**Informatics Patient Safety (IPS) Mobile Application Review Request**

Note: these instructions and review request form are not for requesting a patient safety review of an application’s requirements. To request a requirements review, send an E-mail to VHA10P2AIPSMobileTeam@va.gov and further instructions will be given.

## Review Purpose

Patient safety reviews of mobile applications are conducted by The Veterans Health Administration (VHA) [Informatics Patient Safety Office (IPS)](http://vaww.va.gov/CHIO/IPS/index.asp), whose purpose is to improve the safety of Health Information Technology (HIT) products used by the VA and Veterans, while promoting the use of HIT to make healthcare safer.

IPS reviews are centered on the context of use from user and patient safety perspectives. Specific combinations of user, task, technology and environment are identified and *safety critical tasks* analyzed. A safety critical task is any action or decision whose failure could cause patient harm or a significant delay in care delivery.

## How to request an IPS Mobile Application Review

PMs designated to a mobile application by Connected Care may request an IPS review. In order to help IPS understand the context of use, identify safety critical tasks, walkthrough realistic scenarios, and manage the review process efficiently and effectively, PMs are asked to complete the review request form in its entirety. The PM should then send the completed form and associated documentation via E-mail to VHA10P2AIPSMobileTeam@va.gov. IPS will respond and include the contact information for the person assigned to lead the patient safety review. Note: Requests for a review before the compliance review stage (i.e. wireframe or preliminary executable) may be granted if sufficient IPS resources are available during the time the review is requested.

## IPS Review Results

When IPS has completed its review the PM will receive an email with an attached document that provides a detailed description of the review conducted and any patient safety issues found. IPS welcomes questions about the review results and also requests that after the PM has discussed the results with the application business owner the response to each issue is communicated back to the IPS POC for the application within 2 weeks.

## Re-Review Requests

If a request form was completed for a previous review of this application, the PM should send that form with this re-review request.  Information that has not changed does not need to be repeated, but any changes and updates do need to be provided.  This frequently includes:

|  |  |
| --- | --- |
| * Current version and build number
* Target hardware
* POC/PM information
 | * Application purpose
* Implemented functionality
* Instructions to access the test environment
 |

A summary of actions taken in response to any issues previously identified by IPS must be provided.

|  |  |
| --- | --- |
| **Requestor’s Name:**  | **Requestor’s E-mail:**  |
| **Date of Request:**Click here to enter a date. | **Requested Review Completion Date:** Click here to enter a date. |
| **Application Name and Version (with build #):**  | **Other app names (including former names):**  |
| **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 Developer Testing:**[ ]  N/A (wireframe review request)[ ]  Simple Phone[ ]  Smart Phone[ ]  Tablet[ ]  Laptop[ ]  Other (please specify below) | **System Software used during Developer 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 Requested:** Choose an item. |
| **Previous IPS Reviews:** 1. If issues were identified by IPS in a previous review please ensure that the status of those issues is communicated with this re-review request.
2. List any changes to the purpose/scope of the application:
3. List new functionality (and link(s) to new “user stories” in JIRA), if applicable:
 |
| **For all requests, other than a wireframe or requirements review:**1. Provide instructions for accessing and using the app or the test site environment:
2. Provide POC contact information for technical questions setting up the mobile device/application for testing:
3. Description of any known problems/limitations in the application (e.g bugs, limited availability of testing environment):

**For wireframe reviews:**1. Provide the set of documented wireframe images
 |

# Application Overview

## Application Purpose

Describe the purpose of the application in the space below AND add attachment(s) and/or direct reference to a document(s) (e.g. a link to a file in Jira). If a concept paper and Business Requirements Document are available, please provide both (indicating if there have been any significant changes in either during development).

|  |
| --- |
| Application Description and/or Direct Reference to Documentation |

|  |
| --- |
|  |

## Medical Basis

Describe the medical basis for the design of the application – including reference to standard practices, medical knowledge, or assumptions from a practice innovation.

|  |
| --- |
| Description of the Medical Basis for the Application |

|  |
| --- |
|  |

# Review Request Checklist

## Plan for Interoperability

|  |
| --- |
| 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 | *Describe what data will be shared and with what systems:* |
| [ ]  No | *Describe when a plan is expected to be developed:* |

## Independent External Subject Matter Expert (SME) Review

An independent external SME review will often provide fresh insight and, for patient safety critical tasks, help identify additional potential risks that should be addressed.

|  |
| --- |
| Has an independent external SME review been conducted? |
| ○ Yes | *Description:**Note the affiliation of the independent external SME to VA:* |
| [ ]  No | *Describe any internal SME involvement in the development/review of the app, if applicable:* |

##

## Version Control

|  |
| --- |
| Is version control utilized for management of changes to the app? |
| [ ]  Yes |  |
| [ ]  No | *Describe when and how version control will be implemented:* |

## Usability Evaluation(s)

|  |
| --- |
| Has a usability evaluation been conducted for this application? |
| [ ]  Yes | *Provide a link to the evaluation results or attach the documentation with this review request.* |
| [ ]  No | *Describe why a usability evaluation has not been conducted or provide the status of any ongoing evaluation and POC information:* |

##

## Immediate Help

|  |
| --- |
| 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 | *Summary of how patients can get immediate clinical or mental help (if the application is patient facing) or how healthcare providers can get help with safety critical tasks:* |
| [ ]  No | *Indicate when you intend to add instructions for immediate help or why you do not consider this applicable:*  |

## Limited Release Field Testing

|  |
| --- |
| Is limited release field testing planned or already conducted? |
| [ ]  Yes | *Provide a summary for how this testing will be, or was, conducted – including the sites involved:* |
| [ ]  No | *Describe why this was/is not considered necessary:*  |

## H. Scenarios and Demonstration for Application Walkthroughs

IPS will need to walk-through the application in order to understand how an end user would use the application, particularly for safety critical tasks. If walkthrough scenarios have already been created by the development team these may be used/adapted to support this part of the IPS review.

|  |
| --- |
| Walkthrough Scenarios |
| *Please indicate where documentation of walkthrough scenarios may be obtained or attach such documentation with this review request:* |

A demonstration by a member of the development team and a SME (if available) can be very helpful to communicate how use of the application is intended.

|  |
| --- |
| Demonstration |
| *Please indicate if a demonstration can be facilitated with a SME in attendance:*  |