MEMORIAL SLOAN KETTERING CANCER CENTER
Departmental Standard Working Procedure (SWP)/Guidance Document

Title: Standard Working Procedure for Relying on MSK Institutional Review Board (IRB)

Department: Clinical Research Multi-Site Compliance; HRPP Office **Version date: 9/15/2025**

Purpose: The Standard Working Procedure (SWP) describes the processes and regulatory requirements for sites relying on the MSK IRB to ensure compliance with Memorial Sloan Kettering (MSK) institutional guidelines.

Scope: The SWP covers MSK protocols that are open and/or closed to accrual and have external sites relying on the MSK IRB.

Instructions for MSK Staff: This SWP is applicable to all sites relying on the MSK IRB (including Alliance and Clinical Research Strategic Partnership (CRSP) sites). The list of MSK CRSP and Alliance sites can be located on the CRSP Clinical Research portal page. This SWP excludes Biospecimen Research Protocols (BRP) and Retrospective Research Protocols (RRP).

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1.0 Regulatory Documentation

A. Site Activation

There will be one protocol document, and the relying site will utilize that document. There must be an executed reliance agreement with the MSK Institutional Review Board (IRB) prior to IRB review for the relying sites. The relying site informed consent form (ICF) must be approved by the MSK IRB. Site Privacy Board review must be completed at the relying site as MSK only serves as IRB of Record, unless an exception has been granted to serve this additional review role.

The MSK Local Context Form must be completed by the site's IRB/HRPP Office. After MSK HRPP reviews, an approved Local Context Form will be sent to the relying site HRPP to keep on file. If updates are needed to local context information after the initial review/approval, the relying site HRPP team must complete an updated form.

B. Regulatory Review Prior to Site Enrollment

The following documents must be provided to MSK before the site can be considered active:

- Participating Site acknowledgement of MSK IRB approval
- Participating Site Privacy Board (PB) approval (if applicable)
- Delegation of Authority (DOA) Log
- Site Consenting Professionals List
- Curriculum vitae for the PI and each investigator on the DOA Log
- Medical Licenses for all clinicians on the DOA Log (including RN, NP, PA)
- Documentation of Human Subject Research and Good Clinical Practice Certification for all individuals on the DOA Log. Training must be renewed every 3 years unless MSK accepts a site institutional policy that outlines different timelines.
- Site Statement of Investigator Form or 1572 (If applicable)
- Financial disclosure forms for participating site Investigators on the 1572 (if applicable)
- Confirmation that conflict of interest has been assessed by the site and included in the ICF, if applicable
- Site pharmacy license (if applicable)
- Documentation of SIV attendance and individual training for those who did not attend SIV, for all individuals on the DOA Log
- Participating site laboratory certifications and normal ranges (if applicable)
- Lab director CV (if applicable)

These regulatory documents must be maintained throughout the life of the protocol.

C. Amendments/Modifications

Each change to the protocol document must be organized and documented by MSK and approved first by the MSK IRB. MSK IRB approvals will be sent to the relying site within 2 business days of receipt of approval. The relying site must activate the approval within 30 calendar days of receipt. The site must review each amendment per local guidelines and provide any site acknowledgments to MSK.

If changes to a relying site document (e.g. informed consent form) are needed, the changes should be sent to the MSK Team Responsible. The MSK Team Responsible will submit an amendment to the MSK IRB. Once approved, please follow the above process.

Participant notification requirements will be stipulated on the MSK IRB approval letter and the MSK Team Responsible will communicate at the time of the amendment distribution.

D. Relying Site Face Sheet

Effective 9/15/2025, MSK no longer requires a relying site face sheet listing site investigators and consenting professionals. If MSK IRB has already approved a relying site face sheet, the MSK team responsible will remove it at the time of the next amendment.

E. Relying Site Informed Consent Form

The relying site informed consent form must be modeled after the MSK IRB approved ICF. Please utilize the Relying Site Informed Consent Guidance (Appendix I) when editing the relying site ICF. Please utilize the Relying Site Verbal Consent Guidance (Appendix II) when editing a relying site verbal consent.

F. Relying Site Specific Protocol Addendums

If your site requires protocol supplements or addendums that outline site specific instructions, inform the MSK Team Responsible. The MSK Team Responsible will submit to the MSK IRB for review/approval.

The supplement or addendum should not repeat any content or language that is specified in the protocol. The supplement or addendum should only be used to clarify information in protocol. For example, the addendum could specify that the relying site is only participating in one arm of a multi-arm protocol. The addendum name should follow the naming convention *([Insert Site Name] Addendum).*

G. Continuing Review Approval

Prior to each continuing review, MSK will work with the relying site to collect the required data and information needed for the submission. Continuing review and approval of research at MSK are completed with a Continuing Review Report that is reviewed by the MSK IRB or for some minimal risk studies with a Progress Report that is reviewed by the MSK HRPP. MSK continuing review approvals will be distributed to the site within 2 business days of receipt of approval. The site must review the CR approval according to local institutional guidelines and provide any site acknowledgement to MSK, if applicable.

H. Site Regulatory Binder Maintenance

The MSK PI and site PI will maintain adequate and accurate records to fully document protocol implementation and allow data to be subsequently verified.

The site will ensure that all regulatory documents and local site IRB correspondence are maintained in the site's regulatory binder and are sent to MSK. A regulatory binder for each site will also be maintained at MSK within the institution's Protocol Information Management System (PIMS).

After study closure, the site must maintain all source documents, study related documents and eCRFs for 7 years (for IND studies) or 3 years (for IND exempt studies). If this is a grant funded project and retention of source document requirement differs from above, the retention will follow the grant timeline.

2.0 Research Participant Registration

A. Registration Procedures

Central registration for this study will take place through MSK's Clinical Trials Management System (CTMS).

To complete registration and enroll a participant from relying site, the site must first contact the MSK study coordinator to notify him/her of the participant registration.

Once the MSK study coordinator is notified, the site will document the participant's consent by associating the participant to the protocol in CTMS. This will generate a study ID number that is unique and must be written on all data and correspondence for the participant.

After associating the participant to the protocol, the site will enter the consent status in real-time, but no later than 2 business days, from when the informed consent was signed.

The following documents must be saved to CTMS within 2 business days of documenting consent status:

- The completed or partially completed MSK eligibility checklist
- The signed informed consent and HIPAA Authorization form

The MSK study coordinator will confirm the relying site consent form was signed by a delegated relying site consenting professional. Supporting source documentation for eligibility questions (e.g. laboratory results, pathology report, radiology reports, MD notes, physical exam sheets, medical history, prior treatment records, and EKG report) will be sent to the MSK study coordinator within 30 days of consent so eligibility can be verified. Once the MSK study coordinator verifies eligibility the site will be notified to enter eligibility and on study status in CTMS, which will complete participant registration.

B. Enrollment of Populations Requiring Additional Considerations

As outlined in MSK IRB SOP SC 501, MSK maintains the below procedures for the following populations:

Prisoners

MSK IRB is not constituted to meet the regulatory requirements that would permit participation of prisoners as research participants. Therefore, MSK does not permit research that targets a prison population.

If an active research participant enrolled at a relying site becomes a prisoner, defined by OHRP as any individual involuntarily confined or detained in a penal institution, please contact the MSK Team Responsible and MSK IRB immediately.

Adults with Impaired Decision-Making Capacity

For studies that do not directly target adults with impaired decision-making capacity, MSK IRB will determine if enrollment of adults with impaired decision-making capacity is allowed for the specific study. The initial protocol approval letter will outline if enrollment is allowed and the requirements for documentation of assent. If allowed, informed consent signature pages must include an option for Legally Authorized Representative's signature. The relying site must use the MSK Assent Signature page (Appendix III). Please refer to SOP 703 – Assent, for more information about obtaining assent. If there are local laws regarding the use of LARs that are applicable to the relying site, please follow these and reach out to MSK if there are any conflicts.

Non-English-Speaking Participants

If your site is in an area where the population generally speaks another language, please discuss this with the MSK Team Responsible. A fully translated consent form may need to be utilized for enrollment.

Short Forms

- If the study allows the enrollment of non-English speaking participants, MSK uses the short form consenting process. Relying sites may use MSK's short forms or the MSK IRB can review and approve the relying site's short forms and corresponding certificates of accuracy for use. Review and approval of the relying site short forms must occur prior to consenting a non-English speaking participant.
- Please include copies of all short forms (including English) and the corresponding Certificates of Accuracy when completing the Local Context Form. Links to websites will not be accepted.

Translations

- For any protocol which is therapeutic or under a MSK-held IND or IDE, MSK requires the informed consent form and any other participant facing document (e.g. pill diary) to be translated into the participant's language. Translation is required after the participant is initially consented via the short form consenting process and registered eligible.
    - Once a participant is consented via the short form consenting process and is registered eligible in CTMS, the MSK Team Responsible will submit a translation request on behalf of the relying site.
    - Once the fully translated consent form is approved by MSK IRB, the participant must be reconsented. Please see SOP 704 – Consenting Participants who do not read or speak English for more information.
- If the English informed consent form is amended after the translated relying site consent form is MSK IRB approved, the translated relying site consent form cannot be used. If the relying site needs to enroll or reconsent a non-English speaking participant, the short form consenting process must be used until an amended translated consent is MSK IRB approved.
    - If updates to the translated consent form are required, the MSK Team Responsible will submit a translation request on behalf of the relying site.
- If the protocol includes a validated questionnaire, the MSK Team Responsible will assist with obtaining a version in the participant's native language. If the validated questionnaire is not available in the participant's language, it should not be completed.
- If an English consent form contains embedded questions and there is not enough time to prepare a fully translated consent document, the participant can answer the questions through the short form process. Please see SOP IC 704 for more information.

Assent for Children

Written assent is required for children ages 7-17. Please see SOP IC 703 for more information. The relying site must use the MSK Assent Signature page (Appendix III). If MSK IRB has approved the use of a verbal consent for the study, assent can also be obtained verbally and documented on the verbal consent script.

3.0 Data Management

A. Data

The relying sites will enter data remotely into electronic Case Report Forms (eCRFs) within an Electronic Data Capture (EDC) system specified within the protocol. Data entry guidelines have been generated for this study and relying site staff will receive database training prior to enrolling the first participant. The site PI is responsible for ensuring these forms are completed accurately and in a timely manner. A Data and Source Documentation Submission Timeline is shown in Table 1.

B. Source Documentation

Source documentation refers to original records of observations, clinical findings and evaluations that are subsequently recorded as data. Source documentation should be consistent with data entered

into the eCRFs. Relevant source documentation to be submitted to the MSK study coordinator throughout the study includes:

- Baseline measures to assess pre-protocol disease status (e.g. CT, PSA, bone marrow)
- Treatment records
- Toxicities/adverse events that meet study reporting requirements not previously submitted with SAE Reports
- Response designation
- Any other forms of source documentation required per protocol

Source documentation must include a minimum of two identifiers to allow for data verification. MSK will maintain the confidentiality of any participant identifiable information it may encounter.

Data and source documentation should be entered in the database and available to MSK according to the timelines in Table 1*.

Table 1: Data and Source Documentation Timelines

Time point	Data	Source Documentation
Baseline	**Within 14 days** of enrollment (see section 4.0 of this addendum)	**Within 14 days** of enrollment (see section 4.0 of this addendum)
Study Visits	**Within 14 days** of the study visit	**Within 14 days** of the study visit
Serious Adverse Events	**Within 3 days** of event (see section 7.0 of this addendum); Updates to be submitted as available	**Within 3 days** of event (see section 7.0 of this addendum)

*Sites that have executed Clinical Research Collaboration agreements with MSK will defer to the language in their contracts regarding Data.

4.0 Quality Assurance

A. Monitoring

As defined in the protocol, each data collection site including MSK will be monitored periodically by MSK. The frequency of monitoring visits will be dependent upon the protocol, patient accrual and activity. The monitor and the relying site will identify a mutually agreeable time for each monitoring visit. At least 10 business days ahead of the visit, the monitor will send the site a notification letter that details the date and expectations of the visit. Monitoring may be conducted remotely or in-person. The monitor must be allowed access to all protocol regulatory and source documents to assess compliance with the protocol, federal regulations and GCPs. The monitor will assess data for completeness of source documents and to confirm data being recorded in the eCRFs is accurate. If monitoring will be done remotely, sites must agree in advance to provide source documents as required.

For therapeutic studies with investigational drug(s), during onsite visits, the monitor will also inspect and review the facilities and investigational product storage area. The site will maintain accurate records of dispensing of study drugs for drug accountability. Drug accountability will be reviewed at monitoring visits. Study drug and bottles must be retained until the monitor performs drug accountability of the study drug(s).

a. If the investigational product is manufactured at MSK, a quality assurance review of manufacturing records will also be performed, which includes the following:

i. review of outside laboratory qualification for clinical trial investigational product manufacturing
ii. pre-manufacturing approval of GMP documents
iii. post-manufacturing review of the completed production batch records and testing results

The site Investigator(s) and/or an authorized member of the Investigator's staff should allow sufficient time during monitoring visits to discuss findings. The Investigator(s) or an authorized member of the Investigator's staff will make any necessary corrections during and between monitoring visits.

B. Auditing

Each site accruing participants to this protocol may be audited by MSK for protocol and regulatory compliance, data verification and source documentation. Audits of selected participant records may be conducted on-site or remotely.

Audits will be summarized and a final report will be sent to the PI at the audited site within 30 days of the audit. The report will include a summary of findings, participant-specific case review, recommendations on any performance and/or shortcomings and request for corrective action, when necessary. When corrective action is required, the site must reply within 45 days of receipt of the audit report with their corrective action plan.

5.0 Serious Adverse Event (SAE) Reporting

Relying site(s) are responsible for submitting the MSK External SAE Report form (Appendix IV) to the MSK Team Responsible within 3 calendar days of learning of the event and follow IRB SOP 408.
If the SAE is grade 5 please call the MSK Multicenter Office at 646-227-6041 to notify us of the event.

6.0 Safety Reports & Additional Safety Information

Regardless of sponsor, all outside safety reports will be made available to the relying site(s). Outside safety reports that are reportable to the MSK IRB will be distributed to the relying site(s) with a memo signed by the MSK PI, which indicates an amendment and any additional action that is warranted. Outside safety reports that are not reportable to the MSK IRB, will be sent to the relying site(s) monthly. All site approvals/acknowledgments of safety reports must be sent to MSK within 7 days of receipt from MSK.

As applicable, relying site(s) will be responsible for submitting safety reports to their site per their local guidelines.

7.0 Deviations

MSK IRB SOP RR-407 outlines requirements for prospective, retrospective, and non-reportable deviations.

Prospective Deviations
Deviations to the research protocol that involve patient eligibility, an informed consent procedure change, and/or treatment/pharmacy alterations as outlined in MSK IRB SOP RR 407 require prospective approval from the MSK IRB prior to the change being carried out.

Relying site(s) must contact the MSK PI who will in turn seek approval from the MSK IRB.

Retrospective Deviations
Any deviation that has occurred and may affect the scientific validity of the study, may meet the criteria of serious or continuing noncompliance, and/or have the potential to result in increased risk or decreased benefit to participants. Retrospective deviations require reporting to MSK HRPP.

Relying site(s) are responsible for submitting the Relying Site Retrospective Deviation Form (Appendix V) to the MSK Team Responsible as soon as possible, who will in turn report the deviation to the MSK HRPP as per MSK guidelines.

Non-reportable Deviations
Any deviation that does not meet retrospective or prospective reporting criteria. Non-reportable deviations do not require reporting to MSK IRB/HRPP but need to be filed in the regulatory binder.

Relying site(s) are responsible for submitting the Relying Site Non-Reportable Deviation Form (Appendix VI) to the MSK Team Responsible as soon as possible, who in turn will file the deviation in the relying site regulatory binder.

8.0 Unanticipated Problems

Relying site(s) are responsible for reporting all UPs to the MSK Team Responsible as soon as possible but within 3 calendar days of learning of the event. UPs that are SAEs must be reported to MSK via MSK External SAE Report form. All other UPs must be reported to MSK in a memo signed by the site PI.

9.0 Noncompliance

If a relying site is noncompliant with the protocol document, accrual privileges may be suspended and/or contract payments may be withheld, if applicable, until the outstanding issues have been resolved.

10. Applicable References

A. IRB SOPs

IRB SOPs will be provided to the relying site(s) prior to activation and MSK will notify and distribute any SOP updates to the relying site(s) throughout the lifetime of the study. IRB SOPs as applicable will be reviewed during the Site Initiation Visit.

a) IRB/PB GA 106: IRB of record
b) IRB/PB FO 309: Noncompliance in Human Research
c) IRB/PB FO 310: Suspensions and Terminations of IRB Approval
d) IRB/PB RR 401: Initial Review – Criteria for IRB Approval
e) IRB/PB RR 404: Amendment to IRB Approved Research
f) IRB/PB RR 405: Continuing Review – Criteria for Renewal Approval
g) IRB/PB RR 407: Deviations to IRB Approved Research and IRB SOPs
h) IRB/PB RR 408: Reporting of Serious Adverse Events
i) IRB/PB RR 409: Unanticipated Problems involving Risk to Participant or Others
j) IRB/PB RR 411: Progress Reports – Criteria for Renewal
k) IRB/PB SC 501: Populations Requiring Additional Considerations
l) IRB/PB IC 701: General Requirements for Informed Consent and HIPAA Research Authorization
m) IRB/PB IC 702: Waivers and Alterations of Informed Consent

n) IRB/PB IC 703: Assent
o) IRB/PB IC 704: Consenting Participants Who Do Not Read or Speak English
p) IRB/PB IC 705: Consenting Professionals
q) IRB/PB IC 706: Documentation of Informed Consent and Research Authorization
r) IRB/PB RI 804: Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Certification Requirements

B. Other Resources

a) CTMS Subject Registration Manual
   a. Relying sites – You can gain access to the manual by creating a new account on the Multicenter Office Portal (https://multisiteresearch.mskcc.org/)

Appendix I: Relying Site Written Informed Consent Guidance

Instructions for relying sites:
Please follow the instructions below when incorporating your local language into the MSK informed consent. Your language must align with the information provided in the MSK Local Context Form.

Relying site informed consents must be approved by MSK IRB prior to use. If revisions to local language are needed after initial IRB approval, please reach out to the MSK Team Responsible to submit an amendment to MSK IRB on your behalf.

Local logos, headers and footers can be added to the relying site informed consent per local policy.

Only the below sections can be edited to include your local language. If there is a specific reason to revise any other section, provide a justification in the MSK Local Context Form for consideration.

Reference to MSK throughout the consent can be replaced with the site name, as applicable.

Lead Researcher
Include relying site PI and contact information.

What is the purpose of this study?
Update the site accrual number as applicable to your site. No other changes are permitted.

What extra tests and procedures will I have if I take part in this study?
Changes are not permitted. However, if this section includes a referral to MSK Clinical Genetics in the *Genetic Research sub*-section, replace MSK Clinical Genetics with the appropriate site contact or site referral service.

Is there a conflict of interest for this study?
Add local conflict of interest statements for instutional conflicts of interest and investigator conflict of interests. If MSK has a stated conflict of interest, please do not remove; however, please update this langauge to include your local contact.

Please include a copy of all investigator conflict of interest management plans, when returning the relying site informed consent form.

What are the costs of taking part in this study?
The cost section language should align with the MSK ICF cost section. The MSK Medicare Coverage Analysis will be provided. If the site has a different determination, this must be reviewed and approved by MSK and may have budgetary implications for the external site.

Will I receive payment for taking part in this study?
Changes are not permitted except to language regarding reimbursement to participants. If your site uses a separate reimbursement form that is provided to participants, please include when returning the relying site informed consent form.

What happens if I am injured or hurt because I took part in this study?
Update this section according to any local injury requirements specific to the study.

How will my medical information be protected?
Sites are permitted to update reference to MSK with the site name, as applicable. Do not remove any language. If minor updates are needed to align with local policy/requirements, it must be outlined in

the site local context form. If there is additional required local privacy langauge, please create a subheading *([Insert Site Name] Additional Information)* and add any required language.

Where can I get more information?
Do not remove MSK IRB contact information. Please replace MSK Patient Representative contact information with your local contact information.

Research Authorization
If your site is a HIPAA covered entity: Remove the MSK research authorization and include your local research authorization. If you do not have a local research authorization, you may edit MSK's research authorization by replacing mention of MSK with your site name and contact information. MSK should be included as a party who can receive the participants' PHI in section #3.

If your site requires that the HIPAA research authorization to be a separate document, you can remove the MSK research authorization. The MSK local context form must indicate your site's requirement to have a separate authorization.

If your site is not a HIPAA covered entity: Remove the MSK research authorization and add any required language in the in the "How will my medical information be protected?" section.

Signature Pages
Changes are not permitted to the MSK signature page. However, the use of local signature pages is permitted. If using a local signature page, please remove the MSK signature page and replace with your own. Site signature pages must include all components that are present in the MSK signature page, (e.g. a legally authorized (LAR) signature line if applicable; attestation from the participant that they received a copy of the ICF; appropriate witness signature lines.)

Assent Pages
If the study is enrolling children or individuals with impaired decision-making capacity, MSK IRB requires the use of the MSK Assent Page (Appendix III).

Study Calendar
Changes are not permitted to the calendar unless there are approved changes to the cost section based on local requirements.

Appendix II: Relying Site Verbal Informed Consent Guidance

Instructions for relying sites:
Please follow the instructions below when incorporating your local language into the MSK verbal informed consent. Your language must align with the information provided in the MSK Local Context Form.

Relying site verbal consents must be approved by MSK IRB prior to use. If revisions to local language are needed after initial IRB approval, please reach out to the MSK Team Responsible to submit an amendment to MSK IRB on your behalf.

Local logos, headers and footers can be added to the relying site informed consent per local policy.

Only the below sections can be edited to include your local language. If there is a specific reason to revise any other section, provide a justification in the MSK Local Context Form for consideration.

Lead Researcher
Remove MSK Principal Investigator (PI) and add relying site PI and contact information.

Introduction
Change Department to applicable relying site department if needed. Remove MSK and add relying site institution. No other changes are permitted.

Study Information
Update the site accrual number as applicable to your site. Remove MSK and add the relying site institution. No other changes are permitted.

Conflict of Interest
Add local conflict of interest statements for instutional conflicts of interest and investigator conflict of interests. If MSK has a stated conflict of interest, please do not remove; however, please update this langauge to include your local contact.

Costs of Participation
Changes are not permitted.

Protecting your Privacy
Sites are permitted to update reference to MSK with the site name as applicable. However, do not remove any langague. If there is additional required local privacy langauge, please create a subheading *([Insert Site Name] Additional Information)* and add any required langauge.

Research Authorization
If your site is a HIPAA covered entity: Remove the MSK research authorization and include your local research authorization. If you do not have a local research authorization, you may edit MSK's research authorization by replacing mention of MSK with your site name and contact information. MSK must be included in the bulleted list as a party who can receive the participants' PHI.

If your site requires that the HIPAA research authorization to be a separate document, you can remove the MSK research authorization. The MSK local context form must indicate your site's requirement to have a separate authorization.

Contact Information
Update the researcher name and telephone to the relying site PI's name and phone number. Do not remove MSK IRB contact information. Please replace MSK Patient Representative contact information with your local contact information.

Appendix III: MSK Assent Signature page

MEMORIAL SLOAN KETTERING CANCER CENTER
1275 York Avenue, New York, NY 10065
Approved: 05-FEB-2024

Participant Assent for Clinical Research

Assent is required for a minor age 7 to 17 and/or for a participant with mildly impaired decision-making capacity as described in MSK IRB SOPs SC-501 and IC-703.

Consenting Professional Must Personally Sign and Date		
Consenting Professional's Statement I have explained the study to the participant in age-appropriate terms and the participant agreed to take part in the study. The participant should sign and date below in the participant section. I have given a copy of this form to the participant and the participant's Legally Authorized Representative (LAR). ❑ Check the box if the participant verbally agreed to take part but declined to sign or is unable to sign.		
Signature of consenting professional obtaining assent		**Date:**
Consenting professional name (printed)		
Participant Should Personally Sign and Date		
Participant's Statement I have read this consent, or it was explained to me. All my questions have been answered. I agree to be in this research study.		
Participant signature		**Date:**

For participants younger than 18 years old: If you are still in the study when you turn 18, we will ask for your consent to continue participating in the study.

This form must be accompanied by an IRB-approved consent form signed by a Legally Authorized Representative.

Appendix IV: MSK External SAE Report form

GENERAL INFORMATION	
Site Name:	**Site Principal Investigator:**
Date of Report: ____/_____/______	**Treating Physician:**
	Protocol #:
Check One: ☐ Initial Report ☐ Follow-up Report → Date of original report ____/_____/______	

PARTICIPANT INFORMATION
Subject Initials:
Subject ID:

PROTOCOL INVERVENTION/TREATMENT (*Include N/A if not applicable)
List Intervention/Treatment #1:
Intervention/Treatment Start Date: ____/_____/______
Date of last Intervention/Treatment prior to SAE: ____/_____/______
List Intervention/Treatment #2:
Intervention/Treatment Start Date: ____/_____/______
Date of last Intervention/Treatment prior to SAE: ____/_____/______
List Intervention/Treatment #3:
Intervention/Treatment Start Date: ____/_____/______
Date of last Intervention/Treatment prior to SAE: ____/_____/______

CONCOMITANT MEDICATIONS (*Include only if relevant to the SAE)

Generic Name	**Start Date** mm/dd/yyyy	**End Date** mm/dd/yyyy

SAE INFORMATION (CTCAE Version ___)

SAE Start Date mm/dd/yyyy	**Event**	**Grade**	**SAE End Date** mm/dd/yyyy	**Expected[1]** *Provide expectedness to each intervention noted above*	**Relationship[2]** *Provide a relationship to each intervention noted above*
				#1 Drug/Intervention:	***#1 Drug/Intervention:***
				#2 Drug/Intervention:	***#2 Drug/Intervention:***
				#3 Drug/Intervention:	***#3 Drug/Intervention:***
				#1 Drug/Intervention:	***#1 Drug/Intervention:***
				#2 Drug/Intervention:	***#2 Drug/Intervention:***
				#3 Drug/Intervention:	***#3 Drug/Intervention:***
				#1 Drug/Intervention:	***#1 Drug/Intervention:***
				#2 Drug/Intervention:	***#2 Drug/Intervention:***
				#3 Drug/Intervention:	***#3 Drug/Intervention:***
				#1 Drug/Intervention:	***#1 Drug/Intervention:***

				#2 Drug/Intervention:	***#2 Drug/Intervention:***
				#3 Drug/Intervention:	***#3 Drug/Intervention:***

1. **Expected**: Yes and No
2. **Relationship**: Unrelated, Unlikely, Possible, Probable, and Definite

PRIOR HISTORY (*Include only if relevant to the SAE)

SAE DETAILED INFORMATION

Description of the event, including relevant findings:

Is this SAE related to any protocol test/procedure (e.g., research biopsy) that is not the protocol intervention? If yes, explain.

Does this SAE require a follow-up report? If yes, explain.

Did the SAE occur outside of your site? If yes, provide date of notification of the SAE.

Does this SAE meet unanticipated problem (UP) criteria as per MSK IRB/PB SOP 409? If yes, explain.

REPORTING INFORMATION

SAE Report By (print name):

Site PI/Treating Physician (print name):

Site PI/Treating Physician (signature*): **Date:**

*E-signature using Adobe PDF is acceptable.

Appendix V: Relying Site Retrospective Deviation Form

RELYING SITE RETROSPECTIVE DEVIATION SUBMISSION FORM

Memorial Sloan Kettering Cancer Center

Sites must submit this form to the MSK study team.

MSK IRB number:	
Participating Site:	
Subject Number/ MSK CTMS ID:	
MSK Instructions: Enter both the Site and Subject Number into the MRN/Subject #: field when entering the RD in PIMS.	
Date of Deviation Event:	
Date of identification by site PI/research team:	
Location:	Reliant Site Only
Has this problem increased risk to the participant or future participants:	
Is this problem unexpected:	
Is this problem related to the intervention/ interaction:	
Corrective Action Plan Established:	
Corrective Action Plan:	
Deviation Description:	
Site PI Signature:	

Appendix VI: Relying Site Non-Reportable Deviation Form

RELYING SITE NON-REPORTABLE DEVIATION SUBMISSION FORM

Memorial Sloan Kettering Cancer Center

Sites must submit this form to the MSK study team.

MSK IRB number:	
Participating Site:	
Subject Number/ MSK CTMS ID:	
MSK Instructions: Enter both the Site and Subject Number into the MRN/Subject #: field when entering the non-reportable deviation in PIMS.	
Date of Deviation Event:	
Date of identification by site PI/research team:	
Location:	Reliant Site Only
Has this problem increased risk to the participant or future participants:	
Is this problem unexpected:	
Is this problem related to the intervention/ interaction:	
Deviation Description:	
Site PI Signature:	