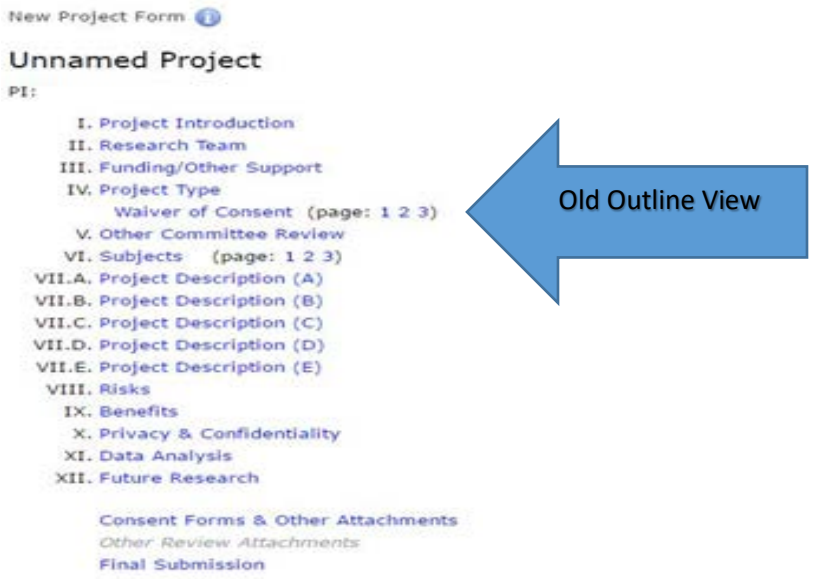
New Index Legend

The Human Subjects Office is excited to introduce the research community to a new educational tool in HawkIRB. We have affectionately referred to it as the HawkIRB Carousel. The carousel is the new index view you will see when you initiate a form in HawkIRB. The new carousel has replaced the current index view for all new, modifications, modification + continuing review, continuing reviews, and reportable event forms.

The Carousel is a rotating view of the IRB application. The index remains the same Roman numeral system you are used to seeing in the old index view with enhanced features to guide you in completing the IRB application. This brief tutorial will provide a detailed breakdown of how to use the new Carousel. The Old view was in Outline format as you see below. The new view contains:

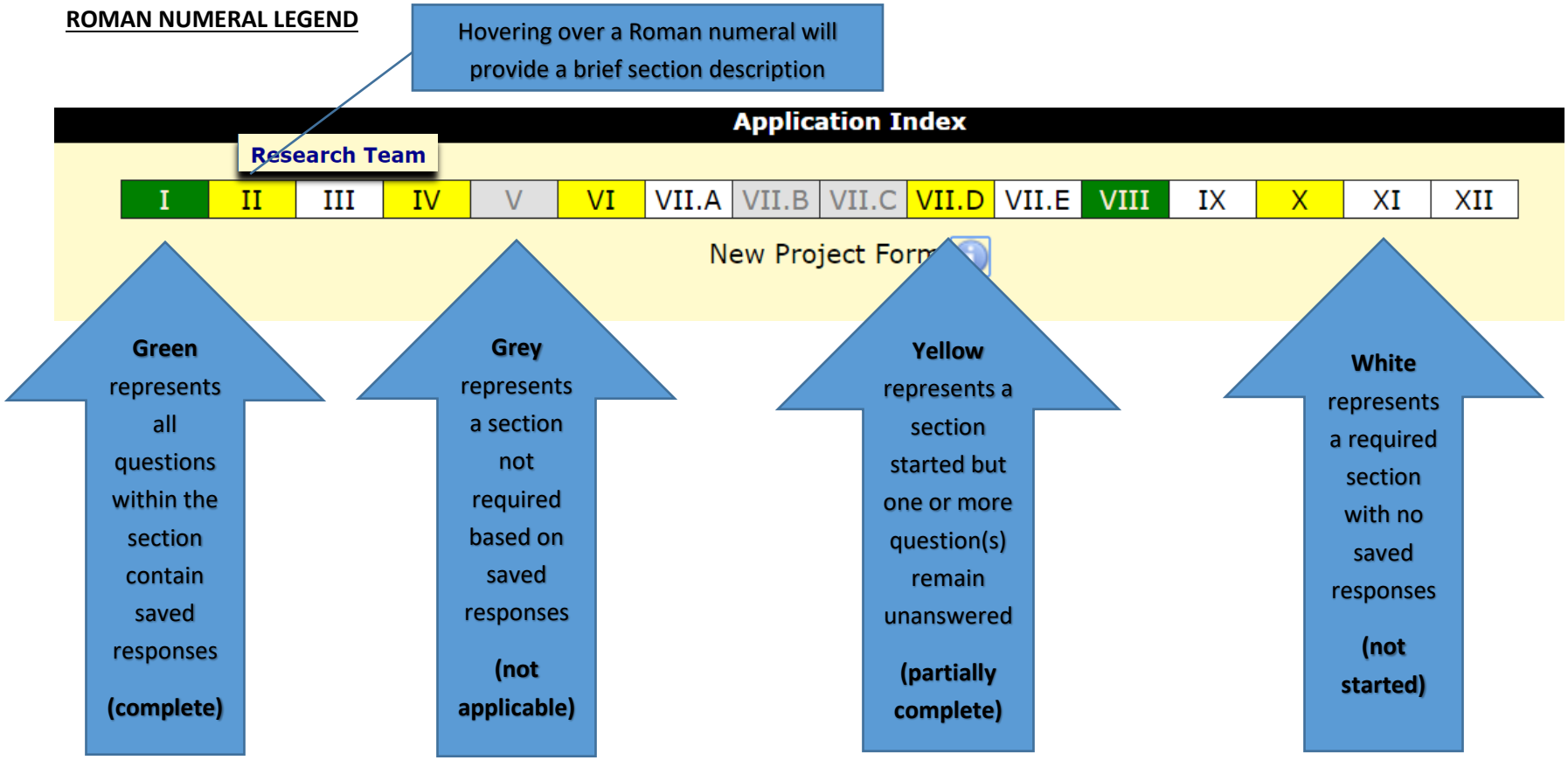
1. Better Section headers
2. Section by section breakdown
3. A "What you need to get started" section
4. A "Why the IRB needs the information" section
5. Visual cues representing when sections are complete



New Index Legend

The Roman numeral index was originally in standard outline format. The new index is two fold, a vertical view as illustrated below.

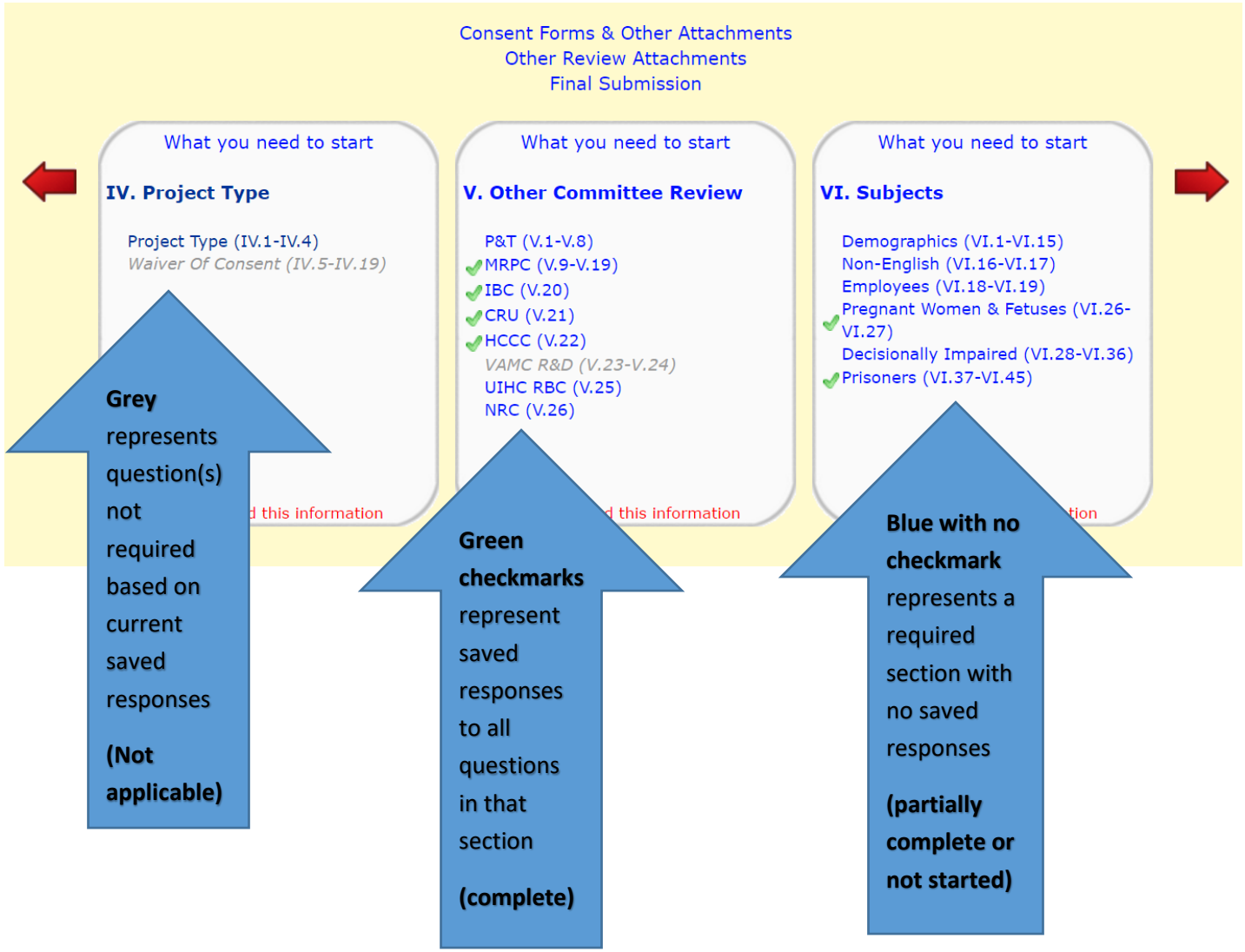
ROMAN NUMERAL LEGEND



New Index Legend

The second expansion is to the project index. Greater detail has been added to each section to provide a better snapshot of what to expect for each of the section of the IRB application. Clicking on the red arrows will move the view from Section I to Section XIV of the draft form.

PROJECT INDEX VIEW



New Index Legend

FULL CAROUSEL VIEW

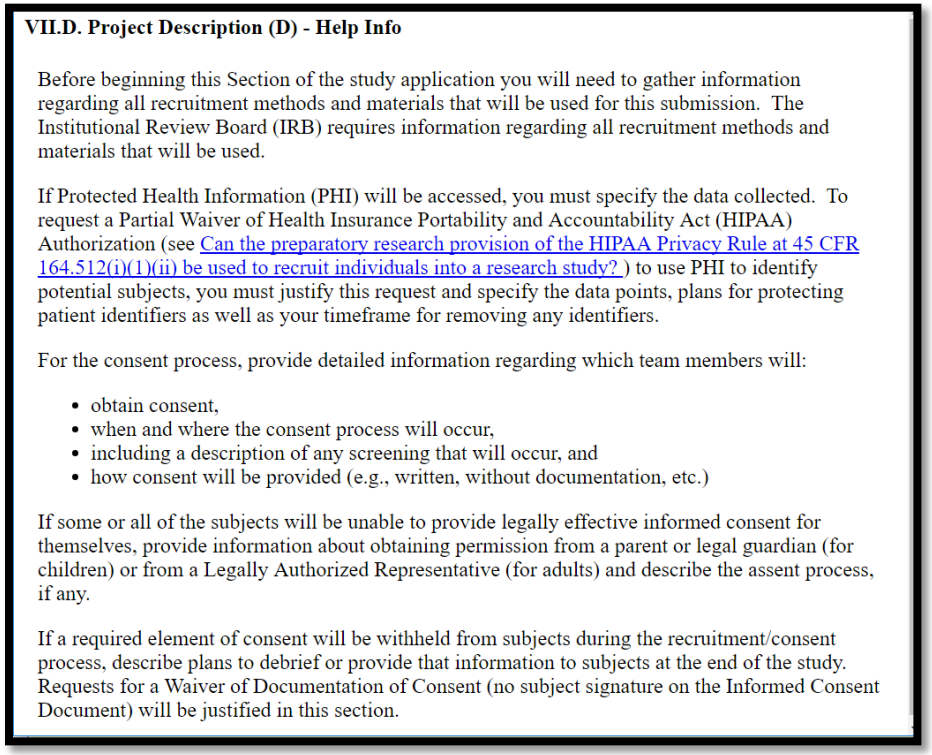
A full view of the Carousel includes the Roman Numeral index as well as the Project Index view. This is the full index view that has replaced the previous project index outline. The last and most important enhancement provides two things:

1. **What information you need to start each section**
2. **Why the IRB needs this information**

New Index Legend

The “What”

- Is a planning tool for researchers to help guide content development of the IRB application.
- Each “What” provides a description of all applicable information required to complete each specific section of the IRB application.



VII.D. Project Description (D) - Help Info

Before beginning this Section of the study application you will need to gather information regarding all recruitment methods and materials that will be used for this submission. The Institutional Review Board (IRB) requires information regarding all recruitment methods and materials that will be used.

If Protected Health Information (PHI) will be accessed, you must specify the data collected. To request a Partial Waiver of Health Insurance Portability and Accountability Act (HIPAA) Authorization (see Can the preparatory research provision of the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(ii) be used to recruit individuals into a research study?) to use PHI to identify potential subjects, you must justify this request and specify the data points, plans for protecting patient identifiers as well as your timeframe for removing any identifiers.

For the consent process, provide detailed information regarding which team members will:

- obtain consent,
- when and where the consent process will occur,
- including a description of any screening that will occur, and
- how consent will be provided (e.g., written, without documentation, etc.)

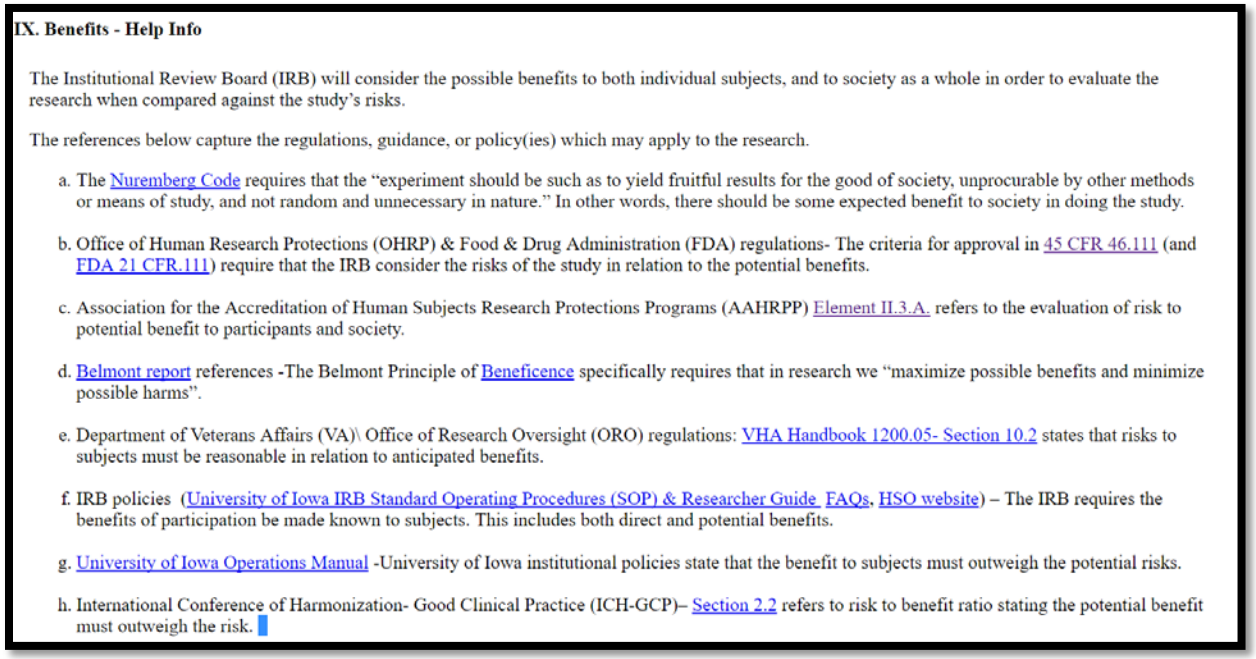
If some or all of the subjects will be unable to provide legally effective informed consent for themselves, provide information about obtaining permission from a parent or legal guardian (for children) or from a Legally Authorized Representative (for adults) and describe the assent process, if any.

If a required element of consent will be withheld from subjects during the recruitment/consent process, describe plans to debrief or provide that information to subjects at the end of the study. Requests for a Waiver of Documentation of Consent (no subject signature on the Informed Consent Document) will be justified in this section.

New Index Legend

The "Why"

- Provides a comprehensive explanation of the basis for the information required in each section of the IRB application.
- Provides federal, state, institutional policies references with active hyperlinks to applicable policies that apply to each section.
- Also provides human subjects research protection program accreditation standards met for each section



IX. Benefits - Help Info

The Institutional Review Board (IRB) will consider the possible benefits to both individual subjects, and to society as a whole in order to evaluate the research when compared against the study's risks.

The references below capture the regulations, guidance, or policy(ies) which may apply to the research.

a. The Nuremberg Code requires that the "experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature." In other words, there should be some expected benefit to society in doing the study.

b. Office of Human Research Protections (OHRP) & Food & Drug Administration (FDA) regulations- The criteria for approval in 45 CFR 46.111 (and FDA 21 CFR.111) require that the IRB consider the risks of the study in relation to the potential benefits.

c. Association for the Accreditation of Human Subjects Research Protections Programs (AAHRPP) Element II.3.A. refers to the evaluation of risk to potential benefit to participants and society.

d. Belmont report references -The Belmont Principle of Beneficence specifically requires that in research we "maximize possible benefits and minimize possible harms".

e. Department of Veterans Affairs (VA)\ Office of Research Oversight (ORO) regulations: VHA Handbook 1200.05- Section 10.2 states that risks to subjects must be reasonable in relation to anticipated benefits.

f. IRB policies (University of Iowa IRB Standard Operating Procedures (SOP) & Researcher Guide FAQs, HSO website) – The IRB requires the benefits of participation be made known to subjects. This includes both direct and potential benefits.

g. University of Iowa Operations Manual -University of Iowa institutional policies state that the benefit to subjects must outweigh the potential risks.

h. International Conference of Harmonization- Good Clinical Practice (ICH-GCP)– Section 2.2 refers to risk to benefit ratio stating the potential benefit must outweigh the risk.

If you have any questions on how to navigate the new project index, please contact the human subjects office at (319) 335-6564 or irb@uiowa.edu.