****

*Department Name*

*Department Address*

*Toledo, Ohio 43614*

*Phone #*

*Fax #*

*After following the instructions, please delete all items in red print.*

*If your Consent/Authorization form has an odd number of pages, please remember to include an additional page labeled "NO TEXT THIS PAGE" as page two of the form before copying the entire form double-sided. Please be sure to assign the "NO TEXT THIS PAGE" a page number and include the IRB number.*

**ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM and AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

**RESEARCH PROJECT TITLE**

*(Capitalized and bolded, must match the title on the IRB application)*

Principal Investigator:       , [*M.D., Ph.D., etc.*]

Study Coordinator: [Optional]

Contact Phone number(s): (419)

Study Sponsor: [If applicable]

**Key Study Information:**

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Toledo or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

The purpose of this study is [Briefly describe the purpose of the study].

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include [Indicate reasonably foreseeable risks. An example is serious health complications.] More detailed information will be provided later in this document.

[SELECT ONE OF THE OPTIONS BELOW]

[This study may offer some benefit to you now or others in the future by [Briefly summarize]. More information will be provided later in this document.

OR

[This study may not offer any benefit to you now but may benefit others in the future by [Briefly summarize]. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be [Indicate total time commitment].

Your participation is voluntary. You can decide not to be in this study, or agree to take part now and change your mind later. If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.

Alternatives to joining this study include [Briefly address alternatives such as standard of care alternatives or other clinical trials]

# **PURPOSE (WHY THIS RESEARCH IS BEING DONE)**

You are being asked to take part in a research study of *state what is being studied****.*** The purpose of the study is to*state what the study is designed to discover or test (if the study is for an investigational drug or device, you should indicate that the study is to test effectiveness and safety of the drug or device when appropriate in addition to including the sentence:* ***“***An investigational drug or device is one which has not been approved by the U.S. Food and Drug Administration (FDA).”

You were selected as someone who may want to take part in this study because *state why the subject was selected and include the approximate (maximum) number of subjects in the study at UT and elsewhere.*

**DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT**

If you decide to take part in this study, you will be asked to *describe the procedures to be followed, including the purposes of the procedures, how long they will take, and their frequency. In describing the procedures involved in the study, you should list and describe standard treatment procedures as well as experimental procedures. Please clearly distinguish which procedures are experimental and which are approved standard of care. For approved standard of care procedures, please indicate which of these are being done solely for the purposes of this research. Include the expected duration of the subject's participation. Please list these procedures in an organized manner (e.g. in the order that the participant will be asked to complete them.) A format using bullet points is recommended for research involving multiple procedures and/or visits*.

*If applicable to the study, include a statement about whether clinically relevant research results, including individual research results will be disclosed to subjects, and if so, under what conditions.*

*If applicable to the study, provide a statement about whether the research study will or might include whole genome sequencing.*

# **RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH**

*Describe reasonably foreseeable risks, discomforts or inconveniences to persons choosing to take part in this research that are associated with the procedure (experimental or non-experimental) that is being done solely for the purpose of this research. This includes health, legal, economic, psychological, privacy, confidentiality and security risks. When there are multiple risks or discomforts, these should be listed in a bullet point or table format. Be sure to state the likelihood and seriousness of the risks. If this is a treatment study, add this statement:* ***“***Your condition may not get better or may become worse while you are in this study.”

*State and explain risks, if any, to pregnant women. If the risk is significant, add the following section (i.e. Risks to Unborn Children). If there is no known additional risk to pregnant women, please state that there are no known additional risk to pregnant women.*

*NOTE: The following section is required if there is a known risk or a potential for risk to unborn children.*

# **RISKS TO UNBORN CHILDREN**

This research represents a significant risk to unborn children. Therefore, if you are a female of childbearing potential, you will be given a pregnancy test prior to the start of this research. If this test is positive, you will not be able to take part in this research. If your pregnancy test is negative at present

and you choose to take part in this research, you will be given information on birth control procedures that must be used while you are taking part in this research so that you can avoid getting pregnant. You also will be told about the danger to the fetus (unborn child) should you become pregnant.

*If applicable, add:* **“**Males who are sexually active must take precautions while participating in this research so that that their female partners do not become pregnant. If you are a sexually active male and wish to take part in this research, you will be offered information on birth control procedures that you and your partner must use while taking part in this research so that your female partner does not become pregnant. You also will be advised as to the danger to the fetus should your partner become pregnant.”

Please be sure to ask the researcher any questions that you may have about acceptable methods of birth control and the risk to you, your partner or your unborn child at any time before or, if you decide to enroll, while you are taking part in this research.

# **POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH**

*Describe any non-financial benefits to the subject or to others that may reasonably be expected from the research. Clearly state if the benefit is expected to be primarily for others. If benefits are mentioned, add:* We cannot and do not guarantee or promise that you will receive any benefits from this research.

# **COST TO YOU FOR TAKING PART IN THIS STUDY**

*Specify what costs are the responsibility of the study sponsor and/or Principal Investigator and which are the responsibility of the subject. If there is a possibility of additional costs to the subject because of participation, this must be disclosed. Please note that billing of third-party payors for costs that a subject would not incur if he/she was not taking part in this research is not allowed according to* [*UT’s policy pertaining to subject injury*](http://hsc.utoledo.edu/research/subject_injury_policy.pdf) *(unless otherwise allowed by written authorization of the Federal government (as with some special uses of devices/drugs). Billing of third party payors for routine medical care is allowed only if the cost of the care is not covered by a grant or through a contract with the sponsor. If your research is sponsored, please refer to the approved grant application or executed contract if you have any questions about this.*

# **PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH**

If you decide to take part in this research you will receive *If the subject will receive any compensation for their participation, describe the amount or nature. Compensation may include money, free treatment, free medications, or free transportation. Money may be offered to reimburse expenses, time, inconvenience and transportation. However, money may not be used as an inducement to assume risks. Pro-rated subject payment based on how much of the study the participant completes must be stated and the method of pro-rating explained*.

*[If applicable, add]:* If you receive payment for taking part in this study, The University of Toledo will collect your name, address, social security number, payment amount, and related information. The information collected will be used for processing the payment to you. The University of Toledo is required to submit this information to the Internal Revenue Service (IRS) when you receive any individual or collective payments greater than $599.

*NOTE: The following section must be included for industry-sponsored research in which the institution is being reimbursed for all or some of the costs of the research.*

# **PAYMENT OR OTHER COMPENSATION TO THE RESEARCH SITE**

The University of Toledo is receiving money or other benefits from the sponsor of this research as reimbursement for conducting the research.

## **ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH**

*Indicate appropriate alternative procedures or courses of treatment, which may be advantageous to the subject, if any treatment is required. Any standard treatment that is being withheld must be disclosed. Include a statement that one alternative is no further therapy. Palliative care should be included as an alternative if appropriate. IF APPLICABLE, state that a potential participant will receive standard care whether or not he/she participates in the research study.*

# **CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION**

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

**How researchers will protect my information?**

Describe procedures that will be followed to keep subject information, specimens, and tissues secure and confidential. For example: “Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record." Or: “Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.”

*New element of consent: Include one of the two options below:*

*1.* The identifiable information or biospecimens that are collected from your participation in this research will not be used or distributed for future research.

*OR*

*2.* With your permission, the identifiable information or biospecimens that are collected from your participation in this research may be used in future research studies without your consent, but only after your identifying information has been removed from the information. If you do not grant permission for your data to be de-identified and used for future research purposes, you **can** still participate in the research described in this document. Your agreement to this is voluntary and there are no consequences should you decline to allow your data to be used for future research purposes. [Indicate any additional risks the future research may pose and describe efforts to minimize them].

If you agree to allow us to use and/or share your de-identified information or biospecimens for future research purposes, please place your initials here: \_\_\_\_ (opt-in) ; if not \_\_\_\_ (opt-out)

**What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Signing this form gives the researchers your permission to obtain, use, and share protected health information about you for this study, and is required in order for you to take part in the study.

# **What else should I know about the use and disclosure of my health information?**

Participation in research involves using and sharing your health information to conduct the research. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. By agreeing to take part in this research study, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

Anything not included in information to be reviewed or recorded should be removed from the list below.

* Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
* Mental health care records (except psychotherapy notes not kept with your medical records)
* Alcohol/substance abuse treatment records
* HIV/AIDS status
* Sexually transmitted disease and/or other communicable disease status
* Genetic counseling/genetic testing records
* Health plan/health insurance records
* All records relating to your condition, the treatment you have received, and your response to the treatment
* Billing information
* Demographic information
* Personal identifiers
* Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects.
* University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the Institutional Review Board may need the information to make sure that the study is done in a safe and proper manner.
* Study sponsors or funders, or safety monitors or committees, may need the information to:
	+ Make sure the study is done safely and properly
	+ Learn more about side effects
	+ Analyze the results of the study
* Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study. Your insurance company may ask us for a signed copy of this informed consent form in order to pre-certify you for the care that is billed to them.
	+ If you agree to allow us to provide a signed copy of this form to your insurance company, please place your initials here: \_\_\_\_ (opt-in);if not \_\_\_\_ (opt-out)

*Do not delete the bullet below unless you are certain that the data or specimens will not be used for future IRB-approved research studies or a technology transfer or licensing agreement. Contact Office of Technology Transfer if you are uncertain.*

* The researchers may need to use the information to create a databank of information about your condition or its treatment.

*Do not delete the first bullet below unless you are certain information will not be included in the medical record.*

* Information about your study participation may be included in your regular UTMC medical record.
* Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but the publication would not include any information that would let others know who you are.

We will use this information to *describe the use of the information or purpose for disclosing the information, or delete the word "to" and state “for the purpose of conducting the research study as described in the research consent/authorization form”*.

The information that we will use or disclose includes *describe the information or nature of information in a specific and meaningful manner, including the source or location of the information*. We may use this information ourselves, or we may disclose or provide access to the information to *[state the name or other specific identification of the persons, class of persons, or agencies that could receive the information (e.g. Food and Drug Administration or other applicable governmental agencies (for the purpose of safety, efficacy and compliance reports), study sponsor and its designees (for study oversight and monitoring), coordinating center (for data collection and study monitoring), outside laboratories (for processing of specimens), other sites participating in this research (for multi-institutional studies), statistician (for analysis of data), etc.]* as part of the research study.

[If applicable, add] “We may also use your information to contact you after this study is closed to update your contact information should we decide it is important to continue following your progress, or to open a new study to follow-up on people who take part in this study.” *If post-study contact is optional, add:* “To authorize research staff from The University of Toledo to contact you to update your information or invite you to participate in a new follow-up study, place your initials here: (opt-in); if not \_\_\_\_ (opt-out).”

Under some circumstances, the Institutional Review Board, or the Research and Sponsored Programs of the University of Toledo or their designees may review your information for compliance audits.  If you receive any payments for taking part in this study, your personal information and limited information about this study will be given to The University of Toledo’s accounts payable department as necessary to process payment to you. We may also disclose your protected health information when required by law, such as in response to judicial orders.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. However, the information we disclose with your permission may no longer be protected by privacy laws. This means your information could be used and re-disclosed by the persons we give it to without your permission.

Your permission for us to use or disclose your protected health information as described in this section is voluntary. However, you will not be allowed to participate in the research study unless you give us your permission to use or disclose your protected health information by signing this document.

*Optional paragraph when subjects’ access to their protected health information is suspended during a research study that includes treatment:*

Your access to your own protected health information *[or describe with particularity how much of the record is restricted]*may be denied during the term of the research study, but you can access your information once the research study is completed***.***

You have the right to revoke (cancel) the permission you have given to us to use or disclose your protected health information at any time by giving written notice to *[list the name and address of the research study personnel that should receive the revocation]*. However, a cancellation will not

apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation as necessary to maintain the integrity of the research study.

Except as noted in the above paragraph, your permission for us to use and disclose your protected health information *[state an expiration date or expiration event that relates to the individual or the purpose of the use or disclosure of information. “Will stop at the end of the research study” or “has no expiration date” may be appropriate, especially if the study involves the creation or maintenance of a research database or repository.]*, unless you cancel it sooner. If you withdraw your permission, you may no longer be eligible to participate in this study.

A more complete statement of University of Toledo’s Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo’s Privacy Officer at 419-383-6933.

[If applicable, add:] “A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*,* as required by U.S. Law. This Web site will not include information that can identify you. You can search this Web site at any time and in order to find information on this trial, you can specifically search for NCTXXXXXXXX.”

[Federally funded, not FDA regulated Clinical Trials, add:] “Once the study has finished enrolling participants, a copy of the template for this consent form will be uploaded to a website called Regulations.gov, in the Docket folder: https://www.regulations.gov/ (Docket ID: HHS-OPHS-2018-0021) as required by U.S. Law. This Web site will not include information that can identify you.”

**What happens to information about me after the study is over or if I cancel my permission to use my PHI?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

* To avoid losing study results that have already included your information
* To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
* To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Toledo Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Toledo “Notice of Privacy Practices”. This information is also available on the web at https://utmc.utoledo.edu/ut-medical-center/patients/pdfs/privacy\_notice\_pract.pdf. Note that once your information has been shared with others as described above, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

*Note for sponsored research: Following review and approval by the sponsor and the UT Research and Sponsored Programs Administration, the UT IRB may request modifications to the indemnification language contained in the “In the Event of a Research Related Injury” section of the Consent/Authorization form. Grayed language has been approved by Legal Counsel and should not be modified.*

# **IN THE EVENT OF A RESEARCH-RELATED INJURY**

If you suffer a research-related injury, medical treatment is available, but you can choose where to go for treatment.

The Sponsor has made conditional plans to reimburse The University of Toledo for medical costs for certain research related injuries. The study doctor can provide further information about reimbursement from the Sponsor. The Sponsor does not offer other compensation. *Delete this paragraph if payment for injury is not available from the sponsor, such as for investigator-initiated or government-sponsored research.*

The University of Toledo and The University of Toledo Medical Center do not offer reimbursement for medical expenses or other compensation for research-related injuries. In the event that any medical expenses are not reimbursed by the Sponsor, they will be billed to you or your insurance.

By signing this form you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact: ***You must provide the name and 24-hour phone number the responsible contact person(s) here. Please be sure to separate this statement from the rest of the sentence so that it can be easily identified.***

# **VOLUNTARY PARTICIPATION**

Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.

# **NEW FINDINGS**

## You will be notified of new information that might change your decision to be in this study if any becomes available.

*Study specific option.*

**POST-STUDY COMPLETION PERMISSION TO CONTACT**

Participation in ***this*** study includes permission to contact you after the study ends (*specify frequency*) to update your contact information so we know how to reach you should we decide that it is important to continue following your progress or open a new study to follow-up on people who take part in this study. We may also ask questions about (*specify)*.

*[If applicable]* **OTHER IMPORTANT INFORMATION**

*If the research involves a study drug or placebo that is being taken home, include:*It is important that you are the only one that takes the study drug or placebo that you are given as part of this research. (*NOTE: Delete “placebo” if not applicable)* It is very important that you keep it (these) out of the reach of children and persons who may not be able to read or understand the label.

*[If applicable]* **GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)**

*If the research involves analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes, insert the following paragraphs:*

Because we are collecting samples from you for genetic testing, we have included this section to inform you of laws and policies that are in place to protect patients.

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Under this law:

* Health insurance companies and group health plans may not request your genetic information that we obtain from this research
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
* Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

* Members of the US Military receiving care through Tricare
* Veterans receiving care through the Veteran’s Administration (VA)
* The Indian Health Service
* Federal employees receiving care through the Federal Employees Health Benefits Plans

# **ADDITIONAL ELEMENTS**

# *Include this section when there is information that needs to be included in this document, but does not apply to the other sections.*

*If applicable to the study, include a statement of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*

*If applicable to the study, include anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent/authorization and procedures for orderly termination of participation by the subject.*

*If applicable to the study, include a statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

*If any member of the research team has a potential financial conflict of interest in the outcome of the study, subjects must be informed about the nature of the conflict. Example text: “[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to [company name] that will be used in this research. This means [conflicted individual] could gain financially from this study.”*

*Note: All of the following information (from "Offer to Answer Questions" to the end of the document) is an integral part of the consent form and cannot be divided between two pages.* *Please remember to insert an additional page in this document (as the 2nd single sided page) with "*NO TEXT THIS PAGE*" typed on it when appropriate (see instructions on top of first page) if this document has an odd number of single-sided pages. If there is a large gap in text between "Offer to Answer Section" and the section prior to it, please type "CONTINUED NEXT PAGE" in the gap.*

|  |
| --- |
| **OFFER TO ANSWER QUESTIONS**Before you sign this form, please ask any questions on any aspect of this study that is unclear to you.  You may take as much time as necessary to think it over. If you have questions regarding the research at any time before, during or after the study, you may contact *[insert name of one or more researchers and their telephone number(s)].* If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, please feel free to contact the Chairperson of the University of Toledo Biomedical [or Biomedical Cancer] Institutional Review Board at 419-383-6796.  |
| **SIGNATURE SECTION** **(Please read carefully)****YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH.** |
|  |  |  |  |  |  |
| **BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.** |
|  |  |  |  |  |  |
| The date you sign this document to enroll in this study, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study*.* Each page of this Consent/Authorization Form is stamped to indicate the form’s validity as approved by the UT Biomedical [or Biomedical Cancer] Institutional Review Board (IRB). |
|  |  |  |  |  |  |
| Name of Subject (please print) |  | Signature of Subject or Person Authorized to Consent |  | Date |  |
|  |  |  |  |  | a.m. |
| Relationship to the Subject (Healthcare Power of Attorney authority or Legal Guardian) |  | Time | p.m. |
|  |  |  |  |  |  |
| Name of Person Obtaining Consent (please print) |  | Signature of Person Obtaining Consent |  | Date |  |
|  |  |  |  |  |  |
| Name of Witness to Consent Process (when required by ICH Guidelines) (please print) |  | Signature of Witness to Consent Process (when required by ICH Guidelines) |  | Date |  |
| **YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.** |

q:\common\shared\forms\regcomp\irb\rga305.doc revised: 087/05