

The Consent Process: Requirements

At **The Consent Process**, D.1, you are asked to indicate categories of subjects from whom you intend to obtain consent/assent (e.g., adults, children, parents).

Note: Part D will not display until all preceding sections of the application are complete.

The screenshot shows a web application interface for managing a study application. The main content area displays the 'D.1. Obtaining informed consent from subjects' section, which includes a question: '1. Will children under the age of majority in their locale (18 years in NC) be enrolled?'. The 'Yes' radio button is selected, and a red box highlights the text 'Required document(s): Parental Permission Form'. Below this, there is a text editor for explaining the process. Another red box highlights a checkbox for '7 - 14 years' under the heading 'Check the characteristics of children to be enrolled:'. A callout points to this checkbox, stating 'Required document(s): Assent Form Ages 7-14'. The right-hand panel shows the 'Application Consent Forms' section, which lists required forms: 'Assent Form Ages 7-14' (marked with a red X), 'HIPAA Authorization' (marked with a green check), and 'Parental Permission Form' (marked with a red X). A callout points to this list, stating 'Accumulated consent form requirements/templates are listed at the application's Consent Forms section.' The sidebar on the left shows a list of sections, with 'Part D. The Consent Process' and 'D.1. Obtaining informed consent from subjects' highlighted in red.

A "Yes" response triggers:

- indication of a consent form requirement, and
- the automated creation of a corresponding template

Accumulated consent form requirements/templates are listed at the application's **Consent Forms** section.