Informed Consent Form
(name of institution)

Informed Consent Template and Guidelines

Guidance is provided in blue. Do not include this blue text in your document.

- *Use Page 1 of 2 numbering on each page as in the footer below*
- *Leave space on each page for the IRB approval stamp*

Use understandable, jargon-free, non-technical language at a 6th-grade reading level.

- *Readability can be evaluated in Microsoft Word:*
  - *Choose "Tools" then "Options."*
  - *Click the "Spelling & Grammar" tab*
  - *Select both "Check grammar with spelling" and "Show readability statistics."*
  - *Readability is displayed after you run a spell check.*
- *In Virginia, minors/children are younger than 18. If your study involves children, complete the VULNERABLE SUBJECTS FORM at http://richmond.bonsecours.com/physicians-forms-irb-submission-forms.html AND insert the following text in the Introductory Paragraph to explain the use of "you" rather than "you/your child"*

Throughout this consent, "***You"*** refers to the parent or legally authorized representative AND your child.

TITLE OF THE STUDY: Evaluation of Efficacy of Clarity vs. Confusion in the Use of Informed Consent

INVESTIGATOR: Dr. John Doe

SPONSOR: Drug Company, Inc.

OTHER INVESTIGATORS:

Participant's Printed Name: _____

Sample Introductory Paragraph

We invite you to take part in a research study *(title*) at *(location*), which seeks to identify a more effective means of treating *(illness, condition*). Taking part in this study is entirely voluntary. We urge you to discuss any questions about the study with our staff. Talk to family and friends and take your time to make a decision. If you decide to participate you must sign this form to show that you want to take part.

Purpose of the Research

- *Use language that is free of jargon and technical or medical terminology.*
- *Define medical/research terms in simple language. For example, "random selection is like flipping a coin."*
- *If conducting research with pregnant women, describe therapeutic benefits that are expected.*

Sample Purpose Statement

You are being asked to take part in this research study because *(state why the individual was selected, e.g., condition, age, or healthy volunteer).* This research study is being done to find out… **OR** The purpose of this research is to …**OR** The purpose of this research study is to obtain information on the safety and effectiveness of

(name of drug, device, etc.). Approximately *(number)* people will take part in this research *(nationwide or worldwide)* and about *(number)* people are expected to take part at *(your location)*.

Procedures

- *Describe all experimental procedures.*
- *If the research receives any funding, include the name of the sponsor(s).*
- *If applicable, explain what a Pilot, Phase I, II, III, or IV drug study is.*

Describe specific procedures and explain exactly what will happen if the individual decides to take part. Describe any selection criteria in detail. Clearly identify procedures that are experimental.

Time Duration of Study and Procedures

- *Specify the time required if a participant commits to take part in the study.*

Sample Time Duration Statement

If you agree to take part in this study, your involvement will last approximately (*length of participation)*. You will be asked to return to the clinic *(number)* times. Each clinic visit will take approximately *(number)* minutes.

Risks and Discomforts

- *Include any foreseeable risks or discomforts, quantifying each risk/discomfort (common, rare, percentage)*
- *If the study involves a placebo, define placebo (eg., "substance that contains NO medication")*
- *Describe any contraindications/complications that may result/arise*
- *Note any precautions that will be taken to protect the participant*
- *Research that will not harm the life or physical integrity of an unborn child is permitted with parental consent.*
- *Therapeutic or potentially therapeutic research on pregnant women is permitted.*
- *Therapeutic research is defined as research that may confer benefit holistically, not only physically.*

Sample Risks and Discomforts Statements

While participating in the study, you are at risk for the following side effects: (list side effects)
These effects may vary from person to person. Drugs may be given to make some of the side effects less serious or uncomfortable. Many side effects go away after the drug is stopped but, in some cases, the side effects may be serious and/or lasting.

If applicable, the following wording is required to conform to Catholic Ethical & Religious Directives:

You cannot take part in this study if you are pregnant or breast-feeding a child. You must agree not to become pregnant while you are in this study. If you are able to have children, you must use safe methods to remain without pregnancy during the study. The ways you agree not to become pregnant must be discussed with and approved by the doctor before you enter the study. The method chosen must continue for the duration of the study. If you become pregnant during the study, you must tell the doctor immediately. You will then be removed from the study. The doctor will advise you regarding your medical care.

Potential Benefits

Describe: 1) potential benefits to the participant; and 2) potential benefits to others. Payment to subjects is not a benefit; it is a compensation for time and expenses of participation. Compensation should not be included here.

Sample Potential Benefit Statement

(For clinical research from which direct benefit is possible) The possible benefit you may experience from (research drug/device/procedure) includes (list benefits that may be reasonably expected). However, there is no guarantee that you will benefit from being in this research.

(For research with no direct benefit) You will not benefit from taking part in this research study.

(Potential benefits to others) *The results of this research may guide the future treatment of…OR Medical science may gain further understanding of….*

Alternatives

- *Include alternative procedures or treatments, if any, that might be advantageous to the participant.*
- *One alternative is always possible: to not participate in the study and, instead, receive routine treatmen*t.

Other (drugs/devices/treatments) can be used to treat (diagnosis/condition). Dr. Doe will explain these.

Privacy and Confidentiality

Describe how all confidential information will be treated, stored, and maintained and for what length of time, as well as how materials will be disposed of at the end of the study.

Sample Statement of Confidentiality

1) Records that are reviewed, stored, and analyzed at *(location)* will be kept in a secured area in (*location*). *If specimens are collected:* Your samples will be labeled with *(code, initials, etc.)* and stored *(location).*

2) Records/samples sent to different entities or labeled differently, will be kept in a secured area in *(describe each confidentiality measure and location separately)* Records/*specimens* sent to *(location)* will not be identified by name, social security number, address or phone number. These records/*specimens* may include (*code, initials, date of birth, etc.)*. The coded list that matches your name will be kept in a locked file in *(location)*.

Mandatory statements for all research studies:

In the event of any publication or presentation resulting from this research, no personally identifiable information will be shared. We will keep your participation in this study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research:

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *For drug/device studies, add the U.S. Food and Drug Administration*
- The Bon Secours Richmond Health System (BSRHS) Institutional Review Board (IRB)
- The study sponsor or any agency/individuals that would have access to data

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

Use of private health information:

Mandatory statements if the research creates, obtains, uses, and/or discloses identifiable health information according to the 18 identifiers listed under HIPAA regulations http://privacyruleandresearch.nih.gov/pr_08.asp

Sample Use of Private Health Information Statements

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the BSRHS Privacy Notice. If you have not received this notice, your doctor will provide a copy. At BSRHS your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the investigator to use your health information. If you do not want the investigator to use your protected health information, you may not participate in this study. *Note when specific therapy is only available through the research.*

(For blinded studies) People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information related to this study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

AND/OR

Your permission to use, retain, and share identifiable health information will [expire] (*date/event that will trigger expiration) OR* upon completion of the research study *OR* when FDA approval of the study drug is obtained ***OR*** [continue] for the period of time necessary for the preparation of a related follow-up research study *OR* indefinitely *OR* until *(agency/sponsor)* notifies the investigator that the information is no longer needed. At that time the research information will be destroyed (*or "will be retained until ___ in order to ___" or "information identifying you will be removed from such research results at (your institution)").* Any research information that is a part of your medical records will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing by writing to Dr. *(PI)* and inform *(him/her)* that you are withdrawing from the study. *(His/Her)* mailing address is *(address)*.

If you withdraw your permission:

- We will no longer use or share medical information *(*samples), except when the law allows.
- We are unable to take back anything we have already done or any information already shared.
- We may continue using and sharing information obtained prior to your withdrawal if necessary for the soundness of the research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

List any and all medical information collected from or about the participant in connection with this research study, e.g. blood and other tissue samples and related tests, medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc. Indicate the span of time from which the records are pulled.

AND/OR

Representatives of the following people/groups within *BSRHS* may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, ___(*name*)___
- BSRHS Institutional Review Board
- BSRHS Pharmacy
- BSRHS Financial Analyst for Clinical Research
- *(List other affiliates who might need to use and/or disclose information from this study.)*

AND/OR

The above people/groups may share your health information with the following people/groups outside BSRHS who may, in the course of monitoring the study, review or copy your records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *(List others NOT affiliated with your institution (fellow researchers or institutions), outside data analysts, a Data Safety Monitoring Board, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant's information might be disclosed.)*
- *(If the study is international, include regulatory agencies in other countries that may review records, including research-related medical reports and information, along with the NIA and/or the FDA.)*

Refusal or Withdrawal without Penalty

- *Describe procedures to terminate participation*
- *Note any consequences that might result from withdrawing from the study.*
- *Note any circumstances under which the PI might terminate participation without the participant's consent.*

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study. You are free to withdraw from this research treatment with this institution. You should return to see the doctor for safety reasons if advised to seek follow-up care.

You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

Costs of Participation

- *Specify any costs that might result from participation in the study (tests, drugs, biologics, or devices).*
- *If there is no cost to the participant, this should be stated.*
- *If standard medical care is being provided during the study include the following statement:*

Sample Costs for Participation Statements

(No agreement to cover costs of research-related injuries) Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay.

(Uncompensated risk of injury) Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

(Agreement to cover costs of research-related injuries) If complications or injuries occur that are the result of a medication, procedure or test required for this study, *(name)* will reimburse the standard charges for the treatment of these complications or injuries. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

(Investigator reimbursement of research-related injuries not covered by the participant's insurance carrier) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *investigator*, *(name)* will reimburse the standard charges for the treatment of these complications or injuries,

provided these charges have not been reimbursed by your medical insurance or other third party. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

Mandatory statement for all research studies:
You will not lose any legal rights by signing this form.

Compensation for Participation

Clearly describe any monetary compensation (total amount, amount per visit, amount per hour, etc.).

- ***Note:*** *Payment may not be based upon successful completion of the protocol.*
- *If a participant earns $600 or more in a calendar year, the following language should be included: "You are responsible for paying any applicable taxes on the payments you receive. You will receive a form* 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your check.

Sample Compensation Statements

You will not receive any compensation for being in this research study. **OR** You will be given $20 for each clinic visit to compensate for time and expenses for participating in this study. Payments will be made at each clinic visit for a total of 5 months. If you complete all 20 clinic visits, you will receive $400.

Research Funding

- *Disclose all grantors, institution(s) or companies involved through funding or grants. If none, say so.*
- *Conflict of Interest: Include all consultative or financial relationships the investigator(s) has with funding companies or granting agencies.*

Sample Research Funding Statement

The (institution) and/or investigators are receiving a grant from *(list companies/grantors)* to support this research. *(For funding disclosure)* The institution will be reimbursed by the NIA for use of this site's facilities and for the work the research staff does for this research.

Voluntary Participation

Sample Voluntary Participation Statements

Taking part in this study is voluntary. If you choose to take part, your responsibilities will include (*list responsibilities. NOTE: Do not include if there are none)*. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or decide to stop taking part at a later date, there will be no penalty or loss of benefits to which you are entitled.

(Optional, if appropriate) Dr. Doe may take you out of the research study without your permission. Some possible reasons for this are: *(list possible reasons, for example: you did not follow the study instructions, etc.)*. Also, the sponsor may end the research study early. If your participation in the research ends early, you may be asked to visit the investigator for a final visit.

(Optional, if appropriate) (For clinical studies) If you are or will be participating in another clinical trial, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.

(Optional, if appropriate) During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Contact Information for Questions or Concerns

- *Clarify the participant's right to have questions answered.*
- *Indicate whom to contact in case of further questions about the research or to report a research-related injury.*
- *Indicate contact information for questions about participant rights and privacy issues.*

Sample Contact Information for Questions or Concerns Statements

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact *(Principal Investigator)* at *(phone number)*.

If you have questions regarding your rights as a research participant or general questions about the research *(add the next phrase if using identifiable health information:* or your privacy, please contact:

Bon Secours Richmond Health System Institutional Review Board
8580 Magellan Parkway, Richmond, VA 23227
(804) 627-5157

Signature and Consent/Permission to be in the Research

Before deciding to enroll in this research study you should have:

- Discussed this study with an investigator,
- Reviewed the information reviewed in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked any questions you have about the research and your questions have been answered. You will receive a copy of this signed and dated form to keep for future reference.

Participant: By signing this consent form, you are voluntarily choosing to take part in this research.

_____	_____	_____
Signature of Participant	Date	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Printed Name

Signature of Legally Authorized Representative is required for people unable to give consent for themselves.
Provide a description of the Legally Authorized Representative's Authority to Act for the Participant.

Person Explaining the Research: Your signature means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____ _____
Signature of person who explained this research	Date	Printed Name

Only approved investigators may explain the research and obtain informed consent. The informed consent must be translated and presented in the subject's native language. A witness is required when the participant cannot read, and it was read to them.

_____	_____	_____ _____
Signature of the Principal Investigator	Date	Printed Name

Retention and Storage of Signed Informed Consent Documents

Signed informed consent forms are legal documents that must be stored in a secure location with access limited to persons who have a right to know their contents, ordinarily, the investigator (co-investigators), a representative of the IRB, and authorized federal officials. ***In compliance with federal regulations, consent documents must be retained for three years following the completion of the research****.*

The CONTINUING REVIEW OR CLOSURE SUBMISSION FORM requires a description of the exact location, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. The IRB cannot approve the continuation of projects that omit this information.

When an investigator moves prior to the end of the three-year retention period for retention of consent forms, he/she must notify the IRB, specifying the new location of the consent documents. Any change of storage location for consent forms should be reported to the IRB

The following applies to optional storage of leftover tissue for future research, optional sub-studies, etc.

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part.

(For research involving optional storage of tissue for future research)

Optional Tissue Storage for Future Use

Your participation in this research study does not require you to provide tissue. However, a part of this study, we would like to study your (*tissue and/or blood and/or cells)*. If you agree, the (*researchers)* will store leftover sample(*s)* of your (*tissue and/or blood and/or cells)* so that your (*tissue and/or blood and/or cells)* can be studied in the future after this study is over. *(Add the following statement if storage is optional)* These future studies may provide additional information that will be helpful in understanding [disease/condition], but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither the investigator nor you will receive results of these future research tests, nor will the results be put in your health record. Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(*s)* (*is/are)* used for this kind of research, the results will not be put in your health records. It is possible that your (*tissue and/or blood and/or cells)* might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact (*PI name)* at (*phone number)*.

(For linked samples) Your leftover samples will be labeled with (*list all that apply: "a code number", "your initials", etc.)*. These samples will be stored (*describe how the samples will be secured: "Dr. (PI's name)'s locked laboratory)* at _____. If you consent to the collection of samples of your ___ (*e.g., blood, tissue, bone marrow)* for future research, the period for the use of the samples is unknown. If you agree to allow your (*tissue and/or blood and/or cells)* to be kept for future research, you will be free to change your mind at any time. You should contact (*PI name)* at (*phone number)* and let (*him/her)* know you wish to withdraw your permission for your (*tissue and/or blood and/or cells)* to be used for future research. Any unused (*tissue and/or blood and/or cells)* will be destroyed and not used for future research studies.

(For unlinked samples) Your samples will not be labeled with any of your personal information, such as your name or a code number. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

(Add the following tissue options or variations if storage is optional) Please Initial below to indicate your preferences regarding the optional storage of leftover (*tissue and/or blood and/or cells)* for future research studies.

a. Sample(s) may be stored and used for future research studies to learn about, prevent, treat or cure (disease/condition). _____ Yes _____ No

b. Sample[s] may be stored and used for research about other health problems. _____ Yes _____ No

c. Sample(s) may be shared with other investigator/groups without any identifying information. _____ Yes _____ No

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional storage of tissue for this research study.

_____	_____	_____
Signature of Participant	Date	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

_____	_____	_____ _____
Signature of Participant's Legally Authorized Representative	Date	Printed Name

Signature of Legally Authorized Representative is required for people unable to give consent for themselves. Provide a description of the Legally Authorized Representative's Authority to Act for the Participant.

Person Explaining the Research: Your signature means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name