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| VA_Seal_BW[1]  VHA Office of Informatics and Analytics (OIA) |
| Informatics Patient Safety (IPS) Mobile Application Certification Checklist |
| Version 1.0 |
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| **1/4/2013** |

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# Informatics Patient Safety (IPS) Mobile Application Certification Checklist

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| **Mobile Application Name:** | | |
| **Software Version:** | | **Review Date:** |
| **Vendor / Development Team:** | | |
| **IPS Analyst Reviewer:** | **IPS Human Factors Reviewer:** | |
| **Description of any Previous Review:** | | |
| **Application Description**  **Users:**  **Main Functionality:**  **Medical Knowledge / Procedures Involved:** | | |

# A. Introduction

The overall approach taken to Informatics Patient Safety (IPS) certification is based on that used for Food & Drug Administration (FDA) certification of mobile devices. That is, IPS will primarily review 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.

This certification will occur after the usability testing certification and clinical review certification so that the results of those reviews can be utilized and redundancy avoided.

# B. Checklist

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| **Relevance to Patient Safety**   |  | | --- | | If the use of this mobile application does not lead to potential patient safety issues (as defined by IPS) the checklist in this section does not need to be completed. Simply proceed to section C "Certification Result" and record the fact this application has been granted an exemption. |   ⬜ **A review of the application's purpose has been conducted and this type of application is considered to have potential patient safety issues for the following reasons:** |

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| **Scenario based testing with realistic context(s) of use and consideration of risks to patient safety**  **⬜ The usability testing certification process (and/or another usability evaluation) involved user centered scenarios with sufficient detail and context, or there is a documented plan to conduct such an evaluation.**  **Description of Scenarios:**  **⬜ End users have in some way been, or will be, involved in evaluations/testing.**  **Description:**  **⬜ Potential patient safety risks have been considered.**  **Description:** |

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| **Integration Agreement with Data Source**  **⬜ An integration agreement exists with the data source or it is not applicable.**  **Evidence of data integration agreement if applicable or justification for this not being applicable:** |

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| **Support Structure**  **⬜ A documented support structure exists that includes a means for users to report problems in using the software and a satisfactory upgrade/patch release process**  **Evidence:** |

# C. Certification Result

Check one of the following options as appropriate to record the result of this evaluation for informatics patient safety certification.

⬜ Exemption Status Granted

The use of this mobile application will not lead to any potential patient safety issues (as defined by the Informatics Patient Safety office).

⬜ Certification Granted

The mobile application has successfully passed a review of each criteria contained in this document. The application developers will be contacted with the result of this evaluation and additionally informed that recertification will be required if there is a significant change in the application (e.g. additional functionality, change in architecture, or use by users or in a work environment not originally proposed).

⬜ Certification Not Granted

The mobile application has not passed all the criteria contained in this document. The application developers will be contacted and told why certification was not granted and what actions can be taken to address the relevant issues and reapply for certification.

# D. References

**(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)

**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>