LIM INFORMATION

Company	
Country	
Sector	Pharma
Region	EMEA&Canada

PHARMA SOP INFORMATION

Pharma SOP Title	Managing Unplanned Deviations in Health Care Compliance & Privacy
Pharma SOP Version	2.0
PharmaDoc number	

IMPLEMENTATION TYPE (choose the option that applies):

	CORE SOP has been implemented as is.
	CORE SOP has not been implemented locally because the topic of the CORE SOP does not apply to activities of the local business.
	CORE SOP has been implemented with changes as described below.
	CORE SOP has not been implemented, as Company has adequate SOP(s) in place. *

***If company has adequate SOP in place, provide the following details:**

SOP Title	
SOP #/Version	
PharmaDoc #	
SOP Effective Date	
Next Review Date	

IMPLEMENTATION SUMMARY:

All local changes/customizations to the Core SOP must be captured here.

IMPLEMENTATION DETAILS:

SIGNATURES:

Local Implementation Signatures		
Name/ Title	**Signature**	**Date**
Name/ Title	**Signature**	**Date**
Name/ Title	**Signature**	**Date**

- **Final Approval by HCC Officer in PharmaDoc**

  Please delete Signature section if all signoffs are done in PharmaDoc

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to set forth the activities and responsibilities for managing and tracking Health Care Compliance, Privacy and Government Contracting & Pricing Compliance (GCC) Unplanned Deviations related to allegations of violations or alleged violations of one or more of the following:

- United States Health Care Regulatory Guidance Documents and related policies and procedures
- The International Health Care Business Integrity Guide (HCBI) and related policies and procedures
- Global Framework for Health Care Compliance Programs
- Global Privacy Compliance Framework and related policies and procedures
- Government Contracting & Pricing Compliance (GCC) guidance documents, policies and procedures
- Relevant regional and country laws, regulations and policies related to HCC, GCC and Privacy
- Other functional policies as applicable, e.g. J&J Travel & Entertainment Policy

For purposes of this document, the items above will be referred to collectively as Health Care Compliance and Privacy Policies & Procedures. This SOP supplements but does not supersede any of the requirements or standards set forth in the Health Care Compliance and Privacy Policies and Procedures.

2. SCOPE

2.1. In Scope

Any Unplanned Deviation that occurs as a result of a potential violation of the Health Care Compliance and Privacy Policies and Procedures within a Johnson & Johnson company (Company).

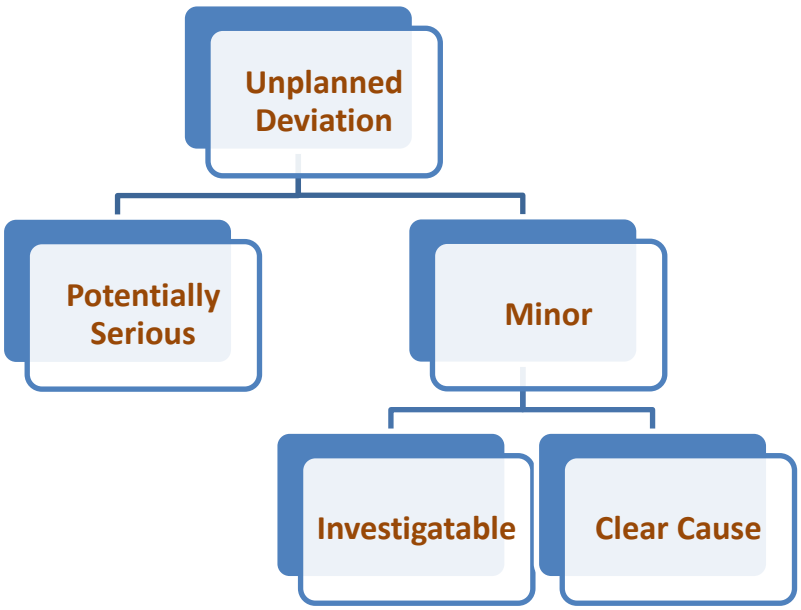
2.2. Out of Scope

- External investigations performed by external authorities/bodies (except to the extent an Unplanned Deviation is identified as a result of such investigations)
- Pharmacovigilance and adverse event reporting compliance
- Product/service complaints
- Investigation of product complaints, including safety complaints
- GxP (Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices)
- Accounting related deviations (U.S. GAAP and local accounting requirements including Sarbanes-Oxley Act, Asset Misappropriation)
- Employment and other HR-related matters
- HCC/HCBI Exceptions: Refer to SOP-13828.

3. UNPLANNED DEVIATION CLASSIFICATION

- **Unplanned Deviation:** Deviation from the Health Care Compliance & Privacy Policies and Procedures that does not fit the criteria of an HCC/HCBI Exception.

- There are two types of Unplanned Deviations: Potentially Serious and Minor



- **Potentially Serious (Escalatable):** An Unplanned Deviation that meets the criteria for escalation under the Escalation Procedure POL-06750. All GCC Unplanned Deviations are escalatable; therefore no further categorization is needed for GCC Unplanned Deviations.

- **Minor**
  - **Investigatable**: An Unplanned Deviation that requires investigation, but does not meet the criteria of Potentially Serious. Includes any Privacy Incident or Privacy Breach.

  - **Clear Cause:** An Unplanned Deviation that is not Potentially Serious and where the circumstances and causes of the Unplanned Deviation are clear so no investigation is needed.

4. POLICY

4.1 Policy Statements: HCC and Privacy

- The HCC&P Officer (or if a dedicated investigation group exists for a particular business unit(s), then the head of the investigation group) must evaluate and classify Unplanned Deviations as Potentially Serious (Escalatable) or Minor.
- Potentially Serious Unplanned Deviations must be escalated per the Escalation Procedure POL-06750.
- Potentially Serious and Minor, Investigatable Unplanned Deviations must be entered in to the approved online case management system, i.e. Navex (formerly EthicsPoint) or Perspectives.
- Minor, Clear Cause Unplanned Deviations should be managed by the Company in a way that allows for patterns to be identified and information to be submitted in the event of an audit.
- Issues or gaps related to Health Care Compliance & Privacy policies and procedures must be managed through the Management Action Plan (MAP) process SOP-13940.
- Summary reports containing adequate information for tracking, trending and reporting, sorted and displayed to optimize trend analysis (with ALL individual identifiers removed), should be reported periodically to the applicable Compliance Committee and other appropriate senior management.

- For the purposes of tracking and managing Unplanned Deviations, (i) all potential mishandling of personal information reported to the company by a third party, (ii) any customer inquiry regarding the uses and disclosures of Personal Information, and (iii) any inquiry from a regulator (such as a state Attorney General or local Data Protection Authority), will be considered a Privacy Unplanned Deviation and should be managed via this process.

- Investigation of Unplanned Deviations involving direction and support from the Law Department may be protected by applicable legal privileges. For such Investigations, the Law Department must be consulted for guidance on what procedures need to be followed to protect such legal privileges.
- Unplanned Deviations reported under the Escalation Procedure as Potentially Serious will be tracked through the Triage Committee process. Potentially Serious Unplanned Deviations will be managed and maintained by the Triage Committee unless directly notified by the Triage Committee that a different procedure will be followed. Once escalated, the Triage Committee will typically communicate appropriate next steps within 5 business days.

4.2 Policy Statements: U.S. Government Contract Compliance (GCC)

- GCC exceptions are managed through GCC *Guidance Document Exceptions* SOP-15010.

- Unplanned GCC deviations and their entry to the approved online case management system are managed through *NAVEX U.S. Government Contracting & Pricing Compliance (GCC) Escalation Management* SOP-14645.

- In the event a GCC Unplanned Deviation requires disclosure to the U.S. Government, the GCC subject matter expert in the Law Department, with input from the Government Business Lead (GBL), or GBL Delegate (or other appropriate business process expert) and other relevant parties (i.e. GCCO, Shared Services Centers of Excellence for Government Contracts), will determine what will be disclosed.
    - Information provided by Government Business Lead or designate will be used to create the disclosure.
    - The GCC subject matter expert in the Law Department will review and approve the disclosure communication.

- The approved disclosure communication will be sent by the applicable Shared Services Centers of Excellence for Government Contracts, if used by the Company. Otherwise, the approved disclosure communication will be sent by the Company.

- Summary reports containing adequate information for tracking, trending and reporting, sorted and displayed to optimize trend analysis (with ALL individual identifiers removed), should be reported periodically to the applicable Compliance Committee and other appropriate senior management.

4.3 Corrective Actions

- It is the responsibility of the HCC&P Designee to ensure that appropriate corrective actions are taken in accordance with local laws, regulations and policy when Unplanned Deviations are found to violate Health Care Compliance & Privacy Policies and Procedures. When such corrective actions are undertaken, it is the responsibility of the HCC&P Designee to ensure that the action is completed and, as part of routine monitoring, ensure that the corrective actions are effective.
- Corrective actions may be assigned to the Line Manager, Government Business Lead (GBL) or delegate or similar and is not necessarily the responsibility of Human Resources or HCC&P.
- For Potentially Serious Unplanned Deviations where the investigation is conducted or overseen by the Law Department, Company management is required to develop a Management Action Plan (MAP) to address the recommendations, with guidance from HCC&P Officer, within 60 days of the email issue date of the final report from the Law Department. The MAP (excluding any disciplinary action plan) should be entered into the EDGE system with a copy sent directly to the responsible CIA Manager and the responsible law department Lawyer.

5. PROCEDURES AND RESPONSIBILITIES

5.1 Classification

Responsibility	Step	Action
HCC&P Designee and Law Department, as applicable	5.1.1	Evaluate and classify the Unplanned Deviation
HCC&P Designee	5.1.2	If Potentially Serious, proceed to Step 5.2
HCC&P Designee	5.1.3	Minor, Clear Cause proceed to Step 5.3
HCC&P Designee	5.1.4	Minor, Investigatable proceed to Step 5.4

5.2 Potentially Serious

Responsibility	Step	Action
HCC&P Designee	5.2.1	Contact Corporate Internal Audit (CIA) per the Escalation Procedure and enter Information into case management system within 3 business days. • GCC: Notify subject matter expert in the Law Department and follow *NAVEX U.S. Government Contracting & Pricing Compliance (GCC) Escalation Management* SOP-14645 for management and entry of all GCC Unplanned Escalatable deviations. • Privacy: Follow guidelines in *Requirements for Establishing a Privacy Incident Response Program* (POL-06635).
HCC&P Designee	5.2.2	Allow up to 5 business days for CIA to evaluate the escalation request. If no response is received after 5 business days, contact the CIA directly.
Triage Committee	5.2.3	Evaluate the case using existing processes and respond (typically) within 5 business days.
HCC&P Designee	5.2.4	Proceed as directed by the Triage Committee.

HCC&P Designee	5.2.5	If Triage Committee determines that investigation will be handled by HCC&P Designee, proceed to 5.4.

5.3 Minor, Clear Cause

Responsibility	Step	Action
HCC&P Designee	5.3.1	Monitor Minor, Clear Cause Unplanned Deviations for trends or deviations that consistently recur.
HCC&P Designee	5.3.2	When trends or similar are identified that require additional action proceed to 5.1.

5.4 Minor, Investigatable

Responsibility	Step	Action
HCC&P Designee	5.4.1	When a Minor, Investigatable Unplanned Deviation is identified, where necessary, assemble an investigation team in consultation with the Law Department and Human Resources. For Privacy, the investigation team should also include Information Security and the relevant Business Unit Head. For GCC, include the business process subject matter expert. In general, individuals best qualified to be part of the team have the following characteristics: • Familiarity with the legal and compliance obligations to which the organization is subject. • Broad knowledge of and some experience in conducting internal investigations. • Authority to facilitate discussion among senior management.
HCC&P Designee	5.4.2	For complex matters, where necessary, create investigation plan in consultation with Law Department and Information Security, where applicable. The plan could include: • Names and titles of investigation team

		• Documents and materials to be reviewed • People to be interviewed (employees and third parties) • Investigation questions that need to be answered • Required deadline for completing investigation, if appropriate • Other Note: the extent of the plan and investigators may vary depending on the complexity of the Unplanned Deviation.
HCC&P Designee	5.4.3	If at any point an Unplanned Deviation is determined to be Potentially Serious requiring escalation, proceed to 5.2.

5.5 Perform Investigation

Responsibility	Step	Action
HCC&P Designee	5.5.1	Re-assess on a regular basis if the classification of the Unplanned Deviation has changed. If developments in the investigation suggest that the violation of law or policy needs to be reclassified to Potentially Serious, put a hold on the investigation and proceed to 5.2.
HCC&P Designee	5.5.2	Conduct a preliminary review of all relevant and available information before proceeding to interviews. • Do basic fact-finding in a confidential manner • Establish timeline or sequence of events • Gather and review all relevant documents related to the issue, such as: o Documents, available emails, Police reports, inventories, SOPs, procedures o Financial documents, expense reports, other reports, training decks

		NOTE: access to company-owned equipment such as computers or other electronic systems/devices requires permission from the Law Department or other appropriate internal body such as Work Councils, and is based on the investigative needs.
HCC&P Designee	5.5.3	Conduct interviews with individuals who are most likely to provide relevant information. Interviews should be conducted by two people and can include appropriately trained HCC staff or HR. One person should be assigned the responsibility of keeping careful notes. Identify potential interviewees such as author(s) and recipients of relevant documents, employees or others who may have direct or indirect knowledge of the incident.
HCC&P Designee	5.5.4	Record the findings of the investigation in case management system. For GCC Unplanned Deviations, provide all relevant information regarding the deviation to the GCC subject matter expert in the Law Department.
HCC&P Designee	5.5.5	Ongoing investigations of greater than 6 months in duration that have not been closed should be re-evaluated to determine if the investigation can be finalized and concluded per 5.6.

5.6 Conclude Investigation

Responsibility	Step	Action
HCC&P Designee and/or investigation team members, HR, Law Department, Information Security	5.6.1	Investigation outcomes are categorized in the case management system as follows: (a) Verified: The allegation was substantiated/true (b) Not Verified: The allegation was not substantiated/true (c) Not Verified with Issues: The allegation was not substantiated/true but there were related control or process issues.*

		*Consult the Law Department and HR to determine what processes need to be followed for investigations where the allegations are found to be Not Verified with Issues. Include the local Privacy representative where removal of Personal Information is necessary.
HCC&P Designee and/or investigation team members, HR, Law Department	5.6.2	Evaluate findings arising from an investigation and inform management of the results as needed.
HCC&P Designee and/or Investigation team members, HR, Law Department	5.6.3	Provide recommendation(s) to Line Manager, Government Business Lead or designate as needed. • Using a Management Action Plan go to 5.7 • Disciplinary or Corrective Actions, go to 5.8
HCC&P Designee	5.6.4	File case according to local record retention policies

5.7 Using a Management Action Plan (MAP)

Responsibility	Step	Action
HCC&P Designee	5.7.1	Utilize EDGE to manage and maintain MAP Items related to HCC, GCC and Privacy
Compliance Committee and HCC&P Designee	5.7.2	At least quarterly, present MAP Items related to HCC, GCC and Privacy to the applicable Compliance Committee. The Compliance Committee is responsible for: • Committing the business to remediate the issue or gap. • Assigning MAP Item Owner • Discussing and assigning resources, as needed • Ensuring appropriate and timely closure
HCC&P Designee	5.7.3	Document all decisions made by the Compliance Committee.

HCC&P Designee	5.7.4	Update MAP metrics on a regular basis including documenting status, completed or delayed items.
HCC&P Designee	5.7.5	Update MAP information in EDGE at the end of each quarter.

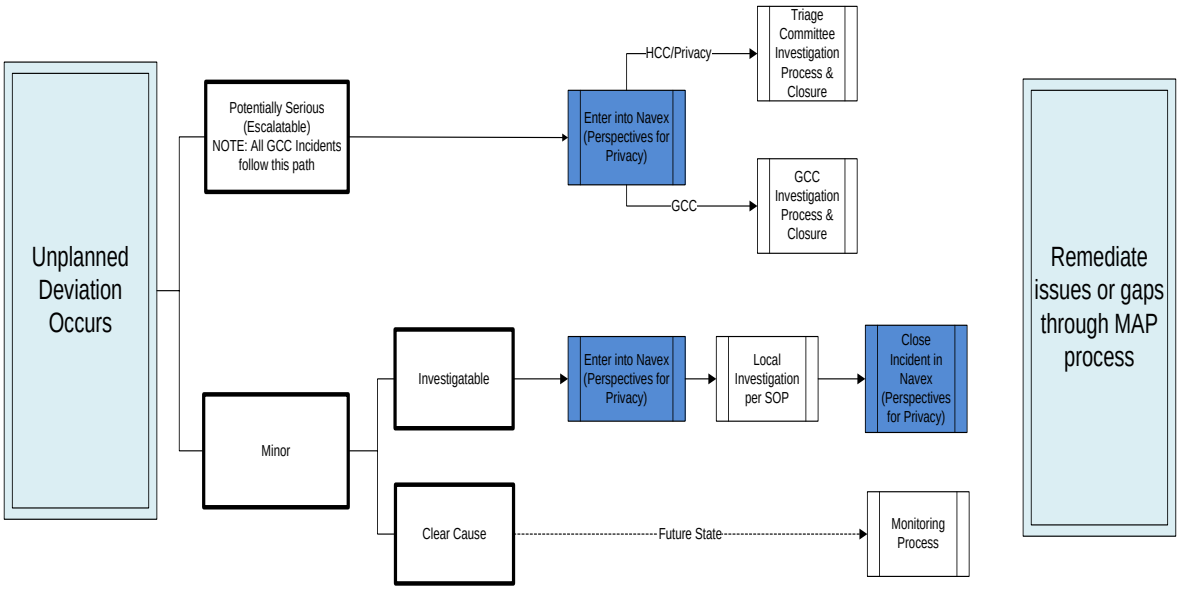
5.8 Disciplinary Action

Responsibility	Step	Action
HR	5.8.1	If disciplinary action is required, follow the applicable Human Resource process.
HCC&P Designee and business partners as needed	5.8.2	If corrective action is required, follow the applicable local process.
HCC&P Designee	5.8.3	Record close out date and activities in case management system.
HCC&P Designee	5.8.4	Notify key stakeholders of closure and actions taken.

5.9 Follow-up Monitoring

Responsibility	Step	Action
HCC&P Designee or Government Business Lead/GBL Delegate (or appropriate business process expert)	5.9.1	Implement and document follow-up monitoring to ensure that corrective actions are effective, when appropriate.

6. DECISION TREE



7. DEFINITIONS AND/OR ABBREVIATIONS

Employee	Includes full-time, part-time, temporary and contracted sales force.
HCC&P Designee	An individual assigned by the HCC&P Officer (or if a dedicated HCC&P investigation group exists for a particular business unit(s),then the head of the investigation group) to support Unplanned Deviations. This individual may not be a temporary or contracted employee.
Sensitive Issue	Once a Potentially Serious Unplanned Deviation is escalated and becomes the responsibility of the Triage Committee then it becomes a Sensitive Issue.

8. OUTPUTS

- Potentially Serious and Minor, Investigatable Unplanned Deviations are tracked in a case management system for Privacy, HCC and GCC in alignment with this document and related documents referenced in Section 10.
- Management Action Plans are tracked in EDGE.

All documentation is maintained according to the Company's document retention policies or applicable local data privacy laws.

9. CONTROLS AND MEASURES

Monitoring: The HCC&P Designee and/or Process Owner ensures that appropriate monitoring of key controls and outputs are in place and carried out on a regular basis.

- Demonstrate corrective action has been implemented, where necessary.
- Once an Unplanned Deviation has been determined to be Potentially Serious it is escalated within 3 business days to the VP of CIA or designee in accordance with the Escalation Procedure.

10. RELATED DOCUMENTS

- Global Framework for Health Care Compliance Programs
- Global Privacy Compliance Framework
- Government Contracting and Pricing Compliance Program Framework
- United States Regulatory Guidance Documents
- International Health Care Business Integrity Guide
- Johnson & Johnson Policy on Business Conduct
- Johnson & Johnson Escalation Procedure and supplement
- Requirements for Establishing a Privacy Incident Response Process (POL-06635)
- HCC/HCBI Exceptions (SOP-13828)
- HCC&P Management Action Plan (SOP-13940)
- GCC Guidance Document Exceptions Process (SOP-15010)
- GCC Ethics Point Escalation (SOP-14645)

11. REVISION HISTORY

Ver. No.	CR No.	Description of Change(s)
1.0	N/A	New SOP
2.0		.

12. SIGNATURE PAGE

Approvers:

Dr Ima Parrondo ***Health Care Compliance Officer, EMEA Pharmaceutical Sector*** Johnson & Johnson HCC & Privacy	Date
Jane Griffiths ***Company Group Chairman*** Pharmaceuticals Europe, Middle East & Africa (EMEA)	Date