**INSTRUCTIONS:**

* When you write a protocol, keep an electronic copy, clean (all changes accepted, all comments deleted). You will need to modify this copy when making changes.
* All referenced checklists, templates, policies, and manuals can be found in the system Library.
* As you are writing the protocol, **remove all instructions in italics so that they are not contained in the final version of your protocol.** Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A.” **Do not delete** the section numbers.

**PROTOCOL TITLE:**

*Include the full protocol title. This title should match section 1 of the Basic Study Information page in the MGS IRB application.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

*\*The version number should remain unchanged during pre-review until initial approval. The version date can be updated to reflect changes that are made.*

**REVISION HISTORY**

**\*This table should only be used during submission of a Modification application to the IRB.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
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# Study Summary

*Please provide a brief summary of the study in the table below. A complete description of the study with detailed information should be provided in the body of the protocol. For sections not applicable to the study, mark them as N/A.*

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Specific Abbreviations/ Definitions**  |  |

# Objectives

2.1 Describe the purpose, specific aims, or objectives. (There should be one or two primary objectives with additional objectives listed as secondary.)

2.2 State the hypotheses to be tested.

# Background

3.1 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Include research references in section 15.0 of this template. Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your full thesis or dissertation proposal.

# Procedures Involved

4.1 Describe and explain the study design.

4.2 Please select the records that will be reviewed in this study (select all that apply):

|  |  |
| --- | --- |
| [ ]  Record Review - Educational | [ ]  Record Review - Employee |
| [ ]  Record Review - Medical | [ ]  Record Review - Publicly Available Dataset |
| [ ]  Record Review - Prisoner | [ ]  Record Review - Other  |
| [ ]  Existing Specimen Analysis |  |

4.3 *Accessing and/or collecting data, describe:*

* *The data that will be collected from the record (e.g. demographics, medical history, etc.). Attach the data capture sheet(s) on the Local Site Documents page in the IRB application.*
* *How the data will be obtained, including how you have the authority to access the data.*

4.4 *If analyzing existing biological specimens, describe:*

* How you have the authority to access the specimens.
* How the biological specimens will be stored.
* How long the biological specimens will be stored.
* How the biological specimens will be used.
* Whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS) and whether the data will be forwarded to the NIH dbGaP.

# Data and Specimen Storage for Future Research

5.1 If data or specimens will be banked for **future research studies**, describe where the data or specimens will be stored, how long it/they will be stored, how the data or specimens will be labelled and how it/ they will be accessed, and who will have access to the data or specimens. Describe whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS) and whether the data will be forwarded to the NIH dbGaP.

5.2 Once this project has ended, list the data to be stored or associated with each specimen.

5.3 Once the project has ended, describe the procedures to release data or specimens for future research studies, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

# Inclusion and Exclusion Criteria

6.1 Describe the criteria that define the records to be included or excluded in your study.

# Vulnerable Populations

7.1 If the research involves records of vulnerable populations, describe additional safeguards included to protect their rights and welfare.

* If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
* If the research involves neonates of uncertain viability, review “CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
* If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.
* If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.

# Data Sources

8.1 Indicate the source of the records and existing specimens

# Risks to Subjects

9.1 List the reasonably foreseeable risks to privacy and/or confidentiality.

# Potential Benefits

10.1 Describe benefits to society or others, if any.

# Data Management and Confidentiality

11.1 Describe the steps that will be taken to secure the data (e.g. training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

11.2 Describe how data will be handled study-wide:

* *What identifiable information will be included in the data or associated with the specimens (e.g. names, MRNs, dates, zip codes, accession number, etc.)?*
* *Where and how the data will be stored, including consent and/or HIPAA authorization forms?*
* *How long the data will be stored? Please refer to the Investigator Manual for data retention requirements.*
* *How the data will ultimately be destroyed?*

*If you plan to share confidential data with anyone outside of the research group (e.g. those not described in the consent and/or HIPAA authorization form), describe:*

* *With whom you will share the confidential data, under what circumstances this will occur and explain how/whether subjects will be informed.*

11.3 *If you will review/access and/or collect/obtain Protected Health Information (PHI), select all that apply:*

|  |  |
| --- | --- |
| [ ]  Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | [ ]  Obtaining Signed Authorization |
| [ ]  Waiver of HIPAA Authorization for Entire Study | [ ]  Data Use Agreement |
| [ ]  Business Associate Agreement |  |

* *Describe the PHI that will be disclosed to or received from individuals outside of the research group (e.g. those not described in the consent and/or HIPAA authorization form), and your plan to maintain an accounting of disclosures.*
* *If you have selected an alteration or waiver in the table above, describe:*
* *The inclusion criteria you will utilize to identify the records (e.g. diagnosis codes (ICD 10), treatments received, etc.).*
* *The time interval of the charts/records involved, if applicable.*
* *The plan to protect identifiers collected under the waiver or alteration from improper use and/or disclosure.*
* *The plan to destroy the identifiers collected under the waiver or alteration at the earliest opportunity consistent with the conduct of the research.*
* *Provide written assurance that the PHI will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.*
* *Why it is not practicable to obtain signed HIPAA Authorizations from the subjects before using or disclosing their PHI in your study.*
* *Why your study cannot be conducted without access to and use of subjects’ PHI.*

11.4 NIH Data Sharing Plan

* If this is a NIH funded study, copy and paste the data sharing plan accepted by the NIH sponsored grant. The IRB needs to consider if the plan to share individual subject data is appropriate with regards to the sensitivity of the data collected and the vulnerability of the subject (i.e., if the population being studied is re-identifiable using modern technology, the IRB may restrict sharing certain data points. They may also mandate the data are not shared in an open database system.)

# Provisions to Protect the Privacy Interests of Subjects

12.1 Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.

# Consent Process

13.1 Select the consent options you will use during the course of the study. Each selection below must have a description in the subsequent section(s). Choose all that apply:

|  |  |
| --- | --- |
| [ ]  Obtaining Signed Consent (Subject or Legally Authorized Representative) | [ ]  Obtaining Consent Online (Waiver of Written Documentation of Consent) |
| [ ]  Obtaining Signed Parental Permission | [ ]  Obtaining Verbal Consent (Waiver of Written Documentation of Consent) |
| [ ]  Obtaining Signed Assent for Children or Adults Unable to Consent | [ ]  Waiving Consent and/or Parental Permission (Waiver of Consent Process) |
| [ ]  Obtaining Verbal Assent for Children or Adults Unable to Consent | [ ]  Waiving Assent/Assent is Not Appropriate |
| [ ] ObtainingeConsent Signatures (Subject or Legally Authorized Representative) | [ ] ObtainingeConsent Parental Permission |
| [ ]  Obtaining eConsent Assent for Children |  |

13.2 If you will be obtaining signed consent or electronic consent (eConsent) from the subject or legally authorized individual (LAR), or will be obtaining signed parental permission, describe:

* Where the consent process will take place.
* *Specify the platform used for eConsent, if applicable. Refer to Question #32 of the Investigator Manual for regulatory requirements.*
* Any waiting period available between informing the prospective subject, subject’s LAR, or subject’s parent about the study and obtaining the consent/parental permission.
* The process to ensure ongoing consent.
* Describe:
	+ The roles of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
	+ The time that will be devoted to the consent discussion.
	+ Steps that will be taken to minimize the possibility of coercion or undue influence.
	+ Steps that will be taken to ensure the subjects’ understanding.

13.3 If you will be obtaining consent online or verbally (no signature), review the “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” and provide justification for the requested waiver. Also, please describe:

* Where and/or how the consent process will take place.
* Any waiting period available between informing the prospective subject and obtaining the verbal or online consent.
* The process to ensure ongoing consent (if applicable; e.g. for studies involving multiple visits).
* The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
* The time that will be devoted to the consent discussion.
* Steps that will be taken to minimize the possibility of coercion or undue influence.
* Steps that will be taken to ensure the subjects’ understanding.

13.4 If you will not obtain consent/parental permission for any part of the study, review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” and provide justification for the requested waiver. Refer to Question #20 in the Investigator Manual for requirements.

13.5 If you will obtain consent from non-English speaking subjects, indicate the different language(s) of the prospective subjects and describe the process to ensure that the oral and written information provided to those subjects will be in their primary/native language, including who will act as translator.

13.6 If you will enroll individuals who have not attained the legal age for consent (children) or individuals who are unable to provide legal consent (e.g. cognitively impaired individuals or individuals requiring a LAR), describe:

* The criteria that will be used to determine whether a prospective subject has not attained the legal age for consent or is unable to provide legal consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.
* For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”
* For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent or cannot provide legal consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted.
* Whether parental permission will be obtained from:
* One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
* Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Signatures from both parents are required for studies that are greater than minimal risk with no prospect of direct benefit.
* Whether permission will be obtained from individuals other than parents, and if so, how you will determine that the individual providing consent has the authority to do so.
* For subjects with a LAR, list the individuals from whom permission will be obtained in order of priority. (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
* The process for obtaining assent from the subjects. Indicate whether:
* Assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.
* If assent will not be obtained from some or all subjects, provide an explanation of why not.
* Assent of the subjects will be documented and the process to document assent.

# Setting

14.1 Describe the sites or locations where your research team will conduct the research and obtain the data.

# References

15.1 *Provide your references.*