**Informatics Patient Safety (IPS) Mobile Application Inspection**

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| --- | --- |
| **Application Name and Version (with build #):**  | **Other app names (including former names):**  |
| **Review Sequence Number (for this app):**  | **Review Request Date:**Click here to enter a date. | **Review Completion Date:** Click here to enter a date. |
| **Target Hardware:** [ ]  Simple Phone[ ]  Smart Phone[ ]  Tablet[ ]  Laptop[ ]  Other (please specify below) | **Target System Software:** [ ]  iOS[ ]  Android[ ]  HTML 5[ ]  Windows 7[ ]  Safari[ ]  Internet Explorer[ ]  Chrome[ ]  Firefox[ ]  Other (please specify below) | **Hardware used during IPS Testing:**[ ]  N/A (wireframe review request)[ ]  Simple Phone[ ]  Smart Phone[ ]  Tablet[ ]  Laptop[ ]  Other (please specify below) | **System Software used during IPS Testing:**[ ]  N/A (wireframe review request)[ ]  iOS[ ]  Android[ ]  HTML 5[ ]  Windows 7[ ]  Safari[ ]  Internet Explorer[ ]  Chrome[ ]  Firefox[ ]  Other (please specify below) |
| **Vendor / Development Team:**  | **Project Manager (PjM):**  |
| **WMS POC:** | **Deployment Manager (DM):** |
| **Business Owner:**  | **Business Office:**  |
| **Jira URL:** | **Wiki URL:** |
| **Inspection Type:** Choose an item. |
| **IPS Primary Reviewer & POC:**Choose an item.  | **IPS Second Reviewer:**Choose an item. |
| **Domain SME:**  | **SME Affiliation:**  |
| **Previous Reviews:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IPS Review ID** | **App Version** | **Review Date** | **Inspection Type** | **Result(s)** |
|  |  |  |  |  |

 |
| **Comments:**  |

# Application Classification

Given the healthcare decisions that will be supported, anticipated frequency of use, the expected users’ knowledge, and support provided, this application is classified as:

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| [ ]  | **High Potential Risk to Patient Safety**Patient record keeping is involved, and supports decision making that, if done incorrectly, could lead to serious patient harm.Example Apps: Antibiogram, Immunization Campaign |
| [ ]  | **Medium Potential Risk to Patient Safety**Patient record keeping is involved, but incorrect decisions made are unlikely to have a serious impact on patient safety.Examples: Annie, CBT-I Coach |
| [ ]  | **Low Potential Risk to Patient Safety**Applications that only provide education/information. These applications involve no journal keeping or other record management. Any decision support involves guidance from a standard health care professional organization or practice. The application does not process user entered information. Examples: Burn Pit Registry, Caring4Women |
| [ ]  | **Exempted from Review**The use of this mobile application is not considered to impact patient safety.Examples: Federal Benefits, Metrics Extract Program |

# Inspection Result

The number of issues found and their level of risk is summarized below:

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 | **High Risk Issues**A high risk issue is one where the problem could easily/frequently lead to serious harm. |
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 | **Medium Risk Issues**A medium risk issue is one where the problem could lead to patient harm, but it is unlikely it would be serious. |
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 | **Low Risk Issues**A low risk issue is one where the problem is unlikely to lead to patient harm, but it could impact the user’s efficiency using the application and cause a minor delay in care. |

# Inspection Method

An IPS inspection reviews the anticipated use of a particular mobile application to identify situations where there is the potential to harm a patient or delay the delivery of care. Such situations may occur because of problems with:

* The medical knowledge applied
* The user interface
* Programming logic and system performance not directly related to the user interface
* Data quality or representation
* Interoperability with other applications and systems
* Integration into care workflow
* Technical support for the application

## Analysis of Intended Use

IPS develops a conceptual model of the system (Johnson & Henderson, 2012) to understand its intended usage by analyzing key system components and their interactions, including users, data/information, tasks, technology, domain knowledge and environment of use (**NISTIR 7804**). From this (or as provided by the development team), IPS develops realistic usage scenarios that utilize key application functionality to understand safety-critical components. IPS may require consultation from domain subject matter experts (SMEs) to fully understand hazards and risks involved from a clinical perspective.

## Development Process Issues

Similar to the Food & Drug Administration (FDA) certification of mobile devices, IPS also reviews documentation of development and testing processes that have already been conducted or are planned to ensure there is appropriate and sufficient consideration of patient safety.

## Design Issues

IPS conducts Healthcare Failure Mode Effects Based Analysis through systematic cognitive walkthroughs (C. Wharton et. al., 1994) of the user interface (and/or reviews documentation of use scenarios already created) looking for safety issues from potential generic human-computer interface error types (Chapman, Taylor, and Wood, 2012), potential errors associated with the current task (e.g. patient selection), or potential errors associated with the application type (e.g. medication ordering).

# Application Overview

## Application Purpose

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| Application Description |

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## Relevance to Patient Safety

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| Does use of this application include safety-critical tasks or does it contain elements that may present a patient safety risk? |
| [ ]  Yes | **Rationale:** |
| *Action for IPS reviewer: Complete all sections of the review report.* |
| [ ]  No | *Action for IPS reviewer: Grant the application an exemption. No remaining sections need to be completed.* |

# Analysis of Intended Use

Note: If a response to any of the sections below is based on application documentation (e.g. concept paper), reference that source.

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| --- |
| Medical Basis (Treatment/Therapy/ Knowledge. Include standard practice/medical basis reference(s) [e.g. journal, website, expert]). |
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| Types of User (Veterans, Nurses, Physicians, etc.) |
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| Main User Tasks/Activities (i.e. what can the user do using the application?) |
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| Decisions Supported (i.e. what healthcare related decisions does the application help the user make?) |
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| Environment of Use (Location, Social Context, etc.) |
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# Development Process Checklist

## Plan for Interoperability

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| If the application needs to share data, has a plan for interoperability been developed? |
| [ ]  N/A | **Evidence (that the application does not need to share data):** |
| [ ]  Yes |  |
| [ ]  No |

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| --- | --- | --- | --- |
| **Item:** |  **First Reported Date:** **Click here to enter a date.** | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:** This application needs to share data, but a plan for interoperability doesn’t exist |
| **Action Item:** ​Any software, middleware, or other mobile apps that the application needs to share data with must be identified and data sharing agreements put in place |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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## Independent External Subject Matter Expert (SME) Review

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| Has an independent external SME review been conducted? |
| [ ]  Yes |

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| Was the SME review conducted through IPS? |
| [ ]  Yes | **Description of review conducted with IPS:** |
| [ ]  No | **Description of review conducted without IPS:** |

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| *Action for IPS reviewer: If this revealed any design issues they should be described in the Design Checklist section, but it should be noted they were found through a SME review* |
| [ ]  No |

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| **Item:** |  **First Reported Date:** **Click here to enter a date.** | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:** With a fresh perspective and different experiences an independent reviewer may identify issues that would otherwise be missed. Getting that perspective before field testing makes it more practical/efficient to address any issues the SME may identify. |
| **Action Item:** Detect potential patient safety issues through an independent review by someone not on the development team with applicable medical and workflow knowledge, before the application goes into field testing.   |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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## Version Control

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| Is version control utilized for management of changes to the app? |
| [ ]  Yes | **Evidence:** |
| [ ]  No |

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| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:** ​Each time a new implementation of the application is shared or released a new version descriptor should make that particular instantiation of the application unambiguous. |
| **Action Item:** ​Ensure there is adequate version control as this impacts what version is given a particular review result, and (when the app is released) ensures that reported problems can be associated with the correct build. |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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## Usability Evaluation

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| Has a usability evaluation been conducted? |
| [ ]  Yes | **Evidence:** |
| *Action for IPS reviewer: If this revealed any design issues that have patient safety implications they should be described in the Design Checklist section, but it should be noted in the description of the issue that they were identified during a usability evaluation* |
| [ ]  No |

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| --- | --- | --- | --- |
| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:** A usability evaluation was not conducted, which is a concern to IPS because usability issues may have patient safety implications. |
| **Action Item:** Ensure a usability evaluation has been conducted. |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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# Design Checklist

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| Instructions followed for running the program during testing |
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## Instructions for Immediate Help

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| Does the application provide easily accessible, salient, and understandable instructions for the user to get immediate clinical/mental help or help with safety critical tasks? |
| [ ]  Yes | **Evidence:** **Screen Capture:**  |
| [ ]  No |

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| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:** |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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## Instructions for Reporting Patient Safety Issues

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| Does the application contain clear and easy to find instructions for the user to report potential patient safety issues? |
| [ ]  Yes | **Evidence:** **Screen Capture:**  |
| [ ]  No |

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| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:** |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Yes |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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| Description of Application Specific Scenarios |
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## G. Issues Found During Cognitive Walkthroughs of Application Specific Scenarios

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| Did Cognitive Walkthroughs of the application specific scenarios reveal any patient safety issues?  |
| [ ]  No | *No action required* |
| [ ]  Yes |

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| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:** |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Choose an item. |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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| --- | --- | --- | --- |
| **Item:** |  **First Reported Date:**Click here to enter a date. | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:**  |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Choose an item. |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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| --- | --- | --- | --- |
| **Item:** |  **First Reported Date:** **Click here to enter a date.** | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:** |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Choose an item. |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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| --- | --- | --- | --- |
| **Item:** |  **First Reported Date:** **Click here to enter a date.** | **Status:**Choose an item. | **Closed Date:**  |
| **Description of Issue:**  |
| **Screen Capture:**  |
| **Action Item:**  |
| **Risk Level:** Choose an item. |
| **IPS Verification Required:** Choose an item. |
| **Response from PM/Development:** |
| Date: Response: Choose an item.Comments and actions that will be taken: JIRA reference for this issue: |
| **Response from IPS:** Date:Comments: |
| **Action Taken:**  |

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# Appendix A – Scenario Walkthroughs

The following walkthroughs document the sequence of user –technology actions taken for specific scenarios included in this review where the interaction sequence is relatively complex/long.

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| Walkthrough Documentation – Scenario 1 |
| **Step** | **User** | **User Action** | **HIT Component** | **HIT Action** | **Issue** | **Screen Capture Ref** |
| 1. | Provider A |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

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| --- |
| Walkthrough Documentation – Scenario 2  |
| **Step** | **User** | **User Action** | **HIT Component** | **HIT Action** | **Issue** | **Screen Capture Ref** |
| 1. | Provider A |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

# References

Carroll, J. M. (1999). [Five Reasons for Scenario-Based Design](http://testingeducation.org/BBST/testdesign/CarrollScenarios.pdf). Proceedings of the 32nd Hawaii International Conference on Systems Sciences.

Chapman R. J., Taylor, L. M., & Wood, S. D. (2012). [Cataloging Errors from Reported Informatics Patient Safety Adverse Events](http://vaww.va.gov/CHIO/IPS/docs/PSI-CAM2012paper.pdf)*.* Proceedings of Human Factors and Ergonomics Society Healthcare Symposium, Baltimore, MD.

Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm>

Johnson, J., ‎ & Henderson, A., (2012). *Conceptual Models: Core to Good Design. Morgan & Claypool.*

**(NISTIR 7804) Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records.** <http://www.nist.gov/manuscript-publication-search.cfm?pub_id=909701>

 [http://www.nist.gov/manuscript-publication-search.cfm?pub\_id=907849#](http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907849)

Wharton, C. Rieman, J., Lewis, C. and Polson, P. (1994). The Cognitive Walkthrough Method: A Practitioner's Guide. In J. Nielsen and R. Mack (eds.) Usability Inspection Methods (New York: Wiley) 105-140.

Wood, S. D., Chapman R. J., Taylor, L. M., Wright, P., & Scott J. (2014). [Identifying Latent Design Issues in Mobile Products to Prevent Patient Harm](http://vaww.va.gov/CHIO/IPS/docs/hfhc2014.pdf). Proceedings of Human Factors and Ergonomics Society Healthcare Symposium, Chicago, IL.