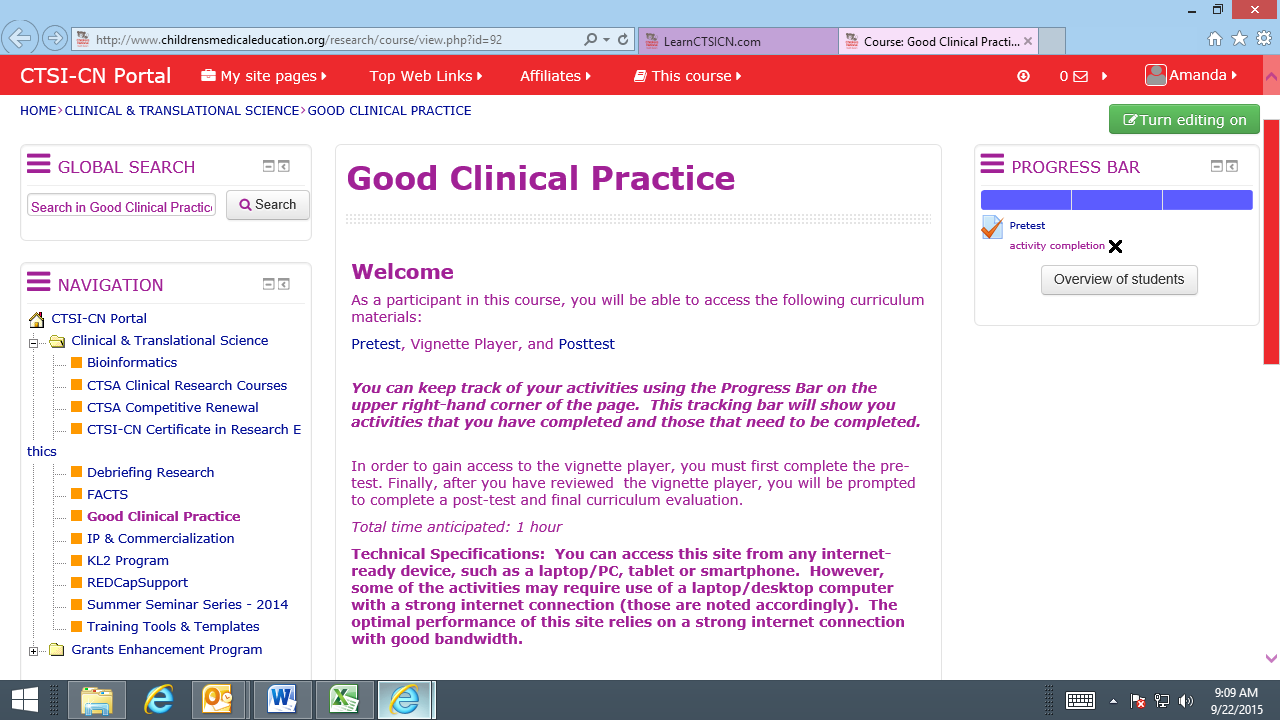
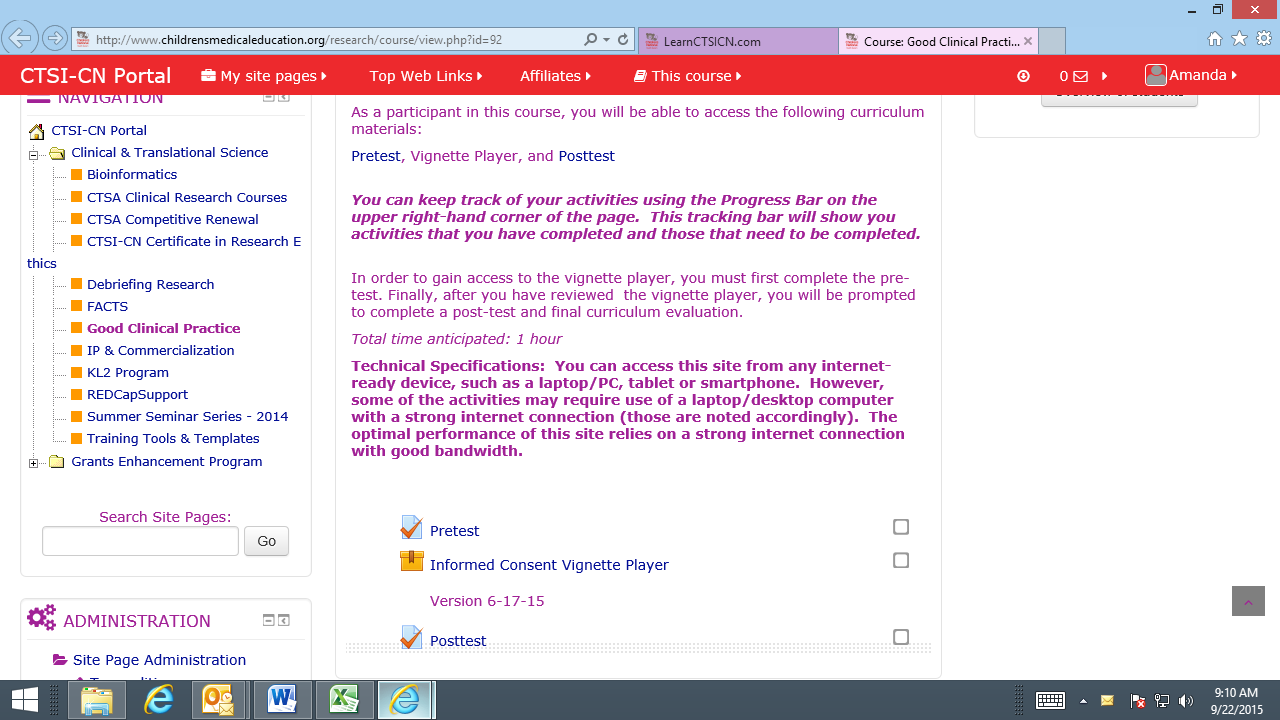
**Appendix A. Good Clinical Practice (GCP) Vignette – *Informed Consent and Assent of Research Participants in Clinical Trials Involving Drugs, Biologics, and Devices***

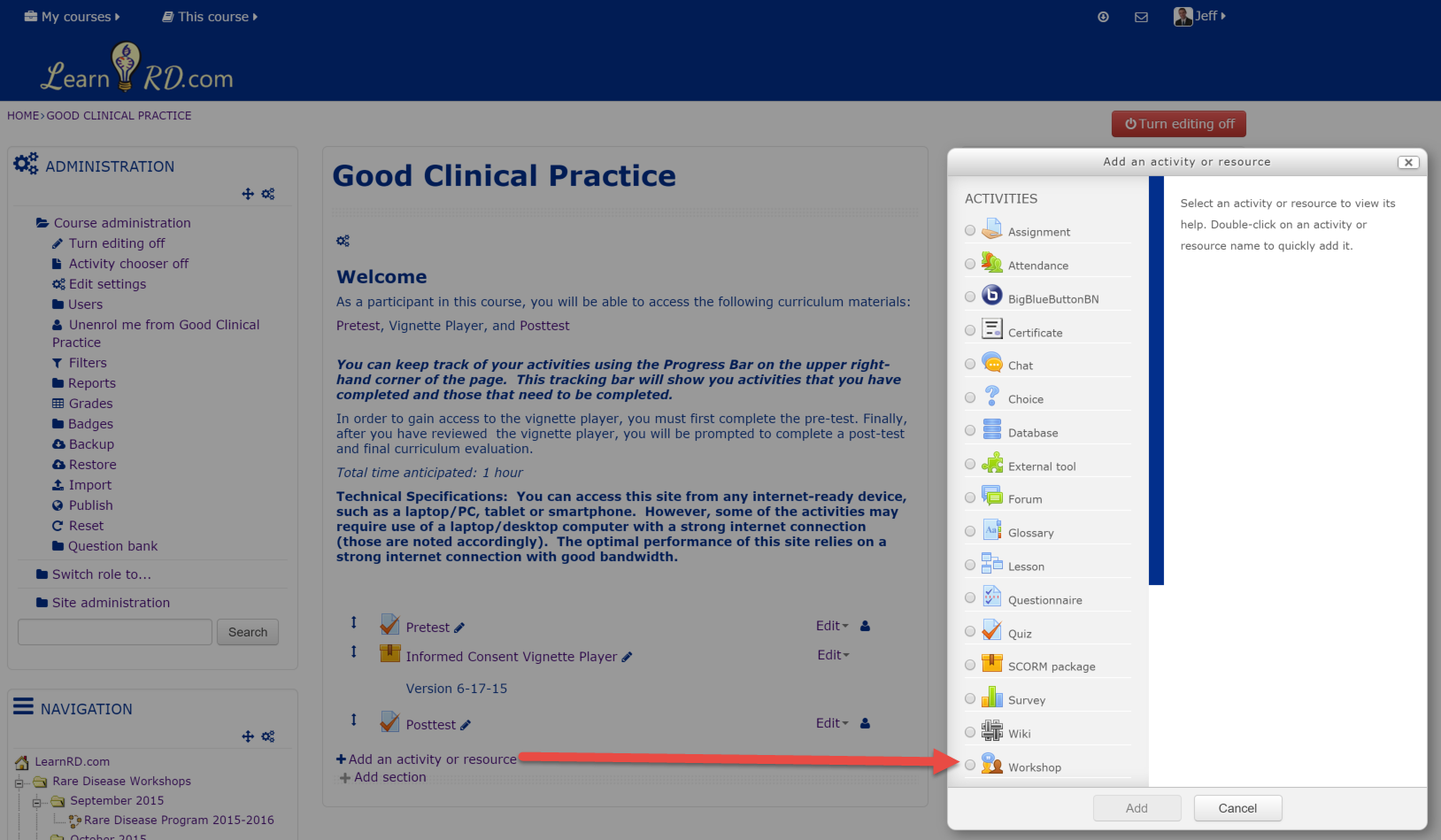
1. Users can select the *GCP vignette player* from a variety of courses available on the CTSI-CN portal, *FACTS* (<http://www.childrensmedicaleducation.org/research/>).



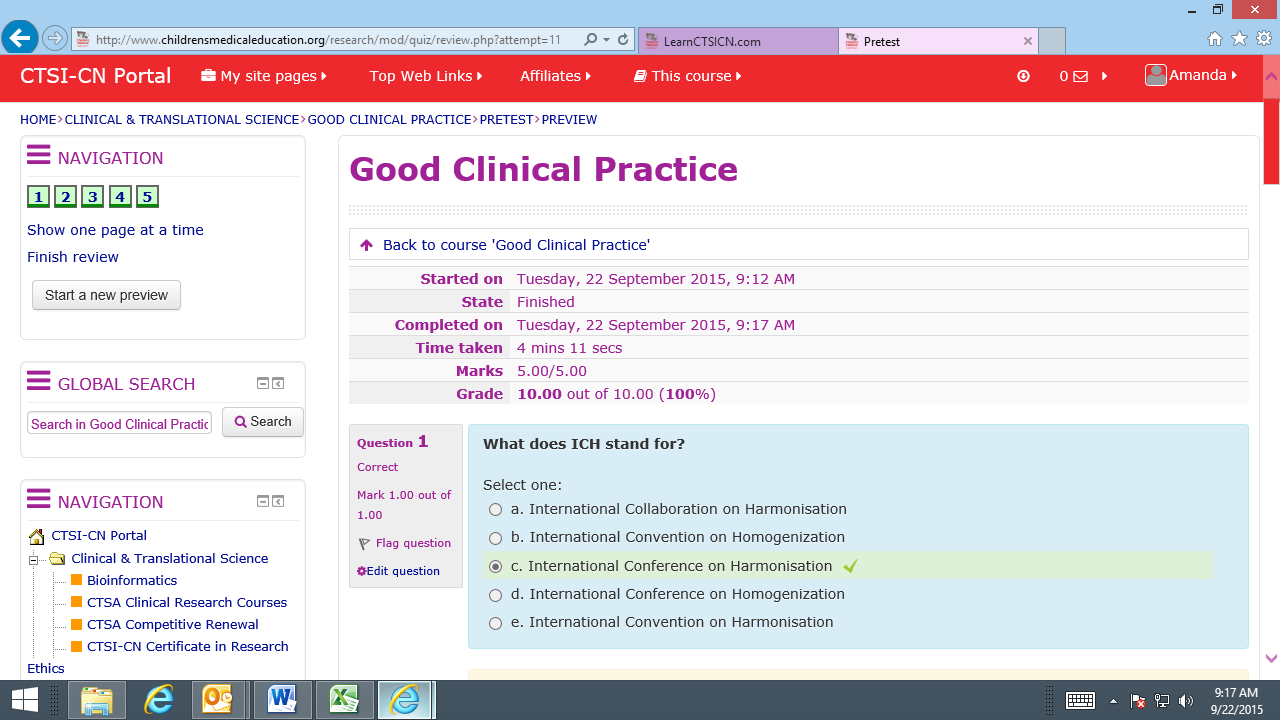
2. Once a user has selected the GCP course, they are directed to the course homepage where they will begin their GCP experience completing the *pretest*.



3. There are over 100 external *plugins* are integrated into the *FACTS* portal including virtual conferencing, game and quiz makers, and more.



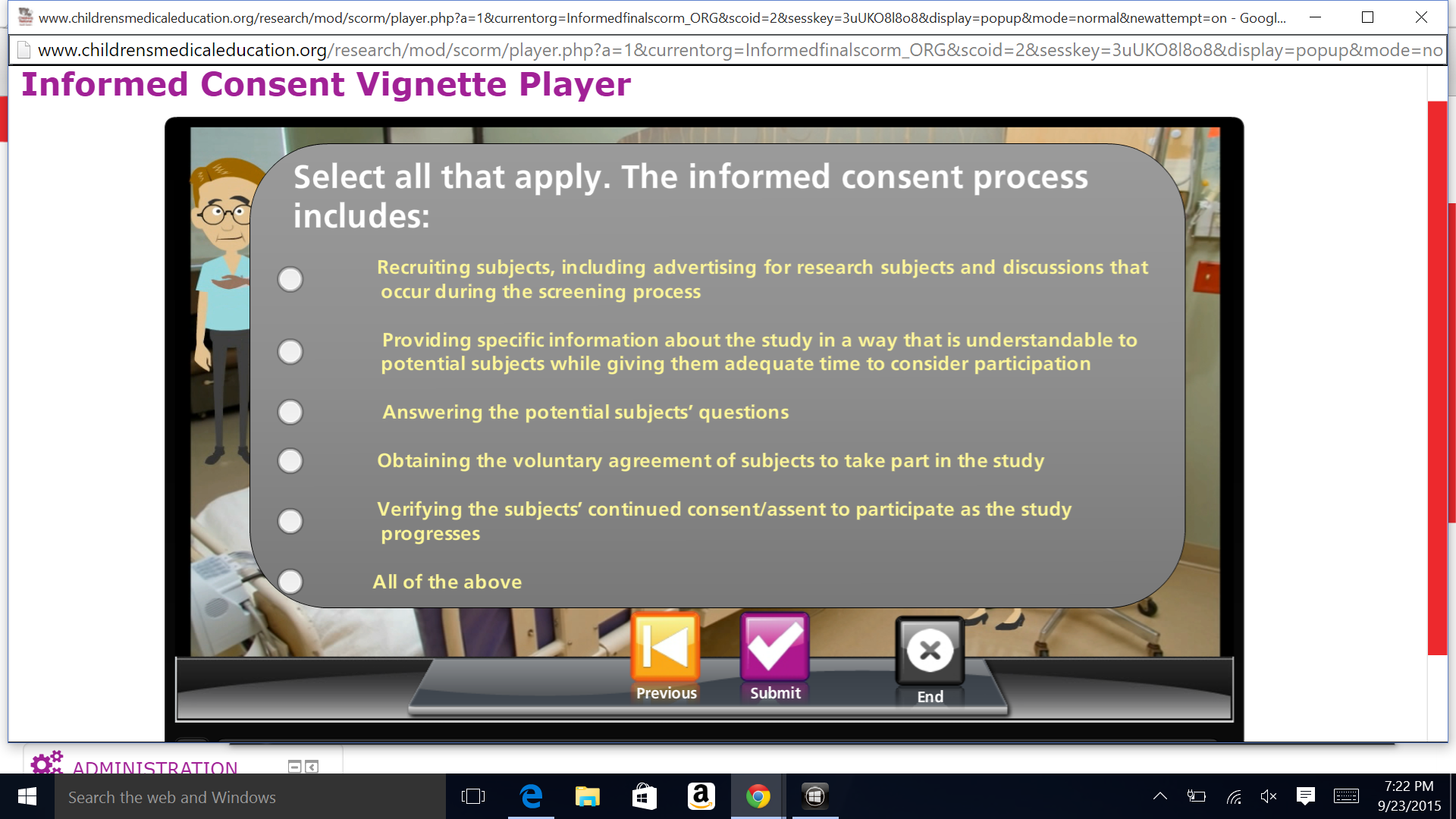
4. Within the *pretest*, existing knowledge of International Conference on Harmonization (ICH) GCP training including: GCP Overview, the Principles of ICH GCP and Investigator responsibilities, as they pertain to informed consent/assent, are assessed. Immediate feedback is given upon completion.



5. Once users launch the GCP vignette, they are taken to the *home page* of the player where they will initiate the course.



6. *Knowledge checks* are performed throughout the various scenes of the vignette player.



7. Immediate *feedback* is given based on the selected response.



8. Finally, a *post assessment* is given at the completion of the vignette player. The user is given further information about where in the ICH document the concept is further explained.

