Frequently Asked Questions: Protocol Templates

What is a protocol?
A protocol is a document that describes all aspects of the research study: how the research will be conducted (objectives, design, methodology, statistical considerations) and the procedures to ensure the protection of the rights and welfare of research participants involved in the study.

Why is the IRB requiring a protocol for IRB submissions?
The reasons for requiring a protocol include the need to eliminate redundancy and enhance compliance as well as the quality and integrity of human research.

- **Eliminate redundancy**
The IRB currently requires a protocol and an IRB application for biomedical research. The IRB application requests information that often can be found in the protocol. Currently researchers and research staff spend time copying-pasting information from the protocol to the IRB application. With the launch of ETHOS, this redundancy is minimized as the protocol will serve as the application.

- **Enhance compliance, quality and integrity of research**
The protocol serves as a guide to the study to ensure that study procedures are followed consistently by the study team over time. By eliminating the IRB applications and appendices, researchers and research staff can rely on the protocol as the source of truth for study conduct.

When will I be required to submit a protocol?
Corresponding with the launch of ETHOS on March 27th, all new studies submitted to the IRB will require a protocol.

If I am a student, am I required to use the protocol template?
Yes. All human research studies to be reviewed by the Institutional Review Board will require a research protocol.

Will exempt research require a protocol?
Yes. If the research study falls within one of the federal exemption categories for human research, a protocol will be required as there will no longer be a set of exempt IRB applications.

What will happen with the determination form?
Researchers seeking a determination of 'not human subjects research' will complete and upload an enhanced Determination form in ETHOS. A protocol is not required for IRB review, but we highly recommend researchers have a research plan that fully describes the study or project. Providing sufficient information to the IRB about the study or project will avoid unnecessary delays.
Is a protocol a required for all studies--biomedical and social/behavioral?
Yes, corresponding with the launch of ETHOS on March 27th, all biomedical and social/behavioral (new) studies submitted to the IRB will require a protocol. Generally, researchers will be required to provide a research protocol using one of the HRPP protocol templates. The following provides information about the templates currently available and a description of intended use:

<table>
<thead>
<tr>
<th>Template (Located under ‘Templates’ in the HRPP Toolkit Library or Forms)</th>
<th>Intended Use</th>
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</thead>
<tbody>
<tr>
<td>HRP-580 - Social Template Protocol</td>
<td>Primarily for those conducting social, behavioral, or educational research.</td>
</tr>
<tr>
<td>HRP-590 - Medical Template Protocol</td>
<td>Primarily by those conducting biomedical research.</td>
</tr>
<tr>
<td>HRP-508 - Site Supplement to Sponsor Protocol</td>
<td>Primarily by those where the main protocol document is received from a study sponsor or non-University of Minnesota research collaborator. May also be used if a researcher intends to use a department protocol template.</td>
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<tr>
<td>HRP-503 - Data Analysis Template Protocol (to be released)</td>
<td>Primarily for those reviewing data (retrospective or prospective)</td>
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Where can I find the new protocol templates?
All protocol templates can be found in the HRPP Toolkit Library or under Forms under the section titled, “Templates.”

Can I submit a completed protocol before the launch of ETHOS?
Yes. Researchers have the option to use one of the protocol templates before the launch of ETHOS. Researchers submitting one of the protocols will not have to submit a full IRB application and appendices. Rather, researchers will be allowed to complete an abbreviated version of the IRB application and appendices (see instructions on Pre-ETHOS Abbreviated IRB Application). This can save researchers significant time in the preparation for IRB submission and review.

Will there be training on protocol development?
Yes. The Human Research Protection Program (HRPP) is sponsoring a protocol development series which will launch this spring. Sign up to receive more information about the series.