NOTE TO INVESTIGATORS: This is the RSRB **Biomedical Protocol Template** with required UR CABIN languageincluded in blue.

We acknowledge there may be some deviations from the established language (all blue text) based on the nature of your study.

**Guideline for Writing a Research Protocol**

 **Biomedical Research**

(RSRB Protocol Template Final v. 01/22/2019)

***Note: You may delete sections that are not applicable to your research.***

For multi-site research, if the study will utilize a reliance agreement or single IRB, refer to the [OHSP Policy on IRB Reliance and Collaborative Research](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_504_RSRB_Reliance_Review.pdf) for additional guidance on study start up requirements for IRB review and approval and the [Guideline for Coordinating Center Studies](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_Coordinating_Center_Studies.pdf) to assist in developing protocols that includes appropriate oversight of research at non-UR sites.

Investigators conducting research in foreign countries should refer to the [*Guideline for Conducting International Research*](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_Conducting_International_Research.pdf) and the [*Guideline for the European Union’s General Data Protection Regulation*](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_for_GDPR_QA_for_researchers_with_graphics.pdf) to ensure that additional protocol elements are considered and adequately described.

*--------------------------------------DELETE THIS LINE AND ABOVE-------------------------------*

**Study Title**

**Principal Investigator – Name**

1. **PURPOSE OF STUDY**

Describe the purpose, specific aims, or objectives. State the hypothesis to be tested or the research questions that will guide the study.

* + - * If the study has more than one phase, clearly map out the different phases.
1. **BACKGROUND AND RATIONALE**

Briefly describe the following:

* The relevant current context of the study and gaps in current knowledge.
* Provide the scientific or scholarly background for, rationale for, and significance of the proposed research based on the existing literature.
* Describe the significance of the research including potential benefit for individual subjects or society at large (i.e., how the research might contribute to generalizable knowledge). Describe how public health and social welfare might be enhanced, if applicable.
* Include applicable references at the end of the protocol.
1. **ADMINISTRATIVE ORGANIZATION**

Describe the participating UR medical center department/units, UR River Campus classrooms or labs, other participating *research locations*, participating *sites* (for multi-site research), central laboratories, data management center, and coordinating center, as applicable.

* A ***research location***is defined as a location where UR faculty will collaborate with and conduct research at locations outside of the University of Rochester, such as: local schools, community centers, public venues, etc. Highland and FF Thompson would also be included as a research location.
* A ***participating site (psite)*** is defined as an institution/organization/university which is not part of the UR and is engaged in the research. Sites are reserved for when the RSRB will be the Reviewing IRB (or IRB of Record) for a non-UR site. See [Guideline and Flow Charts for When the University of Rochester is the Reviewing IRB](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/504b_GDL_UR_Reviewing_IRB.pdf)
1. **STUDY DESIGN**

Provide a description of the following:

* Brief overview of the study design to indicate how the objective(s) will be achieved. Include type of study, i.e., single center or multicenter, double-blind (DB), randomized, crossover or parallel group, the type of control (placebo, active), specific treatment groups, method of subject assignment, and the sequence and duration of the study periods.
* Study outcomes/endpoints
	1. **SUBJECT POPULATION**

Describe the study population (see *Inclusion of Vulnerable Populations* below), including total number of subjects to be enrolled and/or data records/samples to be accessed.

* *If more than one site is involved, describe the total number of subjects at each site.*
* *Total to be enrolled should include the number of evaluable subjects (i.e., those who meet eligibility criteria), as well as the number of anticipated screen failures necessary to obtain the enrollment goal. A subject is considered in the total count once informed consent has been obtained (as applicable). If evaluable subjects who withdraw from the study will be replaced to meet the enrollment goal, this should also be stated here.*

*Inclusion of Vulnerable Populations:*

* **Children:** If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), refer to the OHSP policy for [Research Involving Children](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_601_Research_Involving_Children.pdf) to ensure sufficient information is provided.
* **Pregnant Women:** If the research involves pregnant women where the research activities are expected to affect the pregnancy, or if the research involves neonates of uncertain viability or nonviable neonates where the research activities are expected to affect the neonates, refer to the OHSP policy for [Research Involving Pregnant Women, Human Fetuses and Neonates](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_602_Research_Involving_Pregnant_Woman.pdf) to ensure sufficient information is provided.
* **Prisoners:** If the research involves prisoners, review the OHSP policy for [Research Involving Prisoners](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_603_Research_Involving_Prisoners.pdf) to ensure sufficient information is provided.
* **Decisionally Impaired Adults:** If the research involves adults with decisional impairments, review the OHSP policy for [Research Involving Adults with Decisional Impairment](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_604_Research_Involving_Decisionally_Impaired_Adults.pdf) to ensure that you have provided sufficient information.
	1. **STUDY INTERVENTIONS**
* For drug/biologic/supplement studies
	+ drug(s) being used/investigated, including both active and placebo, as applicable
	+ status of drug (i.e., investigational – with IND or IND exempt, new use of FDA approved drug, or used as FDA approved)
	+ provide IND number or justification for [IND exemption](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)
	+ dose and route of administration
	+ accountability, storage, access, control of drug(s)
	+ blinding/labeling/preparation of agents
	+ toxicities and guidelines for adjustments, withdrawals, etc.
* For device studies
	+ - device(s) being used
		- status of device (i.e., investigational –IDE or IDE exempt, significant risk, non-significant risk, used as FDA approved)
		- provide IDE number or justification for [IDE exemption](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1)
		- studies testing safety or effectiveness of a device, include justification for why the device is [significant or non-significant risk device](https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf)
		- accountability, storage, access, control of device(s)
		- description of how device(s) will be used
	+ For Other types of intervention studies
		- Active intervention description
		- Control group, if applicable
1. **INCLUSION AND EXCLUSION CRITERIA**

List the criteria (such as age range, gender, race, ethnicity, diagnoses, lab values, etc.) that define who will be eligible to participate. Ensure criteria addresses if the subject must be able to consent for themselves, and whether non-English speaking individuals will be included.

1. **RECRUITMENT METHODS**

Describe the different methods for recruiting subjects into the study. Describe how potential subjects will be identified, as well as when/where/how potential subjects will be recruited (include the types of strategies and materials that will be used for recruitment). Review the [OHSP Guideline for Recruitment Methods and Materials](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/703a_GDL_Recruitment_Methods_Materials.pdf) for additional information about the recruitment process and related documents.

* *Note: Only investigators with routine access to prospective subjects (or subject records) may recruit those individuals directly (“routine access” meaning the investigator already has a clinical/academic reason to know/review a patient’s record or is known to the prospective subject). Investigators who do not have routine access to prospective subjects may not contact subjects directly (i.e., no “cold calls”); they must work through the individual(s) with routine access.*
1. **CONSENT PROCESS**
* Describe the consent process, including the following, as applicable:
* How will informed consent and HIPAA Authorization be documented (refer to the RSRB [Biomedical Consent Template](http://www.rochester.edu/ohsp/documents/rsrb/word/Consent_Form_Template_Biomedical.doc))? Note that compliance with HIPAA Authorization is applicable for research that is conducted under a URMC and Affiliates covered entity and protected health information (PHI) is collected ([Policy 702 HIPAA Privacy Rule](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_702_HIPAA.pdf)). *(see below for waiver requests)*
* Where and when will consent be obtained?
* Who will obtain consent?
* How will investigators ensure the potential subject comprehends the information presented?
* How will coercion or undue influence will be minimized?
* Will the potential subject be provided sufficient time to consider their participation?
* Will the subject be provided a signed copy of the consent form?
* If a witness signature line is included on the consent form, describe whether a witness to the consent process is mandatory or optional (and if optional, under what circumstances should they be used). Identify who may act as a witness.
* How will investigators ensure ongoing consent, if appropriate? This may include re-consent for longitudinal studies or if there are multiple stages to a study over time.
* If consent to contact for future research will be an option, describe here (refer to the [Guideline for Research Involving Databases, Repositories and Registries](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_Research_Involving_Repositories.pdf)).
1. Requests for Waiving or Altering Elements of Informed Consent (or Parent Permission) must address the following (refer to [Policy 701 Informed Consent](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_701_Informed_Consent.pdf)):
	* Verify that the waiver won’t affect rights and welfare of subjects.
	* Explain why written consent cannot be obtained from subjects.
	* Describe how and when subjects will be provided additional information after participation, if appropriate.
2. Requests for Waiving Documentation of Consent (or Parent Permission) must address at least *one* the following (refer to [Policy 701 Informed Consent](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_701_Informed_Consent.pdf)):
	* Validate that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, OR
	* Validate that the research is no greater than minimal risk and involves procedures for which written consent is normally *not* required outside the research context.
3. Requests for Waiving or Altering HIPAA Authorization must address the following (refer to [Policy 702 HIPAA Privacy Rule](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_702_HIPAA.pdf)):
	* Indicate if authorization will not be obtained, elements of authorization are being altered (e.g., use of an information sheet), or a partial waiver for recruitment purposes is being requested.
	* Explain why written authorization cannot be obtained from subjects.
	* Explain why the study cannot be conducted without the use or disclosure of protected health information (PHI).
	* Describe the plan to protect identifiers from improper use and disclosure **AND** indicate if identifiers will be destroyed at the earliest opportunity consistent with the research (if not destroyed, provide the health or research justification for retaining the identifiers, or that retention is required by law).
	* State that PHI will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

*Consent Process for Minors/Children (under 18 years of age):*

* Describe how parental permission will be obtained
* If applicable, describe the process for obtaining assent of the subjects

*Consent Process for Adults with Decisional Impairment:*

* Describe the process to determine whether an individual is capable of consent.
	+ If the individual is not capable of giving consent to participate, indicate who will be authorized to give consent (e.g., power of attorney for health care, court appointed guardian for health care decisions, spouse, adult child.)
	+ The RSRB allows the person obtaining assent to document assent on the consent document; therefore, a separate assent document is not required.
* If subjects may lose decision-making ability during the study, describe the process for the subject to identify the Research Proxy, when this will be done, how the Research Proxy will be notified, and how the Research Proxy will be involved in the study. Also describe how decision-making ability will be monitored over the course of the study.

*Consent Process for Non-English Speaking Subjects:*

* If there are Non-English speaking subjects who will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in the language understandable to those potential subjects. Indicate the language that will be used by those obtaining consent. If a translator will be used during recruitment, consent, data collection, or data analysis specify how an appropriate translator will be identified and what the provisions will be for protecting the confidentiality of subjects.

*Certificate of Confidentiality:*

* If the study involves the use of a Certificate of Confidentiality, describe here.

Note: If the study is funded by the National Institute of Health (NIH), the CoC is automatically included as part of the notice of award. Language regarding the Certificate of Confidentiality must be included in the consent form.

1. **STUDY PROCEDURES**
* Provide a description of all study procedures, assessments, and subject activities.
	+ Screening procedures
		- Which screening tests/procedures are part of standard care and which are for research purposes only?
		- What happens with screen failures (including any data gathered during screening)?
	+ Source of record or measures that will be used for any data collection (e.g., medical records, pathology, surveys).
	+ Indicate if any research data will be included in the subject’s medical record (e.g., lab test results, drug assignment, or indication of study participation)
	+ Describe randomization procedures, if applicable.
	+ Duration of individual’s participation in the study and overall anticipated duration of the study.
	+ Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline, as applicable
* Describe plans for return of research results, if applicable
	+ Indicate research results that will be provided back to the subject (e.g., lab results, psychological or neurological assessment results, genetic test results)

The investigator can provide an electronic format of single image of [body part scanned] if subject is interested.

* + When they will be provided (e.g., not until the study is completed, at the time the Investigator receives the result, etc.)
	+ Describe how incidental findings that might have health consequences for the individual subject will be managed, as applicable.

**Discovery of previously unknown conditions** (conditions that can be diagnosed from having access to research quality MRI): Our scans are not read by a radiologist and the subjects are explicitly told that the experiment will not provide information regarding their health status. However, if the researcher suspects something abnormal, he will seek advice from a qualified radiologist.

* Describe genetic/genomic research activities, if applicable
	+ Description and purpose of the test
	+ Whether genetic counseling will be provided to the subject
	+ Indicate individual(s) or organization(s) to whom test results may be disclosed
	+ Indicate whether test results will be provided to the subject
	+ Whether any additional testing will be conducted
	+ Whether samples will be destroyed at the end of the testing process
1. **RISKS TO SUBJECTS**

Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the subjects’ participation in the research. For each risk identified, describe the probability, magnitude, duration, and methods of mitigating the risk. Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, monitoring, withdrawal of the subject upon evidence of difficulty or adverse event; and referral for treatment, counseling or other necessary follow-up. Consider physical, psychological, social, legal, and economic risks as well as community or group harms (e.g., breach of confidentiality is a common risk in social and behavioral research). If applicable, describe risks to others who are not subjects (e.g., group harms, harms to society).

MRI Risks

There is no immediate risk from exposure to magnetic fields of 3 Tesla. Possible anxiety may result from claustrophobia or dizziness experienced by the subjects when placed in the magnet. During the imaging portion of the experiment, subjects must remain in the bore of the magnet, which is approximately 3 feet in diameter. Also, the scanning coil closely encloses the subject's anatomy being imaged. These two factors may increase the likelihood of claustrophobia. Should the subject feel discomfort, the experiment will be terminated upon their request.

In rare cases, contact with the MRI transmitting and receiving coil or conductive materials such as wires, or skin-to-skin contact that forms conductive loops, may result in excessive heating and burns during the experiment. The operators of the MRI scanner will take steps, such as using foam pads, to minimize these risks. The subjects will be informed of the risk and instructed to immediately report any heating sensations. In the rare event that this would occur the experiment will be terminated and if necessary, we will have the subject seek medical treatment.

Subjects will be screened for magnetic material before each study. Subjects with pacemakers, aneurysm clips (metal clips on the wall of large artery), metallic prostheses (including heart valves and cochlear implants) or shrapnel fragments are at risk in an MR environment. Welders and metal workers are also at risk for injury because of possible small metal fragments in their eyes. Those at risk will be excluded from the study.

The effect of exposure to MRI scanning on an unborn child is unknown. Exposure to

MRI scanning might be harmful to a pregnant female or an unborn child. There are no established risks at this time, but the subjects will be informed that there is a possibility of a yet undiscovered pregnancy related risk.

MRI scanning produces a loud tone that can cause damage to the inner ear if appropriate protection is not used. Adequate protections in the form of earplugs or close-fitting silicon-padded headphones will be provided.

* Provide a description of alternative courses of action which are available should the subject elect not to participate in the study. If there are no alternatives available to the subject, this should be stated.
1. **POTENTIAL BENEFITS TO SUBJECTS**

Describe the potential benefits that individual subjects *might* experience from taking part in the research. If there are no anticipated benefits, this should be stated. Do not include subject payments or benefits to society or others.

1. **COSTS FOR PARTICIPATION**

Describe and justify **any costs** that subject’s (or subject’s insurance) may be responsible for because of participation in the research (e.g., study procedure/drug/device and/or standard of care).

1. **PAYMENT FOR PARTICIPATION**
* Describe the payment method (e.g., cash, check) and include how much money will be provided and for what activities, as well as when (timing) compensation will be provided.
* Describe how compensation will be prorated if there are multiple research activities **or** if a subject withdraws from the study before finishing.
* Describe any reimbursement that might be provided (e.g., travel expenses such as hotel or mileage), as applicable, and the process for reimbursement (e.g., collection of receipt).
1. **SUBJECT WITHDRAWALS**
* Describe anticipated circumstances under which subjects will be withdrawn by the investigator from the research without their consent (e.g., non-compliance, termination of funding, worsening of the disease under study, intercurrent illness, pregnancy).
* Describe procedures that will be followed if subjects withdraw from the research, if applicable.
	+ Will they stop treatment and continue to be followed?
	+ Can they withdraw from some of the procedures, but not all?
	+ Will long-term follow up data continue to be collected, if so what?
* Describe the use of subject data after withdrawal.
* Indicate whether subjects withdrawn from the study will be replaced.
1. **PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA**
	* Describe the steps that will be taken to protect subjects’ privacy. “Privacy” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.
	* Indicate how the research team has access to the sources of information about subjects.
	* If subjects will be re-contacted for any reason, describe this process and explain why subjects might need to be re-contacted. If subject will be re-contacted, this must be disclosed in the consent form.
	* Describe the steps that will be taken to maintain the confidentiality of the data and information collected during the study:
		+ Where and how will data (or samples) be stored and, if applicable, how will they be transferred outside of the University? If they will be transferred, how will they be identified? Note: electronic storage of data in both domestic and international research must be secured using adequate protections ([University IT Policies](http://www.rochester.edu/it/policy/index.html)).
		+ How long will the data (or samples) be stored? Note: RSRB policy is 3 years after the completion of the study. If HIPAA applies, it is 6 years after completion of the study. If the study is conducted under an IND or IDE, the FDA requires retention for 2 years following marketing approval (or, if not approved, 2 years following shipment and delivery of the investigational product is discontinued). If there are circumstance when other time frames may apply, describe here.
		+ Who will have access to the stored data (or samples)?
		+ Who is responsible for receipt or transmission of the data (or samples)?
		+ What steps that will be taken to secure the data during storage, use, and transmission (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data)?
			- If internet based research is planned within the protocol, the level of encryption used by the online survey tool must be described as a protection against the risks of loss of confidentiality [(see Guideline on Computer and Internet Based Research).](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_for_Internet_Based_Research.pdf)
* Describe any data/sample sharing, if applicable:
	+ What will be shared and is the information identifiable (if identifiable, provide justification),
	+ Who will have access (e.g., other researchers),
	+ What shared data/samples will be used for (e.g. research purposes, teaching, etc.),
	+ What additional privacy and confidentiality protections in place for what is shared?
1. **DATA / SAMPLE STORAGE FOR FUTURE USE**

If data (or samples) will be stored for future use, describe the following:

* Why the data (or samples) will be stored for future use,
* Where the data (or samples) will be stored (if outside the UR be sure to identify the location/entity),
* How stored information will be identified,
* How long data (or samples) will be stored,
* The plan for managing long-term storage of the data, if applicable,
* Who will have access to the stored data (or samples),
* Procedures to release data (or samples), including: the process to request a release, approvals required for release, who can submit a request, and how requested data will be identified.
1. **DATA AND SAFETY MONITORING PLAN**

Describe the plan to periodically evaluate the information collected regarding risks or harms to determine whether subjects remain safe (refer to [OHSP Policy 506 Data & Safety Monitoring](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_506_Data_Safety_Monitoring.pdf)). Include the following, as appropriate:

* Provide a definition of adverse events, serious adverse events, and any other types of events that will be monitored (refer to [OHSP Policy 801 Reporting Research Events](http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_801_Reporting_Research_Events.pdf), [21 CFR 312](https://www.ecfr.gov/cgi-bin/text-idx?SID=ecd80ee11220c173235aaa33d2f48301&mc=true&node=pt21.5.312&rgn=div5), and [21 CFR 812](https://www.ecfr.gov/cgi-bin/text-idx?SID=ecd80ee11220c173235aaa33d2f48301&mc=true&node=pt21.8.812&rgn=div5), as applicable )
* The frequency of adverse event/safety data monitoring and collection, including when safety data collection starts.
* What information / data are reviewed, including safety data, untoward events, and efficacy data?
* How will adverse event/safety information will be collected (e.g., case report forms, at study visits, telephone calls with subjects)?
* Who will review the data (e.g., safety monitoring board) and at what frequency?
* Describe any conditions where the research team may intervene and what the plan is for intervening (e.g., a subject identifies harm to self or others).
* Describe any stopping rules with regard to efficacy or safety that might trigger an immediate suspension of the research.
1. **DATA ANALYSIS PLAN**
* Describe the sample size and basis for the determination
* Describe the statistical/analytical methods to be used for the research data, as appropriate, to meet the goals of the study purpose and any specific endpoints identified.
1. **REFERENCES**

List references cited within the protocol, as applicable.