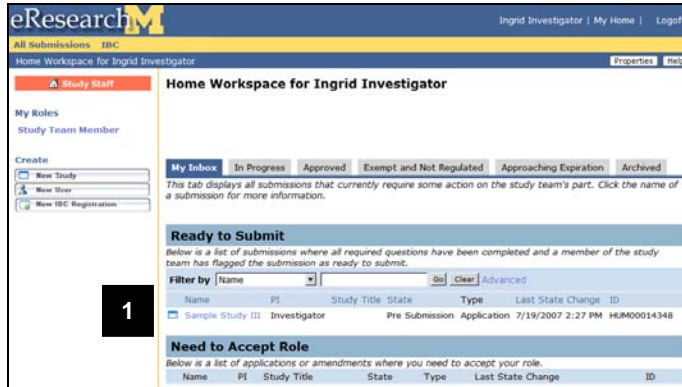


## Application Checklist

### Important Information

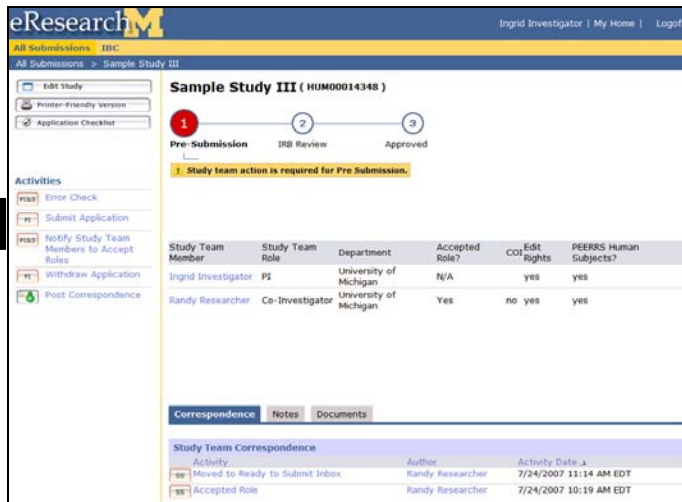
Prior to submitting the application, you can display a list application sections that are not complete by running the **Application Checklist**. You can then jump to incomplete sections and complete all required information.

### eResearch Home Workspace



1. Click the name of the application to be submitted from **Require Action by Study Team** section of **My Inbox**.

### eResearch Study Workspace



2. Click .

Application Checklist Progress Window

Progress **3** Help

Section	Description	Progress
<a href="#">01. General Study Information</a>		Complete
<a href="#">02. Sponsor Information</a>		Complete
<a href="#">03. Performance Sites</a>		Complete
<a href="#">04. Study Abstract</a>		Complete
<a href="#">05. Research Design</a>		Complete
<a href="#">06. Benefits and Risks</a>		Incomplete
<a href="#">07. Special Considerations</a>		Complete
<a href="#">08. Subject Detail</a>		Complete
<a href="#">09. Subject Populations</a>		Complete
<a href="#">10. Informed Consent</a>		Incomplete
<a href="#">11. Confidentiality and Security</a>		Complete
<a href="#">12. Exemption</a>		Complete
<a href="#">13. Subject Payments Or Other Incentives</a>		Not Required
<a href="#">14. Health Care Treatments and Procedures</a>		Not Required
<a href="#">15. Drug, Biologics, Etc.</a>		Not Required
<a href="#">16. Devices</a>		Not Required
<a href="#">17. Placebo</a>		Not Required

- The Application Checklist **Progress** window displays the current progress status of each section of the application.
- Click the name of an incomplete section to jump to that section within the application.

4

eResearch Study Workspace

6.5 \* What is the highest level of risks of harm to the subjects, resulting from this research? ?

Risk Level	Description
<input checked="" type="radio"/> No more than minimal risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.)
<input type="radio"/> Minor increase over minimal risk	Particularly relevant to research involving children.
<input type="radio"/> Moderate risk	
<input type="radio"/> High risk	Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks.

[Clear](#)

6.6 \* Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

Risks to subjects...

\* Required

**6** Save | Edit | Help/Show Errors | Print... | June 2007

- Make the necessary changes.
- Click **Save**.

### Application Checklist Progress Window

Progress <span style="float: right;">Help</span>		
Section	Description	Progress
01. General Study Information		Complete
02. Sponsor Information		Complete
03. Performance Sites		Complete
04. Study Abstract		Complete
05. Research Design		Complete
06. Benefits and Risks		Complete
07. Special Considerations		Complete
08. Subject Detail		Complete
09. Subject Populations		Complete
10. Informed Consent		Incomplete
11. Confidentiality and Security		Complete
12. Exemption		Complete
13. Subject Payments Or Other Incentives		Not Required
14. Health Care Treatments and Procedures		Not Required
15. Drug, Biologics, Etc.		Not Required
16. Devices		Not Required
17. Placebo		Not Required
18. Biological Specimens		Not Required
19. Stem Cells		Not Required
20. Genetic Analysis		Not Required
21. Ionizing Radiation		Not Required
22. Organ/Tissue/Cell Transfer		Not Required
23. Gene Transfer		Not Required
24. Secondary Data Analysis		Not Required
25. Protected Health Information/HIPAA		Not Required
26. Epidemiology		Not Required
27. Deception Research		Not Required
28. Internet/Email		Not Required
29. Survey Research		Not Required
30. International		Not Required
31. Watching/Listening to Audiovisual Materials		Not Required
32. Data Safety Monitoring Plan		Not Required
33. Children		Not Required
34. Neonates		Not Required
35. Pregnant Women and/or Fetuses		Not Required
36. Lactating Women		Not Required
37. Women of Child Bearing Potential		Not Required
38. Prisoners		Not Required
39. Cognitively Impaired Adults		Not Required
40. College Students		Not Required
41. Subjects Vulnerable to Coercion		Not Required
42. GCRC Information		Not Required
43. MADRC Information		Not Required

8 Close

7

7. Keep the Application Checklist **Progress** window open to quickly navigate to incomplete sections within the application.
8. Click Close to close the application checklist and return to the Study Workspace.