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| The purpose of this checklist is to provide support for IRB staff conducting pre-review of informed consent documents and scripts. This checklist is to be completed by the Research Compliance Administrator and uploaded as a document, when applicable for expedited or full IRB review, via the “Submit Pre-Review” activity. This checklist will be retained in the system. The IRB Office (HRPP/HSPO) retains this checklist in the protocol file. | | |
| **IRB Number:** |  | |
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| **Basic Elements of Informed Consent (45 CFR 46.116/21 CFR 50.25)** | |
| **YES NO N/A** | |
| Concise and focused presentation of Key Information (N/A for FDA and DoJ regulated studies only). | |
| **YES NO (If N/A, do not complete)** | |
| The fact that consent is being sought for research and that participation is voluntary. | |
| The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research. | |
| A description of any reasonably foreseeable risks or discomforts to the subject. | |
| A description of any benefits to the subject or to others that may reasonably be expected from the research. | |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. | |
| **YES NO N/A** | |
| A statement that the study involves research. | | | |
| An explanation of the purposes of the research. | | | |
| The expected duration of the subject's participation. | | | |
| A description of the procedures to be followed. | | | |
| Identification of any procedures which are experimental. | | | |
| A description of any reasonably foreseeable risks or discomforts to the subject. | | | |
| A description of any benefits to the subject or to others which may reasonably be expected from the research. | | | |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. | | | |
| A statement describing the extent, if any, to which confidential records identifying the subject will be maintained. | | | |
| For research involving more than minimal risk, an explanation as to whether any compensation will be provided, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained. | | | |
| An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. | | | |
| A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled. | | | |
| Consent form/script does not contain any exculpatory language. | | | |
| One of the following (N/A for FDA and DoJ regulated studies only): | | | |
| **YES NO (If N/A, do not complete)**  A statement that identifiers might be removed from the identifiable private information or biospecimens and after such removal the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; **or**  A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies | | | |
| Version number/date is included (Verbal forms not required as it is not on template). | | | |
| Correct template is being used (i.e., Social Behavioral versus Biomedical) | | | |
| **Additional Elements of Informed Consent** | |
| **YES NO N/A** | |
| A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable. | |
| Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. | |
| Any additional costs to the subject that may result from participation in the research. | |
| The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. | |
| A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject. | |
| The approximate number of subjects involved in the study. | |
| **Other Required Language As Applicable** | |
| **YES NO N/A** | |
| All elements of HIPAA Authorization language. | |
| When protocol references following GCP,  The approval of the IRB.  The probability for random assignment to each treatment.  The subject's responsibilities.  When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.  The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.  When there is no intended clinical benefit to the subject, a statement to this effect.  The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.  If the results of the trial are published, the subject’s identity will remain confidential. | |
| GINA language is included for studies conducting genetic testing. | |
| GWAS language is included for genome wide association studies. | |
| dbGaP language is included for genotype and phenotype studies. | |
| When storing samples for future use, the consent includes where samples will be stored, by whom, for how long, when/how they will be destroyed, and if/how they can be withdrawn by the subject. | |
| For FDA Regulated Research: A statement that the drug/device is investigational.  The possibility that the Food and Drug Administration may inspect the records.  The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.  The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.  For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” | |
| For studies involving radiation above SOC, language regarding exposure is included. | |
| Clinical trials require the ClinicalTrials.gov language: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.” | |
| For online surveys, one of the following is included:  **YES NO (If N/A, do not complete)**  *“It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.”*  *“If completing an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your Data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.”* | |
| For VA regulated research, consent is obtained on the current VA Form 10-1086 dated 7/3/2019 for biomedical or 7/1/2019 for social-behavioral. | |
| For VA regulated research, the research related injury and compensation statements are documented in all ICDs, regardless of risk. | |
| Title IX language is included for applicable studies. | |
| For studies that involve focus groups, the following is included: “*Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.”* | |
| GDPR language is included for studies either: 1.) taking place in the European Union, or 2.) recruiting citizens of the European Union. | |
| For studies that are enrolling MGS employees as subjects AND involve providing compensation to these MGS employee subjects, the following language must be contained in the consent form (compensation section): “If you do not want to complete the tax payer ID form you can still participate in the study, however if the form is not completed you will not be compensated.” | |
| Protecting DNA Privacy Act language is included for studies conducting DNA analysis. | |
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| **Notes** | |
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# MATERIALS

* 1. Consent templates 502a(0-4), 502b(0-8) and 502c, which includes all of the variations of those templates for LAR, parental consent, verbal scripts and assents.

# REFERENCES

* 1. None