

BIOMEDICAL INFORMED CONSENT DOCUMENT

Date of Revision	Section	Approx. Pg #	Description
7/1/2009	all	all	Page 1 of "21" changed to Page 1 of "25" at the bottom of every page.
7/1/2009	all	all	Date at top right hand corner of every page revised from 09.10.08 to OHRS 07.01.09.
7/1/2009	Notes to Informed Consent Authors	2	"COMBINATION PHASE STUDIES (e.g. Phase I/II): Generally, the IRB will review separate consent forms for each phase of the study. Only the consent form for the phase that is open needs to be submitted. Please contact OHRS if both the Phase I and Phase II portions will be open to enrollment concurrently." was inserted as a bullet point at the top of the second page.
7/1/2009	A	2	The last sentence of the first paragraph under Section A was revised from "This research study is evaluating a __ [drug, device, etc.] called __ [if applicable include the following] as a possible treatment for __ [disease or condition]." to read "This research study is evaluating a __ [drug, device, etc.] called __ [insert name of investigational agent][do not include the following for phase I studies:] as a possible treatment for __ [disease or condition]."
7/1/2009	A	3	"If you choose not to participate in this research study, the" replaced "The" in the last sentence of the second to last paragraph under Section A.
7/1/2009	B	3	"If the study is a combination phase study, e.g., Phase I/II, please only describe the applicable phase and a statement such as "This is a Phase I/II clinical trial. You are being asked to participate in the Phase II portion of the study. Phase II clinical trials..." Please contact OHRS if you have any questions." was added as the second sentence of the first paragraph under Section B.
7/1/2009	B	3	"[This section should also clearly explain what portions of the protocol are investigational/experimental from regular cancer care, as appropriate.]" was added as a second paragraph under Section B.
7/1/2009	B	3	"combination of drugs /" was inserted in the second sentence to read: "Phase I clinical trials test the safety of an investigational __ [drug / combination of drugs / intervention]."
7/1/2009	B	3	"/ combination of drugs" was inserted in the third sentence of the third paragraph under Section B to read: "Phase I studies also try to define the appropriate dose of the investigational __ [drug / combination of drugs / intervention] to use for further studies."
7/1/2009	B	3	"/ combination of drugs" was inserted in the fourth sentence of the third paragraph under Section B to read: ""Investigational" means that the __ [drug / combination of drugs / intervention] is still being studied and that research doctors are trying to find out more about it."
7/1/2009	B	3	"/ combination of drugs" was inserted in the last sentence of the third paragraph under Section B to read: "[NOTE: If the study drug has not been approved for any use, please use "...has not approved __ [drug / combination of drugs / intervention]..."
7/1/2009	B	3	"combination of drugs /" was inserted in the second sentence of the fourth paragraph under Section B to read: "Phase II clinical trials test the effectiveness of an investigational __ [drug / combination of drugs / intervention] to learn whether the [drug / combination of drugs / intervention] works in treating a specific cancer."

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	B	3 & 4	"/ combination of drugs" was inserted in the third sentence of the fourth paragraph under Section B to read: ""Investigational" means that the ___ [drugs / combination of drugs / intervention] is still being studied and that research doctors are trying to find out more about it-such as the safest dose to use, the side effects it may cause, and if the ___ [drug / combination of drugs / intervention] is effective for treating different types of cancer."
7/1/2009	B	4	"/ combination of drugs" was inserted in the last sentence of the fourth paragraph under Section B to read: "[NOTE: If the study drug has not been approved for any use, please use "...has not approved ___ [drug / combination of drugs / intervention] for use in patients..."
7/1/2009	B	4	"drug" replaced "treatment" in the second sentence of the fifth paragraph under Section B to read: "Phase III clinical trials compare ___ [e.g.: "the study drug with the treatment..."
7/1/2009	B	4	"[Please briefly describe, using non-technical terminology, the rationale for the study, e.g., why and how researchers think the study drug will affect the cancer cells. Use plurals as appropriate.]" was inserted as the first sentence of the sixth paragraph under Section B.
7/1/2009	C	4	"in bulleted format all" was replaced with "only those" in the first sentence of the first paragraph under Section C to read: "... [include only those items that are appropriate ;..."
7/1/2009	D	5	"[or, if applicable: a calendar]" was inserted in the last sentence of the first paragraph under Section D to read: "[If appropriate, add - "We will also provide you with a chart [or, if applicable: a calendar]..."
7/1/2009	D	5	"treatments" was replaced with "when you take the study drug" in the last sentence of the first paragraph to read: "...that will be an easy reference for you to keep track of the procedures when you take the study drug in this research study."
7/1/2009	D	5	"These" was replaced with "Many of these" in the second sentence of the second paragraph to read: "Many of these tests and procedures are likely to be part of regular cancer care..."
7/1/2009	D	5	Both opening and closing parenthesis were removed from the first bulleted paragraph.
7/1/2009	D	5	"Performance status, which evaluates how you are able to carry on with your usual activities." was inserted as a second bullet.
7/1/2009	D	5	","including tests to measure any additional effect of the study drug and disease status, or if a marker for your particular type of cancer exists" was replaced with "or" in the fourth bullet.
7/1/2009	D	6	"Additional research procedures to be performed at the time of screening: [This section typically lists the procedures that must be completed before registration, but are not procedures to determine eligibility:" was added as a second paragraph on page 6.
7/1/2009	D	6	"Blood tests, [if appropriate: including baseline tests so that we can measure any additional effect of the study drug and disease status], [and/or if appropriate add: or to look for a marker for your particular type of cancer.]" was added as the first bullet under the second paragraph on page 6.
7/1/2009	D	6	"After the screening procedures confirm that you are eligible to participate in the research study: [This section typically lists the procedures that must be completed after registration.]" was added as a third paragraph on page 6.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	D	6	"Recommend that you describe the procedure so the participants understand what will happen and then outline in a table when the procedures will occur." was added as the first bullet under the third paragraph.
7/1/2009	D	6	"State whether the study drug will be available after the study ends." was added as a second bullet under the third paragraph.
7/1/2009	D	6	"After the screening procedures confirm that you are eligible to participate in the research study: [Detail the procedures. Give instructions for clinic visits. State whether the study treatment will be available after the study ends." was removed from the third bullet under the third paragraph.
7/1/2009	D	6	"Specific instructions about how to take the drug, vomited and missed doses, etc., should be included in the drug diary and not in the informed consent document." was added as a fourth bullet under the third paragraph.
7/1/2009	D	6	Opening bracket was removed before "Sample text..."
7/1/2009	D	7	"Medication" was replaced with "Study Drug(s):" in the second paragraph on page 7.
7/1/2009	D	7	"medication" was replaced with "drug" to read: "If you take part in this research study, you will be given a drug-dosing calendar..."
7/1/2009	D	7	"three" was replaced with "____" to read: "Each treatment cycle lasts ____ weeks..."
7/1/2009	D	7	"the first 2 weeks only. During the third week you will not be taking the study medication. You will take your medication (tablets) by mouth, once a day in the morning, preferably on an empty stomach, 1 hour before the breakfast. You will take your medication daily, for 2 weeks." was replaced with "____ (days or weeks) or on (days ____)."
7/1/2009	D	7	"Physical" was replaced with "Clinical" to read: "Clinical Exams:" in the third paragraph of page 7.
7/1/2009	D	7	"treatment" was removed from the first sentence of the third paragraph to read: "Clinical Exams: During all cycles you will have a physical exam..."
7/1/2009	D	7	"Imaging" was replaced with "Photographs" in the fifth paragraph.
7/1/2009	D	7	"treatment" was replaced with "dose of the study drug" in the sixth paragraph to read: "After the final dose of the study drug:..."
7/1/2009	D	7	"The schema from the protocol should not be used as it is generally too complex, however, a simplified version of the schema is encouraged." was revised to read: "The schema from the protocol should not generally be used as it is usually too complex; however, a simplified version of the schema is encouraged. The main purpose of the schema/chart is to tell participants when the procedures described above will be conducted.]"
7/1/2009	D	9 - 12	"Example of a simplified chart" was added on page 9 and a chart was inserted on pages 9-12.
7/1/2009	E	9	", however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study." was inserted at the end of the first sentence of the last paragraph under Section E to read: "In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study."
7/1/2009	F	9	"only" was inserted in the second paragraph under Section F to read: "[Standard language - use only when appropriate for the study:]"
7/1/2009	F	9	"chemotherapy" was replaced with "cancer" in the first sentence of the first paragraph on page 14.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	F	10	"chemotherapeutic" was replaced with "cancer" in the second to last sentence of the last paragraph on page 14.
7/1/2009	F	11	"Do not include information like "one participant experienced xyz...". Instead, include these risks under rare below." was removed from the third check-marked bullet.
7/1/2009	F	11	"Please do not include information that will become out of date or need to be updated. For example, instead of stating "Of the thirty individuals who have received this drug to date, ten have experienced the following side effects..." please generally state: "The following side effects have been experienced by individuals who have received this drug." Similarly, instead of stating "one participant experienced xyz...", please include these risks under the rare risks." was added as the last paragraph on page 15.
7/1/2009	F	11	"Please refer to the Common Risk Language Database available at the OHRS website for lay terminology: www.dfhcc.harvard.edu/ohrs and look under "New Submissions." was added as a check-marked bullet at the top of page 16.
7/1/2009	F	11	"If there are required interventions associated with the administration of the study drug, then those risks should also be included. For example, if the administration of the study drug requires the placement of a central line, then include those risks." was added as the second check-marked bullet on page 16.
7/1/2009	F	11	"Only" was inserted in the first sentence of the first paragraph to read: "NOTE for Cooperative Group Trials Only :"
7/1/2009	F	11	"This often is both the most straightforward way to handle this, avoids potentially missing toxicities that are essential to include for cooperative groups and will be easier to maintain with future amendments." was added as the last sentence of the "NOTE for Cooperative Group Trials Only" paragraph.
7/1/2009	F	11	"the" and "grouped as outlined below" were inserted in the second paragraph on page 16 to read: "NOTE for Phase I Trials: Where known, the percentages, grouped as outlined below, should be used to categorize risks associated with drugs used in the trial."
7/1/2009	F	12	"Additionally, if this is a dose escalation study, please include a statement such as the following: "One risk is that you may get a dose of the study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects." was added as a third paragraph.
7/1/2009	F	12	"this categorization should be adapted to specific study agents by the consent author" was replaced by "if the exact percentages are not known, then the terms likely, frequent, occasional, are rare can be used without including the associated percentage categories." in the fourth paragraph.
7/1/2009	F	12	"NOTE re what risks to include: Please list risks for the following:" was added as the last paragraph on page 16.
7/1/2009	F	12	"Risks associated with the investigational drug, device or biologic" was added as the first check-marked bullet under the last paragraph on page 16.
7/1/2009	F	12	"Risks associated with drugs or combination of drugs being evaluated as part of the study regardless of whether they are used on or off label" was added as the second check-marked bullet under the last paragraph on page 16.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	F	12	"Risks associated with any procedures that will be performed only as part of the research (i.e., the procedures would not be conducted if the participant were not participating in the study)" was added as the third check-marked bullet under the last paragraph on page 16.
7/1/2009	F	12	"Risks associated with any procedures required to administer the drugs, e.g., placement of a central line.] was added as the fourth check-marked bullet under the last paragraph on page 16.
7/1/2009	F	12	"(Chance of more than 50% that this will happen)]" was revised to read: "(More than a 50% chance that this will happen)]" under Likely Risks Associated
7/1/2009	F	12	"(Chance of 10-50% that this will happen)]" was revised to read: "(Between a 10-50% chance that this will happen)]" under Frequent Risks Associated
7/1/2009	F	12	"(Chance of 1-10% that this will happen)]" was revised to read: "(Between a 1-10% chance that this will happen)]" under Occasional Risks Associated
7/1/2009	F	13	"(Chance of less than 1% that this will happen)]" was revised to read: "(Less than a 1% chance that this will happen)]" under Rare Risks Associated
7/1/2009	F	13	"of Sites other than Bone Marrow" was removed from "Risks Associated with Biopsies" in the last paragraph on page 17.
7/1/2009	F	13	"the" was replaced to read: "Include only what pertains to thee research study.]" in the last paragraph on page 17.
7/1/2009	F	13	"Radiation" was removed and "Radiological" was inserted to read: "Risks Associated with Radiological Scans and X-Rays:" in the second paragraph on page 18.
7/1/2009	F	13	"[For studies that involve standard radiation risks, use the following language." was replaced with "If there is a reasoned argument that the scans/x-rays are consistent with clinical care, then these risks need to be included." in the first sentence of the second paragraph on page 18.
7/1/2009	F	13	"radioactive agents" was replaced with "scans utilizing radioactivity" to read: "While you are in this research study, CT scans, PET/CT scans, Bone Scans, x-rays, mammograms, and/or other scans utilizing radioactivity ..." in the second paragraph on page 18.
7/1/2009	F	13	"similar to that which" was replaced with "slightly greater than what" to read: "The frequency of these exams is slightly greater than what you would receive as standard care." in the second paragraph.
7/1/2009	F	13	"There" and "small" were replaced with "In the long term, over many years, there" and "low," respectively, to read: "In the long term, over many years, there is a very low risk of developing a new cancer as a result of the radiological evaluation..." in the second paragraph.
7/1/2009	F	13	"therapy" was removed and "have a" and "greater" were replaced with "further" and "increase the", respectively, to read: "Certain types of drugs or combinations of these drugs with radiation may further slightly increase the risk of developing a new cancer." in the second paragraph.
7/1/2009	F	13 & 14	"[Include only if appropriate:] There is a small risk with using the contrast agent that is injected into a vein during the scan. It may worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study." was added as a third paragraph on page 18.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	F	14	"[Include only if appropriate:] Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast agent. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare." was added as a fourth paragraph on page 18.
7/1/2009	F	14	"[If there is a reasoned argument that the scans/x-rays are consistent with clinical care, then these risks need not be included." was inserted as a first sentence in the fifth paragraph.
7/1/2009	F	14	"that are more frequent than standard of care" was inserted into the second sentence in the fifth paragraph to read: "For studies that involve ONLY mammograms that are more frequent than standard of care, you may use the following language."
7/1/2009	F	14	"Radiation" was removed and "Radiological" was inserted in the second to last sentence of the fifth paragraph to read: ""Risks Associated with Radiological Scans and X-Rays."]
7/1/2009	F	14	"similar to that which" and "small" were replaced with "greater than what" and "low" at the top of page 19.
7/1/2009	F	14	"[If done for screening purposes only, please include the following:]" was inserted at the beginning of the first paragraph on page 19.
7/1/2009	F	14	"MRIs use powerful magnets to make images. Therefore, persons with certain metal implants, such as pacemakers should not have an MRI. (If you have an implant or any metal in your body, please check with your study care doctor to know whether you can have an MRI or not.) For people without metal implants, there are no known health risks associated with exposure to the magnet." was removed from the second paragraph.
7/1/2009	F	14	"only" was inserted into the first sentence of the third paragraph to read: "[Include only if appropriate:]"
7/1/2009	F	14	"Recent information has suggested that gadolinium, the contrast agent, may contribute to kidney disease." was replaced with "It may worsen kidney function in people who already have decreased kidney function." in the third paragraph.
7/1/2009	F	15	"only" was inserted into the first sentence of the fourth paragraph to read: "[Include only if appropriate:]"
7/1/2009	F	15	"Rarely" was replaced with "Uncommonly" and "to the contrast agent. On rare occasions, allergic type reactions" and "have occurred" were replaced with "to the contrast agent" in the fourth paragraph.
7/1/2009	F	15	"or" was replaced with "," and a comma was removed from the last sentence in the fourth paragraph to read: "Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction..."
7/1/2009	F	15	"[For certain agents, such as thalidomide and related compounds, additional risks should be included as appropriate. Additionally, if the sponsor intends to collect information on a pregnant partner, the pregnancy or the delivery outcome, this collection of information is human subject research and the pregnant partner is a research participant. Accordingly, a separate informed consent document should be provided to obtain informed consent from the pregnant partner.]" was added as the second paragraph.
7/1/2009	H	16	"You can still get your medical care from your hospital or doctor" was replaced with "outside of the research study" in the last sentence on page 20.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	H	16	"stopping" and "/ combination of drugs" were inserted in the second paragraph to read: "It is important to tel the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the ___ [drug / combination of drugs / intervention]."
7/1/2009	I	16	A new section was added on page 21 to read the following: " I. Will I Be Paid To Take Part In This Research Study? "
7/1/2009	I	16	"[Please state whether participants will receive payment for participating in this study. If they will receive payment, please describe. Please note that this section should not be used to describe compensation for research related injuries which is covered later in this consent form." was added as the first paragraph under Section I.
7/1/2009	I	16	"When the research might lead to a medical discovery that could result in the commercial development of a product or medical test, include the following statement: We may use your samples and information to develop a new product or medical test to be sod. The sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.]" was added as a second paragraph under Section I.
7/1/2009	J	16	"I." was replaced with "J." at the beginning of "What Are The Costs" in order to begin a new Section.
7/1/2009	J	16	"avoid listing specific costs" was replaced with "state whether the cost of the study drug will be covered. Please do not list who will cover payment for costs for procedures" in the second paragraph under Section J.
7/1/2009	J	17	"[If appropriate, include the following] You will not be charged for ___ [insert drugs]." was added as a third paragraph under Section J.
7/1/2009	J	17	", [if applicable, add "including the following study drugs...."]." was inserted at the end of the second to last sentence at the top of page 22 to read: "You or your insurance company will be charged for portions of your care during this research study that are considered standard care, [if applicable, add "including the following study drugs...."]."
7/1/2009	K	17	"J." was replaced with "K." at the beginning of "What Happens If I Am Injured Or Sick Because I Took Part In This Research Study?" in order to begin a new Section.
7/1/2009	K	17 & 18	"and do not include any exculpatory language, i.e., language that suggests to participants that they are giving up rights or benefits." was added as the last sentence of the first paragraph under Section K.
7/1/2009	K	18	"Institutional Names**" was added as a title at the top of page 23.
7/1/2009	K	18	"Note that DF/HCC is not a legal entity. Accordingly, please use the following table to appropriately identify the institution(s) name to be inserted in the blank below:", as well as a table listing various institutions were inserted below the title on the top of page 23.
7/1/2009	K	18	"DF/HCC" was replaced with " _____ [DF/HCC insert appropriate DF/HCC** institution name here as described in table above, as well as sponsor name if applicable]" in the second paragraph on page 23.
7/1/2009	L	18	"K." was replaced with "L." at the beginning of "What About Confidentiality?" in order to begin a new Section.
7/1/2009	M	19	"L." was replaced with "M." at the beginning of "What About Confidentiality?" in order to begin a new Section.
7/1/2009	M	19	"If you choose to also include sponsor language, please remove duplicative information." was inserted at the end of the first sentence under Section M.

BIOMEDICAL INFORMED CONSENT DOCUMENT

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7/1/2009	N	19	"M." was replaced with "N." at the beginning of "Whom Do I Contact If I Have Questions About The Research Study?" in order to begin a new Section.
7/1/2009	O	20	"N." was replaced with "O." at the beginning of "Privacy Of Protected Health Information" in order to begin a new Section.
7/1/2009	P	22	"O." was replaced with "P." at the beginning of "Optional Research Studies" in order to begin a new Section.
7/1/2009	Q	23	"P." was replaced with "Q." at the beginning of "Documentation Of Assent" in order to begin a new Section.
7/1/2009	R	24	"Q." was replaced with "R." at the beginning of "Documentation Of Assent" in order to begin a new Section.
7/1/2009	R	24	"understand" was replaced with "have been told" in the fourth bullet under section R.
7/1/2009	R	25	" <input type="checkbox"/> participant is a non-English speaker and signed the translated Short Form in lieu of English consent document." was added underneath the box.
7/1/2009	R	25	" <input type="checkbox"/> was inserted before "The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:" at the top of page 30.
7/1/2009	R	25	"parent or legally authorized representative is a non-English speaker and sign the translated Short Form in lieu of English consent document." was added as a second <input type="checkbox"/> under "For Minor Participants"
7/1/2009	R	25	" <input type="checkbox"/> was inserted before "The parent or legally authorized representative did not giev permission for the minor to participate.