

SLIDE 2:

All education, research, and medical institutions are required by the federal government to have an IRB in order to do research with human subjects. Each IRB is charged with protecting the rights and welfare of human research subjects. The IRB reviews proposed research to ensure that the proposed project follows federal guidelines and accepted ethical principles to meet that goal. Federal guidelines require academic and cultural diversity of IRB members to ensure that research proposals are given a thorough review by members with varying interests.

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The **My Human Subjects** list is the most important for most uses with this system. Here are found links to new applications, modifications of previously submitted protocols that are under review, amendments, adverse event reporting, continuing review, final reports, and help. While scrolling down the list the user should choose the link that serves his/her intent. For example, to begin a new application, click **Create New**. If clicking that link does not take the user to the application, check to be sure there is not a pop-up blocker preventing access. If so, disable it.

- I. Selecting the **Show/List** link will take the user to a list of all his or her applications that are under review and have been previously approved. To make modifications to a previously submitted application that is still under review, click the open folder icon to the left of the protocol (under Actions).

SLIDE 11 (CONT):

The **Search For** link will enable the user to access his or her protocols that have been closed. Opening an old application can enable the user to copy and paste from the old to a new application. This can also be accomplished by selecting **Create New** and **checking Copy from Existing Human Protocol**.

II. **Creating a New Regular Initial Application**

This application is to be used by any undergraduate or graduate student who is enrolled in a class that requires completing a research project involving human subjects. This does not include graduate students who are working on their theses, dissertations or other supervised research projects. After logging in, the Principal Investigator (PI) should go into **My Human Subjects** along the left margin and select **Create New**.

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Along the left margin of the formal application is a **Menu** tab. When that is clicked, the PI has the option of saving the application. **Saving** an application periodically is a good idea, so that no information will be inadvertently deleted. **Printing** a copy of the completed application provides a reference for the PI and supervising faculty. It can also be sent to other participating agencies or institutions. You can only print an application once it has been checked complete and the red pdf icon appears next to Complete. **To print**, simply use the Ctrl P on your keyboard.

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Level of Risk (VI A) - The PI should select of the level of risk to participants in terms of physical, emotional, legal, and reputation issues. The PHSC will review the application to determine whether the PI's assumption is accurate.

Procedures (VI C) - Check the types of procedures that will be used in the research. More than one procedure may be checked. At the Components of Initial Review dialogue box (the place where the completed application will be submitted, the PI will be prompted to upload documents related to those procedures.

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Sensitive Subject Matter (VI D) - Choose all that apply.

Maintaining Confidentiality (VI E) - Answer each question.

Managing Risk (VI F) - This is a very important consideration and should be thought through carefully before submitting the application.

Audio or Video Taping (VI G) - Yes or no. When this is to be done, the cover letter or informed consent document must specifically inform the participant.

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Protected Health Information (VIII E) This inquires about recording or sharing protected health information (PHI). This is an issue that is regulated by federal law (HIPAA) and must be careful considered.

Additional documentation is required when a study collects or distributes PHI.

Use of Deception (VII F) If deception is used, a debriefing document should be uploaded where indicated.

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Research Participant Selection and Recruitment (IX A & B) - Check all that apply. The user will be prompted at the Components of Initial Review dialogue box to upload any and all forms of consent that are indicated by the application.

Accessing Records (IX C) - When intending to access records about participants outside the University, appropriate documentation for cooperation/permission from the custodian of the records should be uploaded. Clicking on the plus sign will provide an icon for uploading the necessary documentation.

Compensation and Costs of Participation (IX D) – If PI would like to offer incentives for participation in the project, they should indicate here.

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The PI will be asked to accept a certification that the information is correct and will be asked for login credentials, the user must then click on a gray Continue button and then a gray Submit button. Once that is done, the user should click Done (upper left hand corner) and then log out of InfoEd.

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To return to an application that was either started or submitted earlier, login and choose the **My Human Subjects** tab on the left. Clicking **Show/List** takes the user a list of his or her protocols. To add to a protocol, click the **Open** folder icon, and the submission dialogue box will appear. Open the folder to be taken to the application. To make changes it is necessary to uncheck the **Complete** box on the application. When finished with the revisions, click the **Complete** box and wait for the red pdf icon to appear; the application screen auto-closes. At the **Components for Initial Review** screen, click the Submit button. Before leaving the system, click **Done** and log out of the system.