

HAC Policies and Procedures

Informed Consent Documents/Childrens' Assent Documents

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Informed Consent Documents/Childrens' Assent Document(s) Preparation Guide

A. Formatting Requirements:

1. The first page must use MCG or MCGHI letterhead, if an MCG or MCGHI study. If letterhead is not available, the MCG seal with the trademark TM or the MCGHI symbol with the TM may be used. The trademarked seals and symbols must be used in compliance with their true size and not manipulated (<http://www.mcg.edu/egr/elements.htm>). NOTE: Studies that recruit from or are conducted at the Augusta VAMC must use the VA Form 10-9012 and follow the guidelines in the section for the Augusta VAMC.
2. The first page must state "Research Informed Consent Document" or "Research Children's Assent Document", as applicable.
3. All pages must have a bottom margin of at least 1.25" on each page (to allow adequate room for HAC approval stamp).
4. Do not use a font size smaller than 12 pt (Times New Roman or Arial is recommended). NOTE: If the primary subject pool is visually impaired, this size may be enlarged to accommodate their needs.
5. Pagination – MUST be in upper right corner of each page as follows: Page 1 of ___ Pages (The Header feature in most word processing software is useful for this item.) Paginate ICD and/or CAD independently from the Description of Research Proposal (DRP).
6. Subject's name and medical record number in upper right corner of each page. NOTE: If MCGHI is not a performance site, the medical record number may be deleted. The Header feature in most word processing software is useful for this item.
7. Version date of document must appear in lower left corner of each page as follows: Version date: 10/01/1999. The Footer feature in most word processing software is useful for this item.
8. Include space for the subject's initials on lower right corner of each page for MCG and MCGHI ICD and/or CAD except for the signature page. The Footer feature in most word processing software is useful for this item.
9. Protocol/study title (MUST be word for word identical to title on the protocol, investigator's brochure, [Form FDA 1572](#), all HAC forms and the Division of Sponsored Programs Administration (DSPA) paperwork).
10. Name of Principal Investigator (PI): State the PI's name.
11. PI address: Include the current institutional address of the PI.
12. PI telephone number: The 24-hour number for the PI must be included.
13. Name(s) of Sub-investigators (sub-I): State the name(s) of the Sub-Is. NOTE: Only list those sub-I that are proposed to the HAC to obtain informed consent.
14. Name of Sponsor: State the name of the external sponsor.
15. Study Barcode to include the word "Study" and the barcode for computer scanning

B. Required Sections of the Informed Consent Document (ICD):

Invitation to Take Part in Research:

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Discuss the voluntary nature of the research study. This section should include instructions for the potential research subject to read the consent document carefully and ask questions before they agree to participate. [45 CFR 46.116(a)].

Purpose of the Study:

Clearly explain in language understandable to the subject the study design of the research which [45 CFR 46.116(a)]. NOTE: Although the information is similar to the Description of Research Proposal (DRP), please do not simply cut and paste the information here as these two documents are for two different target audiences.

Information About People Taking Part in the Study:

Indicate the reason why the subject was invited to take part in the study [45 CFR 46.116(a)]. Use lay terms whenever possible.

Give the approximate number of subjects involved in the study at MCG, MCGHI, or other local locations. If this is a multi-center study, indicate how many subjects will be enrolled from all sites. [45 CFR 46.116(a)]

Study Procedures:

Give a clear, concise description of the protocol to be followed, and procedures to be performed, *in language understandable to the subject*. [45 CFR 46.116(a)] This section should explain exactly what the subject's participation would involve, with particular attention to the way it will be experienced by the subject. As applicable, the language should be clear about:

- The frequency and length of hospitalization
- Clinic follow-up
- Types of medications
- Questionnaires
- Videotapes, photographs, or audio recordings
- Diets
- Withholding of standard treatment
- Types and numbers of tests
- Amount of exercise
- Stress to be experienced
- Amount of blood to be withdrawn (in lay terms, e.g. Ounces, teaspoons, number of small tubes)
- Amount of radiation to be received (similar to a chest x-ray, GI series, etc.)
- Size of scar to be expected after biopsy, etc.

Indicate the duration of the research subject's participation, and be specific about the number of visits and how long each will take [45 CFR 46.116(a)].

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Identify any procedures which are experimental.

Identify any procedures that are standard of care.

For drug and device studies, state whether a placebo(s) and/or randomization will be used.

Indicate if the study design is double-blind.

Risks:

Describe any reasonably foreseeable risks or discomforts to the research subject [45 CFR 46.116(a)]:

- Physical
- Psychological
- Social
- Legal

Research subjects should be warned that their condition may not improve or may worsen, despite participation.

Inform the research subject that all concomitant medications, including over the counter (OTC) medications and/or herbal or vitamin and minerals supplements must be communicated to the research team.

For drug and device studies, describe any potential drug interactions with other prescription, over-the-counter (OTC), herbal, vitamin or mineral supplement.

Where applicable, indicate whether a particular treatment or procedure may involve currently unforeseeable risks to the research subject (or to the embryo or fetus, if the subject is or may become pregnant).

For drug and device studies, since some medications may be transferred in seminal fluid, indicate whether that could be a risk to partners of men who are taking study medication, if the partner becomes pregnant. Include information on reproductive risks for embryos, fetuses, women who are pregnant or breastfeeding and men.

Indicate that there may be more risks that are not known or not expected.

For device studies, include an explanation of likely results if the procedure or device should fail if an investigational device is involved.

For research involving more than minimal risk, state whether any compensation or medical treatments are available if injury occurs, and if so, what they consist of, or where

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further information may be obtained. If there is no compensation for research related injury then the informed consent document must state that information and provide an estimate of the costs associated with treatment of the injury.

Benefits:

Describe any benefits to the research subjects or others that may reasonably be expected from the research. State if there are no direct benefits to the research subject. [45 CFR 46.116(a)] Indicate that although society may gain from the results of the study, the research subject may not personally benefit. Payment, free study drug or free treatments for the injury are not benefits to the research subject.

Alternatives/Other Options:

Describe any alternative procedures or courses of treatment that might be advantageous to the research subject. [45 CFR 46.116(a)] State if the only alternative is not participating in the study.

Ending the Study:

Where applicable, indicate that any significant new findings that develop during the study, which may affect the research subject's willingness to participate, will be provided to the research subject and state how the information will be provided. [45 CFR 46.116(a)]

Where applicable, indicate the investigator regardless of the research subject's consent may terminate the research subject's participation, and if possible, describe the circumstances under which this might happen. [45 CFR 46.116(a)]

Where applicable, describe the consequences of a research subject's decision to withdraw, and the procedures for orderly termination of participation by the subject. [45 CFR 46.116(a)]

Financial Information:

State whether the research subject will be paid for participation or for reimbursement of expenses, and if so, how much and when. Indicate if the payment or reimbursement will be prorated and paid at each visit or paid upon completion of the study. Indicate if the study was approved for cash payments as a means for compensation for participation in a confidential research project. Indicate if the subjects will be paid via check and give an approximation of the time lapse between the visit and the payment, if applicable. If the study involves children, then indicate that the parent will receive the check, if applicable.

Indicate the reporting requirements to the IRS if participation fees will be \geq \$600 in any one calendar year.

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Clearly indicate costs to the research subject and state whether additional costs may result from participation in the research. [45 CFR 46.116(a)]

For research involving more than minimal risk, state whether any compensation or medical treatments are available if injury occurs, and if so, what those consist of, or where further information may be obtained.

If the study has no outside indemnification of the institution, inform the research subjects of the potential risks, but also the costs of such injuries will have to be borne by the research subjects or their third party payer. The ICD should also note that the third party payer may refuse to pay these costs.

New Findings or Information about the Study:

Where applicable, indicate that any significant new findings that develop during the study, which may affect the research subject's willingness to participate, will be provided to the research subject and state how the information will be provided. [45 CFR 46.116(a)]

Banking and Future Use of Tissue Samples and Cultures: (If Applicable)

Indicate if there is a possibility or products of commercial value coming from the research, e.g., a cell line of commercial use.

Confidentiality, Privacy Notice and Authorization to Use or Disclose (Release) Health Information:

Explain the extent (if any) to which confidentiality of records will be maintained [45 CFR 46.116(a)]

Provide a complete description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record (NOTE: The Description of Research Proposal (DRP) must provide justification for the use of all information in the medical record, if requested, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.) Be as specific as possible for this study.

Indicate what confidential information will be collected, used and shared with others.

Indicate who will collect, use and share the research subject's confidential information.

Discuss the research subject's rights to review a copy of their confidential information that has been collected, used, or shared with others under the authorization.

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Indicate what will happen to the research subject's confidential information after the study is over or if they cancel their authorization.

Indicate how long the research subject's confidential information will be used and shared with others.

Include information on the Certificate of Confidentiality and the use of the research subject's confidential information, if applicable. This section is not applicable if this study has not received an approved Certificate of Confidentiality from the National Institutes of Health (NIH).

Contact Information for Answers to Your Questions:

Indicate whom, and how, the subject should contact for answers to pertinent questions about the research, the rights of research subjects, whom to contact about concerns or complaints about the research, and whom to contact in the event of research-related injury of the subject. [45 CFR 46.116(a)]. For drug and device studies, an emergency (24/7) phone number must be provided for the local PI or sub-I who is familiar with the study.

Voluntary Participation:

Indicate that participation is voluntary, and that the subject may refuse to participate, or may later withdraw from the study without penalty or loss of benefits to which they are otherwise entitled [45 CFR 46.116(a)].

Include a checklist of documents the subject will receive, if applicable.

C. Required Language

Financial Information Section

Payment to Subject

You will be paid no more than \$____ (not to exceed \$500) for your participation in this project. You certify that you are not presently a participant in any other research project conducted by the Medical College of Georgia (MCG) during the same calendar year that you are participating in this project. If you are a participant, you agree to disclose all other payments that you have received.

Or

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If you receive \$600 or more in payment in one (1) calendar year for participating in research studies at the Medical College of Georgia (MCG), this will be reported to the Internal Revenue Service (IRS) as required by law.

Costs to the Subject

You will be responsible for the costs of transportation to the Medical College of Georgia (MCG) for clinic visits, but there will be no hospital or doctor bills for the study.

Or

There may be some hospital or doctor bills for the study which may be billed to you or your insurance company. Your insurance company may not pay for any medication (device, treatment) that is experimental. If they do not pay, you may become responsible for the costs associated with this treatment.

The Medical College of Georgia (MCG) assumes no obligation to pay any money or provide free medical care in case this project results in any harm to you. If you become injured as a direct result of your participation in this clinical study, medical treatment will be provided and the costs of such treatment will be paid by (sponsor's name).

Or

The Medical College of Georgia assumes no obligation to pay any money or provide free medical care in case this project results in any harm to you. The possible risks of participation were described to you and discussed with the investigator. The costs, which may include medical treatments, laboratory tests, and a possible stay in the hospital, may amount to (**cost approximation here**), or more. The exact costs cannot be determined at this time since any harm to you would be unforeseen. Your insurance company may not pay for such treatments, in which case payment of the costs will be your responsibility. By agreeing to this you do not give up your rights to seek compensation in the courts.

Required HIPAA Language for the Privacy Notice and Authorization for Disclosure

Privacy Notice

The researchers are asking for your written authorization before using your health information or sharing it with others in order to conduct the research as described. However, under certain circumstances, the researchers may use and disclose your

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health information without your written authorization if they obtain approval through a special process to ensure that research without your written authorization poses minimal risk to your privacy. Under no circumstances, however, would the researchers allow others to use your name or identity publicly.

The researchers may also disclose your health information without your written authorization to people who are planning a future research project, so long as any information identifying you does not leave our facility.

Information about people who have died may be shared with researchers using the information of deceased persons, as long as the researchers agree to not to remove from our facility any information that identifies these individuals.

Only the investigator, the members of the research team, the sponsor (*include sponsors name*), authorized officials from state and federal governments such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP) and authorized representatives of the MCG Health System will have access to confidential data which would identify you, unless specifically required to be disclosed by state or federal law. You will not be identified in any reports or publications resulting from the study.

By federal law, (insert approved PI name) cannot be required to identify you in a disclosure to anyone not connected to the research. However, if you are paid for participation, you will be identified to the person at the Medical College of Georgia (MCG) who authorizes payment to you.

MCG/MCGHI is required by law to protect your health information. By signing this document, you authorize MCG/MCGHI to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your health information with others without your permission, if permitted by laws governing them.

Use one or the other from the examples of optional elements that may be relevant to the participant:

If we remove all identification from your information, then we may use it or disclose it for other purposes.

When the research involves treatment and is conducted by MCG Health System:

To maintain the integrity of this research study, you generally will not have access to your personal health information. At the conclusion of the

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research and at your request, you generally will have access to your health information MCG Health System maintains in a designated record that includes medical information or billing records. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you. If it is necessary for your care, your health information will be provided to you or your physician.

If you revoke this Authorization, you may no longer be allowed to participate in the research.

Please note that **[include only the appropriate statement(s)]**:

You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.”

Use when the research involves treatment and is conducted by the MCG Health System or when the covered entity provides health care solely for the purpose of creating protected health information to disclose to a researcher

This will not affect your ability to receive other treatment.

Use the language below when the research does not involve research-related treatment by the MCG Health System or when MCG Health System is not providing health care solely for the purpose of creating protected health information to disclose to a researcher

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke your Authorization, **[name or class of persons at the MCG Health System involved in the research]** may still use or disclose your information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator at the address on page one of this document.

This Authorization will expire on (expiration date or event, such as **“end of the research study.”**)

Or

This Authorization does not have an expiration date.

The following paragraph must be included:

If you have questions concerning the privacy of your information, please contact the MCG Privacy Officer, Christine Adams at (706) 721-5631, or through our

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Toll Free Hotline, 1-800-576-6623. Written inquiries or complaints may be sent to the: Privacy Officer, Medical College of Georgia, Room HS-3135, 1120 15th Street, Augusta, Georgia 30912.

New Findings or Information about the Study:

You are to be informed if the study provides any new information that might affect your decision to participate, so that you may decide whether to continue the study. This information may be shared with you at your scheduled study visit.

Your doctor may ask you to stop participation in the study for scientific reasons or for your safety, or if (the sponsor stops the study)...

Your doctor has told you that if you should decide to withdraw from the study, you should not stop the medication without contacting him/her so that ...

Banking and Future Use of Tissue Samples and Cultures: (If Applicable)

The tissue samples taken from you will be made available to the Medical College of Georgia and other scientists engaged in research, which may ultimately lead to the development of medical products or processes. The sample may also be made available to the public and private organizations that are participating in research with the Medical College of Georgia. MCG makes no commitment to provide financial compensation or property rights to you.

Answers to Your Questions

(insert investigator's name), who can be reached at (insert telephone number) will answer any further questions you may have at any time concerning the study, the procedures, and any injuries that may appear to be related to the research. In case of an emergency, (insert investigator's name) may be reached at (insert emergency number). If you have any questions about your rights as a research subjects, you may contact the Chairperson of the Human Assurance Committee, Dr. George Schuster at (706) 721-2991.

Voluntary Participation

Your participation in this study is voluntary. You may revoke your consent and withdraw from the study now or any time in the future without penalty or loss of care or other benefits to which you are otherwise entitled.

You have read this form that serves as an informed consent document. This form also serves as your authorization for MCG/MCGHI to use and disclose your protected health information in the manner described as a study participant. You have been given the opportunity to ask questions about the information on this

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form. If you have questions later, you can contact (*insert contact person name*) at (*insert telephone number of contact person*). You will be given a signed copy of this form for your records.

Signature Block

A parent or guardian must sign for all children (<18 years of age). Children aged 7 or older, when appropriate, must participate in the informed consent process and give signature as described above.

Subject's Name (print)

Subject's Signature

Date

Legally Authorized Representative or Parent/Guardian's Name (print)
(*if applicable only*)

Legally Authorized Representative or Parent/Guardian's Signature
(*if applicable only*)

Date

Witness' name (print)

Signature of Witness to the informed consent
process and the signature of the subject and/or subject's
legally authorized representative or parent and/or legal guardian

Date

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the subject's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the subject's medical record or research chart, as applicable. A copy of this document will be given to the subject or the subject's legally authorized representative.

Printed name of investigator obtaining consent

Signature of investigator obtaining consent

Date

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Are There Templates for Different Types of Research Consents?

Yes. Please refer to the HAC web site.