subjects conducted at BHMC will have periodic monitoring by assigned monitors from the Research and Development Unit.The monitors will verify ICD and other related documents to ensure that informed consent from all research subjects/participants in each research study have been obtained and documented in accordance with this W/P, GCP and applicable regulations. |

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| **9. Reference**http://bmc.bdms.co.th/_layouts/images/blank.gif |
| 1. World Medical Association, Declaration of Helsinki, <http://www.wma.net/en/30publications/10policies/b3/index.html> (accessed on 14 May 2014)
2. International Conference on Harmonization (ICH) Guideline for Good Clinical Practice, <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf> (accessed on 14 May 2014)
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**Relevant Documents:**

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| **Document Code** | **Document Name** | **Revision** |
| [F/M-03.1-IRB-001](http://bmc.bdms.co.th/dms/_layouts/DMS/Forms/DMS0I077.aspx?ID=3864) | หนังสือแสดงเจตนายินยอมเข้าร่วมโครงการวิจัย (Informed consent form) | 00 |
| [F/M-04-RSD-003](http://bmc.bdms.co.th/dms/_layouts/DMS/Forms/DMS0I077.aspx?ID=3867) | Clinical Study Staff Signature and Delegation of Responsibility Log | 02 |
| [F/M-04-RSD-004](http://bmc.bdms.co.th/dms/_layouts/DMS/Forms/DMS0I077.aspx?ID=3868) | Informed Consent Document Review and Approval Checklist | 02 |
| [F/M-02.2-IRB-001](http://bmc.bdms.co.th/dms/_layouts/DMS/Forms/DMS0I077.aspx?ID=3876) | เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย/อาสาสมัคร (Participant Information Sheet) | 02 |
| [W/I-01-RSD-001](http://bmc.bdms.co.th/dms/_layouts/DMS/Forms/DMS0I077.aspx?ID=4110) | โครงสร้างองค์ประกอบหน่วยงานวิจัยและพัฒนา คุณสมบัติบทบาทบุคคลากร และการอบรม (Research and Development Organization, Personnel Qualification and Training) | 07 |