Florida State University
INSTITUTIONAL REVIEW BOARD (IRB)
MEMBER MANUAL

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FSU IRB MEMBER MANUAL Revision History

Version	Version Date	Summary of Changes
1	November 1, 2020	New

Acknowledgement
The content of this IRB Member Manual is based upon business practices utilizing the RAMP IRB HRPP Toolkit, including the Toolkits' compilation of Standard Operating Procedures, forms, Worksheets, Checklists and templates.
Appreciation is extended to all whose work have contributed to the content used in this FSU IRB Member Manual, including FSU IRB members and FSU Office for Human Subjects Protection (OHSP) staff, who provided valuable suggestions and feedback.
Gratitude is also extended to the University of Minnesota Office of the Vice President for Research Institutional Review Board, which graciously granted permission for use of the University of Minnesota IRB Member Manual as a template.

IRB Member Roles and Responsibilities

1.   What is the purpose of this manual?

This document, HRP-101 - FSU IRB MEMBER MANUAL, is designed to guide you through IRB membership expectations and related information for your service on the IRB at the Florida State University (FSU). This manual also includes guidance on the review of Human Research[1] and other related information.

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2.   What is the role of an IRB Member?

As an IRB Member, you are a key member of what may be described as the FSU's Human Research Protection Program ("HRPP"). An *HRPP* is described by The National Academies of Sciences, Engineering, and Medicine as—

> An institution's *system composed of interdependent elements that come together to implement policies and practices that ensure appropriate protection of research participants*.[2]

The FSU "HRPP" system includes—in addition to the IRB—the FSU Office of the Vice President for Research, with the Vice President for Research serving as the Institutional Official (IO) who is legally authorized to represent FSU with regard to FSU's Federalwide Assurance (FWA). The FWA is FSU's formal agreement with the U.S. Department of Health and Human Services (DHHS) that provides as a condition of federal support (funding) that FSU will comply with ALL applicable laws[3] and policies pertaining to the protection of Human Research Subjects. The FWA is accepted by other federal agencies that also provide support to FSU to conduct

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[1] Throughout this manual, double-underlined text are included as definitions in HRP-001 - SOP - Definitions.

[2] Responsible Research: A Systems Approach to Protecting Research Participants. The National Academies of Sciences, Engineering, and Medicine (NAS) (2002). The NAS report goes on to state that the "exact structure of an HRPP will vary among research organizations and protocols according to the protection needs intrinsic to a particular study. Despite this flexibility, however, there are basic protection functions necessary to ensure the safety of participants and it is essential that all be met. These functions include comprehensive review of protocols (including scientific, financial conflict of interest, and ethical reviews); ethically sound participant-investigator interactions; ongoing and risk-appropriate safety monitoring; and quality improvement and compliance activities. Furthermore, to be effective, HRPPs should operate within environments that emphasize accountability for the provision of participant protection, assure adequate resources for robust protection activities, provide ethics education programs to those conducting and those overseeing research with humans, and seek open communication and interaction with all stakeholders in the research enterprise" (pp. 1-2). If you would like an electronic copy of the NAS monograph, contact OHSP staff.

The term "research participants" in this IRB Member Manual is intended to refer to "Human Subjects" as that term is used in the applicable federal regulations. While other individuals such as investigators and other study staff and organizations such as sponsors and FSU may also be considered involved in a research activity, for which individuals and organizations' behest or behalf the IRB may perform certain functions, the term "research participants" will here be used to refer only to Human Subjects.

[3] One of the most important laws, and the law that requires institutions to have an FWA as a condition of receiving federal support, is Title 45 of the U.S. Code of Federal Regulations, Part 46 (45 CFR 46, and colloquially referred to as the Common Rule due to analogous versions adopted by many other federal departments and agencies). The IRB review procedures outlined in this manual have as their basis the requirements found in the Common Rule.

research, for example, the U.S. Departments of Commerce, Defense, Education, Energy and Justice, as well as the National Science Foundation and Environmental Protection Agency.

The FSU HRPP also includes the Office for Human Subjects Protection (OHSP), whose Director serves as FSU's Human Protections Administrator under the FSU FWA. The OHSP provides the IRB with professional, technical and administrative support, performs pre-IRB and post-IRB review, conducts and renders non-IRB regulatory reviews and determinations, and maintains IRB and other regulatory documentation. Some OHSP staff serve on the FSU IRB.

The role of an IRB Member is to protect research participants by determining whether Human Research submitted for review meets, or continues to meet, the regulatory criteria for approval. This means that you may play a role at initial review of research, review of modifications to previously approved research, continuing review of previously approved research, and review of reports of new information (e.g., events that represent potential problems for participants or others).

You have been formally appointed to serve in this role because you are able to make a valuable contribution to the HRPP's mission, whether due to your subject matter expertise, background or your experience with participant populations. When appointed, you were assigned as either a regular member or an alternate member.

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3.   What should I know about IRB authority and independence?

Under federal regulations, the IRB has the authority to:

- Approve, Require Modifications in (to secure approval), or Disapprove all Research Activities[4]
- Conduct Continuing Review, when required
- Monitor Consent Process/Conduct of Research
- Suspend/Terminate IRB Approval
- Investigate Unanticipated Problems Involving Risks to Subjects or Others or any Serious or Continuing Non-Compliance with Applicable Requirements or Determinations of the IRB

If the IRB disapproves a protocol, defers a protocol or requires protocol modifications as a condition for approval, no other University official or outside committee may overturn the IRB's decision. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution.[5]

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[4] For a study to be approved it must have the approval of a majority of members present at the meeting, which should reflect a deliberative process from which a consensus among members is achieved.

[5] Section 46.112 of 45 CFR 46 provides that *research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB*. FSU generally has no requirement that studies for which IRB approval or disapproval has been granted are subject to further review by FSU officials, with the exception that due to the COVID-19 national emergency that in-person study activities for which social distancing is not implemented undergo ancillary review by the FSU Office of the Vice President for Research (OVPR); in these cases OVPR may exercise its authority under §46.112 of 45 CFR 46 to disapprove or require modifications (to secure approval) in such studies.

The IRB must perform its responsibilities to protect human research participants without interference by University officials or others to comply with the regulations as well as the ethical standards of the Belmont Report. Attempts to unduly influence any member of the IRB or OHSP staff threatens the independence of the IRB and the integrity of the HRPP and requires prompt reporting to the Institutional Official or their delegate.

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4. *What are the expectations for an IRB Member?*

As an IRB Member, you are expected to do the following:

- Prepare for IRB meetings by reviewing all submissions listed on the meeting agenda.

- Utilize this manual, the Research Administration Management Portal (RAMP) IRB module and other HRPP Toolkit documents in preparation for IRB meetings.

- Contribute to the collegial discussion of agenda items at IRB meetings.

- Confirm attendance for and attend at least 6 IRB meetings per year (or approximately 50% of scheduled IRB meetings in a calendar year). An OHSP IRB Coordinator may ask for your assistance with identifying an alternate to substitute on your behalf when you are unable to attend, review a study or have a Conflicting Interest. You may also be asked to serve as an alternate for another IRB Member when that IRB member is unable to attend a meeting, review a study or has a Conflicting Interest. Alternates and the members for whom they stand in will generally have similar experience and expertise.

- Communicate well in advance to OHSP staff or your assigned OHSP IRB Coordinator when you cannot attend an IRB meeting or when you need assistance with accessing or interpreting submission or review materials.

- Report any Conflicting Interest for IRB Members to your assigned OHSP IRB Coordinator, IRB Chair, or the OHSP Director (see HRP-001 - SOP - Definitions for a definition).

- Serve as a Designated Reviewer (for submissions reviewed through the expedited or Non-Committee Review pathway—i.e., reviews that are not performed through a scheduled IRB meeting) no later than at the time of 90 days of IRB service or sooner if requested due to gaps in expertise. There are occasions when IRB members may be asked to provide time-critical reviews under special circumstances identified by OHSP staff; if these time-critical reviews are not possible, IRB members should promptly notify the OHSP staff so that review by another IRB member may be arranged. For more detailed information about Designated Reviewer responsibilities, different routes for review, as well as conducting Non-Committee Reviews, see sections 5, 16 and 17 below, respectively.

- Serve as a primary reviewer (for submissions reviewed by the convened or full IRB review pathway at a scheduled IRB meeting) no later than at the time of 90 days of IRB service or sooner if requested due to gaps in expertise. Primary reviewers may receive notification of their assignment at least 10 (ten) business days, usually more, before the scheduled IRB meeting at which the submission for which they serve as primary reviewer will be reviewed by the full IRB. For more detailed information about different routes for

review as well as conducting Committee Reviews, see sections 16 and 19 below, respectively.

● Stay current with all training requirements (see section 6 below).

● Treat all oral and written information obtained as part of the review process as confidential; IRB members must not disclose or use confidential information without prior authorization, which includes refraining from communicating review results to investigators separately from any official IRB communication.

● Unless asked to do so by the Institutional Official, refrain from issuing statements about HRPP or IRB operations, policies, tools, systems, or other related topics in a manner that would appear to be speaking on behalf of the HRPP or IRB.

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5.   What are the expectations for a <u>Designated Reviewer</u>?

A <u>Designated Reviewer</u> is an IRB Member who conducts <u>Non-Committee Reviews</u>. Generally, after 90 days of service as an IRB member, you may be asked to serve as a <u>Designated Reviewer</u>. In the event of a gap in expertise, you may be asked to become a <u>Designated Reviewer</u> sooner. When you are asked to serve as a <u>Designated Reviewer</u>, you will be assigned submissions to review on your own outside of a regularly scheduled convened IRB meeting. Depending upon the background or expertise needed to provide review, one or more IRB members may be asked to serve as <u>Designated Reviewer(s)</u> on an assigned submission.

Under the applicable regulations, a <u>Designated Reviewer</u> may not disapprove of a submission. Therefore, if a <u>Designated Reviewer</u> is unable to approve a submission, then the submission must undergo Committee Review at a convened IRB meeting. A <u>Designated Reviewer</u> should, as soon as practicable, notify their OHSP IRB Coordinator when approval of a submission cannot be extended, so that the submission is timely added to an upcoming IRB meeting agenda. The <u>Designated Reviewer</u> may be asked to serve as the primary reviewer of the submission for purposes of the Committee Review.

When conducting <u>Non-Committee Reviews</u>, you are responsible for utilizing HRPP Toolkit documents such as HRP-314 – CHECKLIST – Criteria for Approval and HRP-313 – WORKSHEET - Expedited Review.

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6.   What training does an IRB Member need to review <u>Human Research</u>?

You must complete the following trainings before you may assume your IRB Member responsibilities:

● *Orientation and Onboarding*: The purpose of orientation and onboarding is to inform members about the status of the FSU FWA, the current state of the FSU IRB, the organizational structure of the FSU HRPP (including OHSP), to discuss roles and responsibilities of IRB membership, and share the next steps for training and mentoring, as may be applicable. Follow-up orientation and onboarding meetings or training (including use of RAMP IRB and review materials) will be arranged.

- *CITI Program Human Subjects Research (HSR) Training for FSU IRB Members* is an online course that presents an in-depth exploration of the function and purpose of IRBs through an interactive interface. The course addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of Human Subjects Research. During orientation and onboarding, you will receive instructions for accessing this online course. The FSU IRB Members Course is distinct from the courses that are required of FSU researchers and OHSP staff. Initial and continuing CITI Program training (after three years) is required. Completion of the initial course may take 11 or more hours, and the continuing course 6 or more hours.

- *Mentoring*: Depending upon an FSU IRB member's experience in reviewing Human Research, including use of review materials and electronic protocol management system(s) (such as RAMP IRB), IRB members may be paired with an Experienced IRB Member to review studies and to assist in new members' transition to more seasoned IRB members.

As IRB policies and procedures change, there may be additional training requirements. The OHSP will communicate that information to you, generally by email or in the monthly IRB meetings. For any questions regarding IRB Member training, contact the OHSP.

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7. *How is an IRB Member provided with feedback about their IRB service?*

Your service as an IRB member is greatly valued and a high-performing IRB is crucial to an effective HRPP. A well-functioning IRB also enhances FSU's ability to safely conduct Human Research, adhere to applicable human subjects protections, and obtain and sustain related intramural and extramural support. Furthermore, it inspires confidence in both Human Subjects and research and regulatory communities that the rights and welfare of study participants will be protected. In order to provide IRB members with actionable feedback about their contribution at IRB meetings and on Non-Committee Reviews, the IRB Chair and OHSP Director may annually provide you with information about your reviews, attendance and meeting participation. This feedback may include both strengths and opportunities for development. The HRP-327 – WORKSHEET – Feedback for IRB Members will be used for this purpose.

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8. *How long does an IRB Member serve?*

An IRB Member generally serves on the IRB for a two-year term. Your particular term of service is included in your IRB appointment letter. If you have any questions about your term of service, contact the OHSP.

Near the end of your term, OHSP staff will inquire whether you wish to continue to serve on the IRB. If you wish to continue, OHSP staff will submit a request to the IRB Chair and FSU Vice President for Research for you to remain on the committee. The OHSP staff, in consultation with the IRB Chair and Vice President for Research, may then extend an invitation for you to remain on the IRB for an additional term.

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9. *How is an IRB Member compensated?*

The Office of the Vice President for Research (OVPR) provides compensation for all members serving on the IRB.

- All Members

  Receipt of compensation is conditional upon the member meeting the minimum meeting attendance requirement of at least 50% of scheduled meetings in the calendar year (approximately 12 scheduled meetings take place each year) and otherwise being in good standing (i.e., have completed all required training, attend regularly, complete reviews, review all materials, etc.). As continuing education is generally provided at each meeting and members may have few other opportunities to discuss human research protection matters with other member colleagues, members are strongly encouraged to attend all scheduled meetings. Mechanisms may be provided for members to "make up" meetings that they are unable to attend in order to meet the attendance requirement. In very limited circumstances, the Institutional Official may consider prorating compensation to members unable to meet the attendance commitment if the member is in otherwise good standing.

- Affiliated Members – Members from the University

  For FSU faculty and staff, affiliated IRB member compensation is set by the FSU Standard Operating Procedure (SOP) 7-IRB-40 – Funding Allocated to IRB.

  All affiliated members are expected to serve as Designated Reviewers as qualified and needed.

  Payment is not made to the member. All funds are provided directly to the department. Individual members are responsible for negotiating any allocation of those funds with their respective departments. Neither the IRB, OHSP nor OVPR is responsible for any department-level decisions regarding compensation use, allocation of time or reallocation of responsibilities, payment of additional compensation, etc.

  Payment will be made annually to the department at the beginning of the fiscal year for continuing IRB members or at the time of appointment for new members. Members appointed after January 1 of each year will receive a prorated amount.

  OVPR staff will be in contact with departmental accounting and finance staff to confirm payment amount, obtain the appropriate accounting information for fund transfer, and process the transfer of funds.

- Unaffiliated Members – Not Associated with the University

  Compensation is also provided for all members not otherwise associated with FSU-(community volunteers and consultants as described by Florida Statutes Chapter 110.501-05 and 768.28, and FSU Policy 4-OP-C-7-J4). Unaffiliated IRB member compensation is set by the FSU SOP 7-IRB-40 – Funding Allocated to IRB.

  All unaffiliated members are expected to serve as Designated Reviewers as qualified and needed.

  Payment will be made annually to the appointed community or consulting member at the

beginning of the fiscal year for continuing IRB members or at the time of appointment for new members. Members appointed after January 1 of each year will receive a prorated amount.

OHSP Staff will coordinate with the appointed community or consulting member(s) and the FSU Office of the Controller to manage and process the transfer of funds. With permission from the Institutional Official, unaffiliated members may also be eligible for the IRB Chair role with compensation to be prorated accordingly.

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10. *What is the role of an IRB Chair and Vice Chair?*

The IRB Chair is an IRB Member with certain additional responsibilities. The role of an IRB Chair is to guide IRB Members through the review process as outlined in this manual, manage IRB meetings, to serve as a mediator within the IRB to help resolve controverted issues, and to designate individuals to serve as Designated Reviewers. The IRB Vice Chair serves in the absence of the IRB Chair and when so doing has the same expectations for the Chair that are outlined in section 11 below; the Vice Chair may assist or support the IRB Chair in carrying out one or more of these expectations.

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11. *What are the expectations for an IRB Chair?*

An IRB Chair is expected to do the following:

- Stay in regular contact with OHSP staff to facilitate an efficient review process at IRB meetings; this includes holding regular check-ins to assess quorum or to review agenda items for any potential issues to be flagged or addressed prior to IRB meetings.

- Confirm that OHSP IRB Coordinators have assigned agenda items to appropriate primary, secondary, or other reviewers (including expert consultants). Coach the designated OHSP IRB Coordinator on how to make these assignments when necessary.

- Request and communicate the need for expert consultants to your OHSP IRB Coordinator if they have not already identified this need.

- Preside over meetings of the fully convened IRB and ensure that the IRB carries out and documents its duly authorized responsibilities and required determinations as required by federal regulations, ethical principles, state laws, and FSU policy as represented in the HRPP Toolkit or other supporting materials.

- Ensure, at each meeting chaired, that the members present are sufficiently qualified through experience and expertise to review all research activities on the agenda, and that expert consultants have contributed, if applicable.

- Review and approve the minutes of each meeting chaired when asked by an OHSP IRB Coordinator or other OHSP staff.

- Work with OHSP staff to ensure that membership of the IRB is recruited, appointed, and oriented such that the IRB is duly qualified to fulfill its obligations to review and

approve, require modifications to secure approval, defer, or disapprove research protocols that represent the breadth of research submitted to the IRB by FSU or affiliate researchers.

- Act on requests for emergency use of investigational drugs, biologics, or devices.

- Serve as a liaison as requested between the HRPP and the University research community to promote communication and understanding of the concerns of the IRB, the research community, and other HRPP partners.

- Respond to local and federal Investigations relating to protocols and actions, as required.

- Provide support and expertise as needed with respect to Investigation of complaints or Allegations of Non-Compliance received by or referred to the HRPP.

- Work with IRB members, the Institutional Official, investigators and OHSP staff to ensure that the rights and welfare of research participants are adequately protected.

- In conjunction with HRPP leadership, assist with the development, revision and dissemination of HRPP and IRB policies, procedures and guidelines to stay current with societal thinking, regulatory changes and national best practice standards.

As an IRB Chair, you are also expected to do the following:

- Designate or assist OHSP staff with designating individuals to serve as Designated Reviewers to conduct Non-Committee Review. Conduct Non-Committee Review when feasible.

- Participate in routine review and assessment of the HRPP per HRP-060 – SOP - Annual Evaluations of the HRPP.

- Contribute to compiling feedback for IRB members regarding members' reviews, attendance and meeting participation, and assist with member development as needed.

- Serve as a member of an advisory committee, if applicable, to consider and advise FSU leadership, the OHSP Director and IRB members regarding human research protection issues.

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12. How is an IRB Chair provided with feedback about their IRB service?

You will be provided with feedback on a regular basis. HRPP leadership and IRB Coordinators may provide informal feedback about IRB meetings and Non-Committee Reviews.

In addition, you will be formally provided with feedback on an annual basis using HRP-060 – SOP - Annual Evaluations of the HRPP. The feedback will encompass meeting preparation, meeting management, and communication. This feedback may include both strengths and opportunities for development. As an IRB Member, you may also be provided with feedback as described above. This feedback is a mechanism for providing you and your department/division head with meaningful information about your service as IRB Chair and IRB member.

HRPP Toolkit and Review Process

13. *What is the HRPP Toolkit?*

The HRPP Toolkit refers to a comprehensive set of manuals, workflows, standard operating procedures (SOPs), Worksheets, Checklists, and templates. Select HRPP Toolkit forms, templates and other documents are available at this OHSP web page; all HRPP Toolkit materials are available in the RAMP IRB Library. The HRPP Toolkit provides IRB Members and OHSP with the tools needed to perform review and document decisions about submissions in an efficient and compliant manner. The HRPP Toolkit also provides the FSU research community with tools and resources for developing and submitting their research for IRB review, and provides transparency about the review and approval processes and criteria that the IRB and OHSP use in review of research.

As an IRB Member, you will use primarily the Worksheets and Checklists within the HRPP Toolkit. The SOPs provide the FSU policy and business process basis for these Worksheets and Checklists. Although Worksheets and Checklists may look similar, there is a major distinction between them to keep in mind:

- Worksheets include regulatory decision-making elements that you must consider when conducting your reviews. Worksheets are for your own use but may be submitted if desired to document your reviews.

- Checklists include regulatory decision-making elements that you must consider *and document* when conducting your reviews. Checklists should be submitted as documentation as part of your reviews.

For example, the regulatory criteria for approval of non-Exempt Human Research (i.e., research that must without exception be reviewed by the IRB[6]) are included within HRP-314 – CHECKLIST - Criteria for Approval. The applicable federal regulations require that IRB members consider and document whether each of the criteria for approval have been satisfied when reviewing this type of research (e.g., research risks have been minimized, selection of research participants is equitable and informed consent will be sought from prospective study subjects). Using HRP-314 – CHECKLIST - Criteria for Approval you will document that you approve the research; entailed by that approval is that you have considered all the approval criteria.

In certain cases, you must consider *and document* your decisions and your rationale for those decisions. For example, you may, using HRP-416 – CHECKLIST – Children review a non-Exempt Human Research study that involves children as the study population. In this case, you must consider whether the study may be approved, whether children may be included and under

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[6] Under 45 CFR 46, §46.104, certain research activities are categorically not subject to (i.e., exempt from) the requirements for IRB review and approval. The list of these exempt activities is found at §§46.104(d)(1)-(8). With some exceptions, IRB members are generally not expected to conduct reviews of exempt research activities. The exception is for exempt research activities that require limited IRB review; these activities are found at §§46.104(d)(2)(iii), (3)(i)(Cc), (7) and (8). Research activities that are otherwise subject to 45 CFR 46 are considered "non-exempt". See 45 CFR 46, §101(a).

what category research involving children is permitted, and the consent procedures the investigator must follow. Similarly, you must consider whether waiver or alteration of study subjects' consent to take part in research may be approved and consider *and document* whether each of the criteria for waiver or alteration have been satisfied. Other criteria for IRB approval and use of related Worksheets and Checklists, such as criteria for approval of a short form of consent using HRP-317 – Worksheet – Short Form of Consent Documentation, will apply depending upon risks and study population. Keep the above distinction between use of Worksheets and Checklists in mind when reviewing research. OHSP staff, principally IRB Coordinators, are available to assist you as you begin working with the documents in the HRPP Toolkit.

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14. *Where do the Non-Committee and Committee Review processes begin?*

An IRB member's review process for a submission of any type begins after staff in the OHSP, typically IRB Coordinators, triage the submissions and finish conducting pre-review. Triage and pre-review include evaluating the submission for applicable regulatory authorities and FSU policies; required type and scope of review; completeness of submission; and possible reviewer assignment. Based upon triage and pre-review, a study may preliminarily be deemed as not research, not involve human subjects, exempt (and therefore generally not require IRB review or only required limited IRB review[8]), eligible for expedited or convened IRB review, and require ancillary (second-level FSU administrative) review. The goal is to make a submission "review ready" by ascertaining in part that all required study materials have been submitted, notifying investigators to submit or provide clarification for any missing or incomplete materials, and seeking clarification from investigators regarding any issues with the submission that might pose a challenge for the review itself.[7] Any substantive issues found during pre-review may be noted and left for IRB Members to address in the review process.[8] Links to or attachments for any HRPP Toolkit Worksheets and Checklists that should be used for review of a submission by an IRB member may be provided by the IRB Coordinator as part of their pre-review. If no links or attachments are provided, or if you have questions about which Worksheets and Checklists to use, contact the IRB Coordinator for assistance.

After pre-review is complete, the OHSP IRB Coordinator will route a submission for either Non-Committee Review[9] (to be reviewed by an IRB subcommittee or Designated Reviewer) or by the convened IRB (including review by an IRB primary reviewer(s)) at a scheduled meeting. Effective June 21, 2019, FSU requires that all Human Research activities be submitted for review using FSU's RAMP IRB electronic protocol management system. Human Research

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[7] IRB Coordinators use HRP-021 – SOP - Pre-Review and HRP-308 – WORKSHEET - Pre-Review and other necessary HRPP Toolkit documents to complete pre-review. Triage and pre-review may involve other activities, such as determining if study activities have been conducted in the absence of IRB review, whether and how other non-FSU institutions or researchers may be involved, funding, and the need for required human subjects training.

[8] If, for example, an OHSP IRB Coordinator discovers a section missing from a consent form, this will be addressed during pre-review. However, supposing all sections are present, evaluation of the content of a consent form should be handled during the review itself.

[9] The majority of Non-Committee Review submissions of any type assigned to you will be for non-Exempt Human Research. However, you may occasionally be asked to make an Exemption determination, particularly where Limited IRB review may be required. Details regarding these submissions are included in Appendix A.

activities submitted to and approved by the IRB using legacy systems will transition to the RAMP IRB system.

15. *What are the different submission types?*

There are five types of submissions in RAMP IRB:

- New Study (STUDY): New studies are submissions that have generally not before been submitted in RAMP IRB for review. In RAMP IRB, all new studies will be presented with the same online application. That application is a "SmartForm," in that different questions or sections of the application are hidden or shown depending on how an investigator responds. Ultimately, IRB Coordinators will determine the level and route of review required for any new study.

- Modification to previously approved research (MOD): Modifications involve changes or revisions to currently approved studies. A MOD is considered a follow-on submission related to an existing study in RAMP IRB.

- Continuing Review of previously approved research (CR): Continuing reviews are required annual or more frequent reviews of currently approved studies. Not all studies require continuing review. A CR is also considered a follow-on submission related to an existing study in RAMP IRB.

- Modification and Continuing Review (MODCR): This is a single submission incorporating the two types above.

- Report of New Information (RNI): This submission in RAMP IRB may be associated with one or more studies depending on the nature of the information reported. RNIs involved required reporting to the IRB of select incidents as specified by federal law. See section 21 below. An RNI may be considered a follow-on submission related to an existing study in RAMP IRB.

The naming convention for RAMP IRB submission identification includes the submission type as a prefix as indicated in the above parentheticals, followed by a number of up to eight (8) digits. The submission identification indicates its review type as well as the sequence in which all submissions of that type are received within RAMP IRB. While identification for subsequent submissions for parent studies do not include direct reference to the parent studies' identification, the RAMP IRB workspace for the subsequent submission includes in the panel above the workflow the parent study identification for ease of reference. Each parent study will also have a "Follow-on Submissions" tab on the study workspace listing subsequent related submissions.

16. *What are the different routes of review?*

As stated above, an OHSP IRB Coordinator will route a submission for either Non-Committee Review or review by the convened IRB, with some caveats noted below.

- Non-Committee Review: A Designated Reviewer conducts Non-Committee Review; that is, review by an IRB subcommittee or a single individual that is an IRB member.

This route of review entails all IRB review determinations made outside of the convened IRB.

- Committee Review: The convened IRB conducts Committee Review, usually at a regularly scheduled monthly meeting. Generally, an IRB member(s) will be assigned to serve as the primary reviewer for a particular submission, present review recommendations, and make a motion for approval or disapproval. Your service as an IRB member includes participation in Committee Review. At such meetings, the IRB will have a handful of submissions to review.

IRB Coordinators select the route of review based on considerations outlined in the HRPP Toolkit. For example, if an OHSP IRB Coordinator finds based upon regulatory criteria that a new study or submission entails no greater than Minimal Risk and that the procedures included in the research fall under one or more of the expedited review categories included in HRP-313 - WORKSHEET: Expedited Review the OHSP IRB Coordinator will route that study for Non-Committee Review.

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17.   How do I conduct Non-Committee Review for a new study?

When an OHSP IRB Coordinator assigns you a submission to review as a Designated Reviewer, you will receive an email notification and that submission will appear in your RAMP IRB Dashboard under the "My Reviews" tab.

Once you have logged into RAMP IRB, navigate to the Dashboard, select a submission under your "My Reviews" tab, and follow these steps:

1. Click into the "Reviews" tab to view any pre-review issues or other notes the OHSP IRB Coordinator left for you. Pay attention to the issues the coordinator deemed relevant when conducting your review.

2. The OHSP IRB Coordinator will identify or provide you with RAMP IRB HRPP Toolkit documents (i.e., Worksheets and Checklists) you will need to use to complete and/or document your review. If not provided, navigate to the RAMP IRB Library to open the relevant documents. Scroll through each document to familiarize yourself with the content and to understand what you should be looking for and documenting with your review. As you review the study, you may identify other relevant HRPP Toolkit documents that should or may be used or completed.

3. Next, click "View Study" under Next Steps to review the SmartForm application and attached study documents.

4. Although you must review all study information prior to making a determination, you may want to develop a routine to help you organize your review. For example, many IRB Members find it useful to peruse the online application, using the "View Study" feature, for high-level study details before reading over the consent form (if any).

   After reading the consent form and getting a general understanding of the proposed research from the participants' perspectives, IRB Members will typically read the study protocol, which is available through the "View Study" feature or under the "Documents" tab of the submission. As you proceed with the protocol, consent forms, and other

materials, note any questions, concerns, or clarifications you may need to address; these may be noted in the Worksheets and Checklists. You may be able to resolve these issues on your own as you read through the different materials. Other issues you may not be able to resolve; in those cases, you may need to use the RAMP IRB "Add Comment" or "Request Clarification" activities to directly ask the study team to provide additional information; alternatively, ask the IRB Coordinator how to perform these functions.

5. While reviewing the study materials, you should begin deciding whether the study may be approved and, if so, under what category. Because IRB Coordinators will generally route to you only those new studies which they cannot review themselves (such as studies deemed not research, not research involving Human Subjects, or research that is exempt from IRB review), the majority of new studies you will review qualify for expedited review. To determine whether the new study should be approved, and under what approval category or categories, you will use HRP-313 - WORKSHEET - Expedited Review, HRP-314 - CHECKLIST - Criteria for Approval, and any other relevant Worksheets or Checklists. As you walk through all of the approval criteria, decide whether they have been satisfied or whether the questions, concerns, or clarifications you identified earlier require resolution before you can determine that the approval criteria have been satisfied.

6. If you are satisfied that the study can be approved, click "Submit Designated Review" on the study workspace in RAMP IRB, select "Approved", complete the remaining required fields, and upload any relevant (and completed) Checklists. After you select "OK", the new study that you approved will be routed back to the OHSP IRB Coordinator for post-review activities.

7. If you are not satisfied that the study can be approved without additional information or edits, you have two options in RAMP IRB. For your first few reviews, you should consult with the OHSP IRB Coordinator assigned to your study to decide which option is preferable.

   a. Option 1: Request clarification directly from the investigator or study team. Utilizing this option, the study team will be alerted to your requests for additional information and/or clarification. When re-submitted, the study will return to your "My Reviews" tab.

   b. Option 2: Open the "Submit Designated Review" activity and select Modifications Required to Secure "Approved." Then, complete the remaining required fields, enumerating any changes the investigator is required to make. Complete any Checklists and Worksheets and upload them in this activity at that time. If you are not able to complete any Checklists until edits have been made, then you may complete and upload them when the study is re-routed back to you. If the changes you requested were minor, the OHSP IRB Coordinator may review the changes on your behalf. If the changes you requested were substantive, the OHSP IRB Coordinator will re-route the submission to you for a second round of review.

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18.   How do I conduct <u>Non-Committee Review</u> for a follow-on submission?

Follow-on submissions include MODs (modifications to the study), CRs (continuing reviews), and MODCRs (combination of modifications and continuing review) as stated above. The same approval criteria that are applied at initial review of the study also apply with these submissions. For these submissions, the main question is whether the criteria for approval *continue to be satisfied*. As such, you will use the same HRPP Toolkit documents you (or another IRB Member) used for initial review.

1. As you begin your review, click "Review Modification/CR" to understand what changes are being proposed. The first page of the MOD or MODCR form will include the purpose and scope. The next page, if a MODCR, will be the Continuing Review/Study Closure Information form (discussed below). The following page will be the Modification Summary Information form. For Modification Information, note the study enrollment status, which participants (if any) will be notified of the proposed changes once approved, and the summary of the modifications. After reviewing the Modification Information, continue scrolling to view the SmartForm application itself.

   Each time an investigator modifies a study, the investigator makes changes directly to the application pages and adds, updates, or deletes documents, files or personnel within those pages. This means that the IRB application is now a "living record." As part of your current review, you will want to note what has changed since the last review. To do this, look at the left-hand navigation panel of the SmartForm, which will indicate the sections that have changed by a pencil symbol. You will then see where answers to the application have changed or where new, updated, or deleted documents were uploaded or removed. From there, review the changes in relation to what was previously approved to determine whether the changes are acceptable.

2. A CR-only submission does not allow for the investigator to make any changes to the online application or study documents previously reviewed. This means the left-hand navigation panel of the SmartForm will say "No changes found." Instead, review the Continuing Review/Study Closure Information form, then at the very top of the CR SmartForm application after the words "You Are Here:" click the link to review the original study's SmartForm application and documents to determine whether the study may continue for another approval period.

   Pay special attention to unchecked items in Section 6 ("Check the items that are true since the last IRB approval for all sites involved in the study") of the Continuing Review/Study Closure Information form for any red flags. For any unchecked item, the investigator must provide an explanation. If the explanation provided is lacking or insufficient, then you should request clarifications from the investigator (using either Option 1 or Option 2 from the [previous section](#)). In cases where it is unclear whether the information included in an explanation has been previously reported to the IRB, ask the OHSP IRB Coordinator assigned to your submission. The OHSP IRB Coordinator will show you how to find that information within the study record.

There are specific criteria for being able to review follow-on submissions by <u>Non-Committee Review</u>. For non-Exempt <u>Human Research</u>, these criteria are included in <u>HRP-313 -</u>

WORKSHEET: Expedited Review and HRP-314 – CHECKLIST - Criteria for Approval. Since you receive Non-Committee Review assignments from IRB Coordinators and since they have been trained on when Non-Committee Review is appropriate, you will likely be asked to review only those follow-on submissions that are actually eligible for this review route. However, if you have concerns about an IRB Coordinator's routing decision or find that you cannot provide approval, seek clarification from the IRB Coordinator. You may also contact the OHSP Director for further discussion. If a Non-Committee Review submission cannot be approved by the Designated Reviewer, then the IRB Coordinator may route the submission for review by the convened IRB. Include a note in the text box so the assigned OHSP IRB Coordinator can see your rationale for proposing a change to the route of review.

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19. How do I conduct Committee Review for a new study?

As stated above, IRB Coordinators are responsible for deciding whether a new study should be routed for Non-Committee Review or review by the convened IRB (Committee Review). If routed for review by the convened IRB, then the OHSP IRB Coordinator for the new study will prepare the study for review. Preparing the new study for review entails assigning primary (and possibly secondary) reviewers, deciding whether additional expertise is needed from an outside consultant, and generating and distributing an IRB meeting agenda to which review of the study will be added.

Once the agenda has been distributed, all IRB members will receive an email notification. That notification will include a link to the meeting agenda as well as a link directing you to the RAMP IRB meeting workspace for the scheduled convened meeting to which the agenda pertains. All submissions on the agenda, including any new studies, will appear in the meeting workspace. Primary and secondary reviewers are identified in the meeting workspace by having their names appear in the rightmost column under the "Agenda Items" tab.

To begin preparing for review of a new study at the IRB meeting, follow these steps:

1. Look at the list of Agenda Items and note those for which you are listed as a primary or secondary reviewer. Primary reviewers should have already received an earlier notification from an IRB Coordinator about their assignment as a primary reviewer. As the email notifications about the meeting agenda are sent to all IRB members about a week or more in advance of the meeting, all members should have sufficient time to review submissions that require their discussion and voting. All IRB members are expected to review all submission materials; however, primary and secondary reviewers also assist the IRB Chair with review by presenting a brief, high-level overview of the new study, identifying key issues for other IRB members' consideration and discussion, and guiding other IRB members through each of the regulatory criteria for approval, including whether in the primary reviewer's judgment each criteria for approval has been satisfied.

2. Click into a new study to view any pre-review issues or other notes the OHSP IRB Coordinator left for you. These may be located under the History tab as a Private Comment directed to you, or under the Reviews tab; any links or attachments for your use in completing your review will be available in these locations. Take note of the issues raised as these may be relevant when preparing for the convened IRB meeting.

3. The OHSP IRB Coordinator will likely identify or provide you with HRPP Toolkit documents (i.e., Worksheets and Checklists) you will need to use to prepare for the IRB meeting. If not provided, navigate to the RAMP IRB Library to open the relevant documents. Scroll through each document to familiarize yourself with the content and to understand what you should be looking for with your review. As you review the study, you may identify other relevant HRPP Toolkit documents that may be required; these are often referenced within a particular Worksheet or Checklist depending upon study particulars, such as involvement of vulnerable study subjects, use of FDA-regulated drugs or devices, use of protected Identifiable Private Information (e.g., health or student records), or requests to waive or alter informed consent.

4. Next, click "Review Study" to review the online application and attached study documents.

5. You may want to develop a routine to help you organize your review. For example, many IRB members find it useful to examine the online application for high-level study details before then reading over the consent form (if any).

    After reading the consent form, recruitment materials and getting a general understanding of the proposed research from the participants' perspectives, IRB members will typically read the study protocol. The format of these protocols and consent forms are usually standardized, since these templates (which protocol and consent templates may vary, respectively, depending upon study type, such as social/behavioral/educational or biomedical research, or study sample, such as adults or children) are made available to the research community. All templates have embedded instructions, and are available in RAMP IRB under the IRB Library "Templates" tab.

    As you proceed with the protocol, consent forms, and other materials, note any questions, concerns, or clarifications you may need to have addressed. You may or may not be able to resolve these issues on your own as you read through the different materials. In the latter case, you may want to leave a note for your fellow IRB members to see what you would like resolved (see below).

6. While reviewing the study materials, you should begin deciding whether the study may be approved.

    To help guide your own considerations about whether a new study should be approved, you may use HRP-314 – CHECKLIST - Criteria for Approval and any other relevant Checklists, which are Checklists that Primary reviewers will also complete. As you walk through all of the approval criteria, decide whether they have been satisfied or whether the questions, concerns, or clarifications you identified earlier require resolution before you believe the convened IRB can determine that the approval criteria have been satisfied. Note that this Checklist is editable and you can insert notes or comments in any checkbox field.

7. As stated above, you may want to record review notes prior to the IRB meeting. You are encouraged to do so and you have two options in RAMP IRB.

    a. Option 1 (Add Review Comments): Click "Add Review Comments" from the Study Workspace and record your comments in the text box provided. To help organize your thoughts, you should choose to use HRP-314 – CHECKLIST - Criteria for Approval.

This "Add Review Comments" feature in RAMP IRB includes a text box and the ability to upload documents, such as your completed Checklists and Worksheets. Your fellow IRB members are able to see whatever you write or upload. You can even input a comment, post it, and return later to revise it, but note that your prior comment cannot be deleted once posted. All Review Comments and attached files will be removed from the system upon approval, so you should also save any completed documents in your own files.

b. Option 2 (Request Clarification by Committee Member): *This option is reserved for the primary reviewer, IRB Chair, or IRB Coordinator.* If you are the primary reviewer and would like for the investigator to clarify any items prior to the IRB meeting, click "Request Clarification by Committee Member" and type in your clarification request. The investigator may respond to your request for clarification; however, this mode of communication does not open the submission to the study team to make edits. The information provided back to you may help clarify an item, but resolution of that item, e.g., a change to the consent form, may still require modifications prior to securing approval.

8. Repeat Steps 1-7 for each new study on the agenda.

9. If you would like to view your IRB colleagues' review notes, click on the "Reviews" tab in the study workspace. This will allow you to know what questions, comments, or concerns other members have noted as you prepare your own. If you are the first member to submit a review comment, you can come back to the "Reviews" tab on the day of the IRB meeting to see what others have added, or click the "History" tab to see any other comments or private comments.

    a. Note: the "Reviews" tab will only display other members' review comments if they utilize the "Add Review Comments" feature. This is distinct from the "Add Comment" or "Add Private Comment" activities on a study. Regular comments or private comments are only logged in the study "History" tab whereas Review Comments are logged under the "Reviews" tab only while the study is under review and then all comments and attached files on Review Comments will be removed from the system upon approval.

10. When it is time to review a new study at the IRB meeting, the IRB Chair or OHSP IRB Coordinator will ask the primary reviewer to lead the discussion. If you are the primary reviewer, you should lead the discussion as follows:

    a. Provide a brief, high-level overview of the study, including the main study procedures, population(s) included, and any notable features of the study, e.g., a rare disease or condition. *Remember: All members should have prepared for the IRB meeting, so you do not need to discuss all study details.*

    b. After your brief overview, ask your fellow IRB members whether there are any aspects of the study they do not understand, e.g., they may need your help understanding how a particular procedure is carried out. Use this time specifically for clarification. If you are unable to clarify a particular aspect of the study, note that you may need to revisit that issue below.

    c. Using HRP-314 - CHECKLIST - Criteria for Approval, walk the IRB through the

criteria for approval. Identify key issues for other IRB members' focused consideration and discussion, and guide other IRB members through each of the regulatory criteria for approval, including whether in the primary reviewer's judgment each criteria for approval has been satisfied. If the IRB is able to determine that a particular criterion has been satisfied, then move to the next one. If the IRB is not able to determine that a particular criterion has been satisfied, identify the modification(s) required by the investigator to satisfy that criterion. At this point, you should refer to the review comments your fellow IRB members included. Be sure to clearly articulate for the OHSP IRB Coordinator what modifications are required and why so the OHSP IRB Coordinator may relay this information to the investigator.

d. After walking through the main criteria for approval, walk the IRB through any additional required Checklist(s). For example, if children are participants in the study, complete HRP-416 – CHECKLIST - Children to document the IRB's determinations for that population.

e. Before making an official motion, review all of the information discussed in steps a-d above to make sure that your feedback to the investigator, if any, is reasonable and coherent. Every required modification should tie back to an approval criterion. If the IRB is unable to justify a particular required modification against the criteria for approval, then remove it from the list.

f. When a convened IRB contemplates a determination to:

- defer a decision on a study;

- disapprove a study;

- Suspend or Terminate a study; or

- make a determination of Serious or Continuing Non-Compliance,

A call to the investigator during the meeting should be considered and may be necessary (if the investigator has provided contact information and confirmed that s/he will be available during the scheduled meeting). The call will be documented in meeting minutes.

Preparing for the call:

- Identify the primary reason(s) for the Committee's likely determination and how the reason(s) will be communicated. The call need not be used to list every required modification. Focus on the issues of greatest concern and consensus.

- Place the concern in the context of the applicable Worksheet or Checklist.

- Decide whether one person or all members will speak.

  See HRP-041 – SOP - IRB Meeting Conduct for procedural details and Appendix B Communication with Investigators Script for talking points.

g. Make a motion.

- If all of the criteria for approval have been satisfied without any modifications required, motion to approve the study as submitted.

- If modifications are required, *and those modifications are prescriptive in nature (such that, if made as directed, the study could be approved without further IRB review)*, then motion to approve with modifications required to secure approval.

- If modifications are required, *and those modifications are not prescriptive in nature (such that, when made, further IRB review is required to determine whether they satisfy the criteria for approval)*, then motion to defer the study. Deferral will require another round of review by the convened IRB.

h. The IRB Chair will ask for another member to second your motion and, once seconded, will call for a vote.

i. Repeat steps 1-10 for each new study on the agenda.

20.   How do I conduct Committee Review for a follow-on submission?

Follow-on submissions include MODs, CRs, and MODCRs as stated above. The same approval criteria that applied at initial review of the study also apply with these submissions. For these submissions, the main question is whether the criteria for approval *continue to be satisfied*. As such, you will use the same HRPP Toolkit documents the IRB used for initial review.

To begin preparing for review of a follow-on submission at the IRB meeting, follow these steps:

1. Look at the list of Agenda Items and note for which ones you are listed as a primary or secondary reviewer. All IRB members are expected to review all submission materials; however, reviewers also assist the IRB Chair with review by presenting a summary of the follow-on submission and guiding other IRB members through the criteria for approval.

2. For MOD or MODCR, as you begin your review, click "Review Modification/CR" to understand what changes are being proposed. The first page of the MOD or MODCR form will include the purpose and scope. The next page, if a MODCR, will be the Continuing Review/Study Closure Information form (discussed below). The following page will be the Modification Summary Information form. For Modification Information, note the study enrollment status, which participants (if any) will be notified of the proposed changes once approved, and the summary of the modifications. Other study information will follow.

    Each time an investigator modifies a study, the investigator makes changes directly to the application pages and adds, updates, or deletes documents, files or personnel within those pages. This means that the IRB application is now a "living record."

    As part of your current review, it is important to note what has changed since the last review. After reviewing the Modification Information, look at the left-hand navigation panel of the SmartForm under Modification Details to view the changes, which are indicated by a pencil symbol. You will then see where answers to the application have changed or where new, updated, or deleted documents were uploaded or removed. From there, review the changes in relation to what was previously approved to determine whether the changes are acceptable.

3. A CR-only submission does not allow for the investigator to make any changes to the

online application or study documents previously reviewed. This means that the left-hand navigation panel will always say "No changes found." Instead, review the Continuing Review/Study Closure Information form, then at the very top of the CR SmartForm application after the words "You Are Here:" click the link to review the original study's SmartForm application and documents to determine whether the study may continue for another approval period.

Pay special attention to Question 6 in Continuing Review/Study Closure Information form for any red flags. For any item left unchecked, the investigator must provide an explanation in an attached supporting document. If the explanation provided is insufficient, then you should request clarifications from the investigator (using either Option 1 or Option 2 below). In cases where it is unclear whether the information included in an explanation has been previously reported to the IRB, ask the OHSP IRB Coordinator assigned to your submission. The OHSP IRB Coordinator will show you how to find that information within the study record.

4. While reviewing the follow-on submission materials, you should begin deciding whether the submission may be approved.

   To determine whether the follow-on submission should be approved, you will use [HRP-314 – CHECKLIST - Criteria for Approval](#) and any other relevant Checklists. As you walk through all of the approval criteria, decide whether they *continue* to be satisfied or whether the questions, concerns, or clarifications you identified earlier require resolution before you believe the convened IRB can determine that the approval criteria have been satisfied.

5. You may want to record review notes prior to the IRB meeting. You are encouraged to do so and you have two options in RAMP IRB.

   a. Option 1 (Add Review Comments): Click "Add Review Comments" from the submission workspace and record your comments in the text box provided. To help organize your thoughts, you should choose to use [HRP-314 – CHECKLIST - Criteria for Approval](#). This "Add Review Comments" feature in RAMP IRB includes a text box and the ability to upload documents, such as your completed Checklists and Worksheets. Your fellow IRB members are able to see whatever you write or upload. You can even input a comment, post it, and return later to revise it, but note that your prior comment cannot be deleted once posted. All Review Comments and attached files will be removed from the system upon approval, so you should also save any completed documents in your own files.

   b. Option 2 (Request Clarification by Committee Member): *This option is reserved for the primary reviewer or the IRB Chair.* If you are the primary reviewer and would like the investigator to clarify any items prior to the IRB meeting, click "Request Clarification by Committee Member" and type in your clarification request. The investigator may respond to your request for clarification; however, this mode of communication does not open the submission to the study team to make edits. The information provided back to you may help clarify an item, but resolution of that item, e.g., a change to the consent form, may still require modifications prior to securing approval.

6. Repeat Steps 1-5 for each follow-on submission on the agenda.

7. If you would like to view your IRB colleagues' review notes, click on the "Reviews" tab in the submission workspace. This will allow you to know what questions, comments, or concerns other members have as you prepare your own. If you are the first member to submit a comment, you can come back to the "Reviews" tab on the day of the IRB meeting to see what others have added, or click the "History" tab to see any other comments or private comments.

    a. Note: the "Reviews" tab will only display other members' review comments if they utilize the "Add Review Comments" feature. This is distinct from the "Add Comment" or "Add Private Comment" activities on a study. Regular comments or private comments are only logged in the study "History" tab whereas Review Comments are logged under the "Reviews" tab only while the study is under review and then all comments and attached files on Review Comments will be removed from the system upon approval.

8. When it is time to review a follow-on submission at the IRB meeting, your OHSP IRB Coordinator or IRB Chair will ask the primary reviewer to lead the discussion. If you are the primary reviewer, you should lead the discussion as follows:

    a. Provide a brief overview of the MOD, MODCR, or CR forms, the changes being proposed, and any relevant information about the study as a whole, including the main study procedures, population(s) included, and any notable features of the study, e.g., a rare disease or condition. *Remember: All members should have prepared for the IRB meeting, so you do not need to discuss all study details.*

    b. After your brief overview, ask your fellow IRB members whether there are any aspects of the follow-on submission they do not understand, e.g., they may need your help understanding why a particular proposed change is necessary or how a particular procedure is carried out. Use this time specifically for clarification. If you are unable to clarify a particular aspect of the study, note that you may need to revisit that issue below.

    c. Using HRP-314 – CHECKLIST - Criteria for Approval walk the IRB through the criteria for approval. If the IRB is able to determine that a particular criterion continues to be satisfied, then move to the next one. If the IRB is not able to determine that a particular criterion continues to be satisfied, identify the modification(s) required by the investigator to satisfy that criterion. At this point, you should refer to the review comments your fellow IRB members included. Be sure to clearly articulate for the OHSP IRB Coordinator what modifications are required and why so the OHSP IRB Coordinator may relay this information to the investigator.

    d. After walking through the main criteria for approval, determine whether the changes proposed impact any previous Checklist determinations. If so, walk the IRB through any other required Checklist(s). For example, if children are included as participants in the study and the changes proposed affect the category under which the study was approved or the justification for that category, complete a new HRP-416 – CHECKLIST - Children to document the IRB's determinations for that population.

    e. Before making an official motion, review all of the information discussed in steps a-d above to make sure that your feedback to the investigator, if any, is reasonable and

coherent. Every required modification should tie back to an approval criterion. If the IRB is unable to justify a particular required modification against the criteria for approval, then remove it from the list.

f. Make a motion.

- If all of the criteria for approval have been satisfied without any modifications required, motion to approve the study as submitted.

- If modifications are required, *and those modifications are prescriptive in nature (such that, if made as directed, the study could be approved without further IRB review)*, then motion to approve with modifications required to secure approval.

- If modifications are required, *and those modifications are not prescriptive in nature (such that, when made, further IRB review is required to determine whether they satisfy the criteria for approval)*, then motion to defer the study. Deferral will require another round of review by the convened IRB.

g. The IRB Chair will ask for another member to second your motion and, once seconded, will call for a vote.

h. Repeat steps a-g above for each follow-on submission on the agenda.

21. How do I conduct Committee Review for a Report of New Information?

A Report of New Information (RNI) may be related to a study, but it is not a follow-on submission in the same way that a MOD, MODCR, or CR is since a MOD, MODCR or CR is submitted within a specific study; an RNI may be submitted outside of an active study. An RNI exists outside of the standard study/submission review workflow; however, the information in the RNI may impact whether a study should be modified, suspended, or terminated.

The pre-review process for an RNI is also different than for new studies and follow-on submissions. For those submissions, the aim of pre-review is to get the submission "review ready." For an RNI, pre-review is just the decision of whether an RNI requires review by the convened IRB.

When an RNI is submitted, an OHSP IRB Coordinator will select one of the following determinations:

1. Additional review required before making a determination

2. Unanticipated Problem Involving Risks to Subjects or Others

3. Suspension or Termination of IRB Approval

4. Serious Non-Compliance

5. Continuing Non-Compliance

6. Non-Compliance that is neither serious nor continuing

7. Allegation of Non-Compliance with no basis in fact

8.   None of the above

If the OHSP IRB Coordinator selects any or all of the first four (4) options in that list, the RNI will be routed to the convened IRB for review. The IRB will then review the RNI and determine whether the IRB Coordinator's initial determination was correct and whether or not any additional action is required to resolve the RNI.

To begin preparing for review of an RNI at the IRB meeting, follow these steps:

1.   Look at the list of Agenda Items and note for which ones you are listed as a primary or secondary reviewer. All IRB members are expected to review all submission materials; however, reviewers also assist the IRB Chair with review by presenting a summary of the RNI and guiding other IRB members through the criteria for approval.

2.   As you begin your review in preparation for the IRB meeting, open HRP-321 – WORKSHEET - Review of Information Items. This Toolkit document will guide you through RNI review considerations.

3.   Next, select the RNI from the agenda and from the RNI workspace click "Review RNI" to understand what information is being reported. Each item on the RNI form is important. As you review the RNI form, note whether the RNI is related to one or more studies or MODs. This will be indicated in Question 6. If the RNI is related, review the relevant materials to help determine whether and how the report submitted affects or is affected by the content of the study or MOD.

4.   You may want to record review notes prior to the IRB meeting. You are encouraged to do so and you have two options in RAMP IRB.

   a.   Option 1 (Add Review Comments): Click "Add Review Comments" from the RNI workspace and record your comments in the text box provided. To help organize your thoughts, you should choose to use HRP-314 – CHECKLIST - Criteria for Approval. This "Add Review Comments" feature in RAMP IRB includes a text box and the ability to upload documents, such as your completed Checklists and Worksheets. Your fellow IRB members are able to see whatever you write or upload. You can even input a comment, post it, and return later to revise it, but note that your prior comment cannot be deleted once posted. All Review Comments and attached files will be removed from the system upon approval, so you should also save any completed documents in your own files.

   b.   Option 2 (Request Clarification by Committee Member): *This option is reserved for the primary reviewer, IRB Chair, or IRB Coordinator.* If you are the primary reviewer and would like for the investigator to clarify any items prior to the IRB meeting, click "Request Clarification by Committee Member" and type in your clarification request. The investigator may respond to your request for clarification; however, this mode of communication does not open the RNI to the study team to make edits. The information provided back to you may help clarify an item, but resolution of that item, e.g., an explanation about timing of submission, may still require additional action prior to RNI resolution.

5.   Repeat Steps 1-4 for each RNI on the agenda.

6. If you would like to view your IRB colleagues' review notes, click on the "Reviews" tab in the RNI workspace. This will allow you to know what questions, comments, or concerns other members have as you prepare your own. If you are the first member to submit a comment, you can come back to the "Reviews" tab on the day of the IRB meeting to see what others have added, or click on the "History" tab to see any other comments or private comments.

7. When it is time to review an RNI at the IRB meeting, your OHSP IRB Coordinator or IRB Chair will ask the primary reviewer to lead the discussion. If you are the primary reviewer, you should lead the discussion as follows:

   a. Provide a brief overview of the RNI and any relevant information about related studies or MODs. *Remember: All members should have prepared for the IRB meeting, so you do not need to discuss all study details.*

   b. After your brief overview, ask your fellow IRB members whether there are any aspects of the RNI they do not understand, e.g., they may need your help understanding any descriptions of severity of the event. Use this time specifically for clarification. If you are unable to clarify a particular aspect of the RNI, note that you may need to revisit that issue below.

   c. Using HRP-321 – WORKSHEET - Review of Information Items, walk the IRB through the possible RNI review determinations. Select all determinations that apply. At this point, you should refer to the review comments your fellow IRB members included.

   d. As you walk through HRP-321 – WORKSHEET - Review of Information Items determine whether the RNI requires the study to be modified, suspended, or terminated.

   e. Before making an official motion, review all of the information discussed in steps a-d above to make sure that your feedback to the investigator, if any, is reasonable and coherent. Every required modification to a related study should tie back to an approval criterion in HRP-314 – CHECKLIST – Criteria for Approval. If the IRB is unable to justify a particular required modification against the criteria for approval, then remove it from the list.

   f. When a convened IRB contemplates a determination to:

      ● defer a decision on a study;

      ● disapprove a study;

      ● Suspend or Terminate a study; or

      ● make a determination of Serious or Continuing Non-Compliance,

      A call to the investigator during the meeting should be considered and may be required (if the investigator has provided contact information and confirmed that s/he will be available during the scheduled meeting). The call will be documented in meeting minutes.

      Preparing for the call:

- Identify the primary reason(s) for the Committee's likely determination and how the reason(s) will be communicated. The call need not be used to list every required modification. Focus on the issues of greatest concern and consensus.

- Place the concern in the context of the applicable Worksheet or Checklist.

- Decide whether one person or all members will speak.

  See HRP-041 – SOP – IRB Meeting Conduct for procedural details and Appendix B Communication with Investigators Script for talking points.

g. Make a motion.
  - Unlike a new study of MOD, MODCR, or CR, the motion for an RNI is just the combination of determinations and considerations selected in HRP-321 – WORKSHEET - Review of Information Items. You are not making a motion to approve or disapprove the RNI—this is another major distinction between an RNI and a study or follow-on submission.

  - If modifications are required, indicate whether the investigator should submit additional information to resolve the RNI after the investigator submits a MOD.

h. The IRB Chair will ask for another member to second your motion and, once seconded, will call for a vote.

i. Repeat steps a-h above for each follow-on submission on the agenda.

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22.   *Whom do I contact for help?*

Your primary resource for any questions, concerns, or other issues is your assigned OHSP IRB Coordinator. Please reach out to this individual first. If you do not have contact information for this individual, search the OHSP Staff Directory.

If your question, concern, or issue is about your IRB Coordinator, please reach out to the OHSP Director, contact information also located here.

You are always welcome to contact anyone from FSU OVPR leadership for any other reason; go here for contact information.

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Appendix A: How do I make an Exemption determination?

As mentioned above (footnote 5), the majority of submissions routed to you for Non-Committee Review will be for non-Exempt Human Research. This is because IRB Coordinators have been trained to review other types of submissions eligible for Non-Committee Review. Occasionally, however, due to workload or complexity, an OHSP IRB Coordinator may assign you an Exemption determination request.

An investigator submits an Exemption determination request by using the same RAMP IRB application as any other study.

The HRPP Toolkit approach to Exempt determinations places the Exemption determination in the hands of the reviewer. So, an investigator is not asked up front to decide whether the study submitted qualifies for an Exemption. You make that decision. In this sense, reviewing an Exempt study is no different in principle than reviewing a non-Exempt study—only the review outcome is different.

To begin your review of an Exemption determination, follow these steps:

1. Navigate to the RAMP IRB Library and open HRP-312 – WORKSHEET - Exemption Determination. Familiarize yourself with the Exemption categories. It is possible that a study fits into more than one Exemption category.

2. Select the study from your "My Reviews" tab and click on "Review Study". Review the protocol uploaded to Question 8 on the Basic Study Information page and other submission materials just as you would for Non-Committee Review of non-Exempt Human Research.

3. You are likely receiving this submission to review because the OHSP IRB Coordinator needed additional assistance. Therefore, the OHSP IRB Coordinator will likely have left pre-review questions or comments for you. Click on the "Reviews" tab in the study workspace to review those questions or comments, if any.

4. If the activity is Exempt and you are finished reviewing the submission, select "Approved" in item 1 ("Determination") in the "Submit Designated Review" activity. As an exempt activity, select "No greater than minimal risk" in item 2. Select "Exempt" as the review level in item 3 and the applicable Exempt categories in item 4. Add notes and supporting documents as applicable. Select whether you have a Conflicting Interest in item 7; if you have a Conflicting Interest (click on the "?" help button to see the definitions for a Conflicting Interest), you cannot perform the review. In that case, click the "Cancel" button at the bottom of the form. Then contact the IRB coordinator listed near the top of the screen to request re-assignment of the review.

    When you have completed your review, select "Yes" in item 8, and then click "OK". You are now finished with your review and the submission will route back to the OHSP IRB Coordinator for final processing.

5. If additional information is required before you can make an Exemption determination, you have two options for communicating with the investigator.

    a. Option 1: Request clarifications directly from the investigator. Utilizing this option will open up the study for the investigator to edit. When re-submitted, the study will

return to your "My Reviews" tab.

b. Option 2: Open the "Submit Designated Review" activity and select Modifications Required to Secure "Approved." Then, complete Question 5, enumerating any changes the investigator is required to make to secure that determination. If the changes you requested were minor, the OHSP IRB Coordinator may review the changes on your behalf. If the changes you requested were substantive, the OHSP IRB Coordinator will re-route the submission to you for a second round of review.

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Appendix B: Communication with Investigators Script

In general, calls should follow this script:

1. Thank you for making yourself available for this call. In the room we have members of the IRB who have reviewed your submission for the [Insert IRB study number and study title] study. The committee has discussed your submission but has not yet voted on a decision. Their discussion has been guided by [Insert checklist or worksheet HRP-###]. A copy of this Checklist and/or Worksheet was attached to the meeting announcement sent to you in RAMP IRB. Are you currently logged in to RAMP IRB? It may aid our discussion if you also have this Checklist or Worksheet open.

2. If the committee would like to place a time limit on the duration of the call, share that with the investigator at the beginning of the call.

3. The committee is primarily concerned by the following:

    a. Provide key reasons for potential deferral or other finding...

4. Do you have any information that could assist the IRB that was not included in the IRB submission materials?

5. Thank you for taking the time to join us today. At this point the IRB will discuss the information you have shared and make a decision. You will receive your letter from the IRB within one week. Questions about the decision should be directed to the OHSP IRB Coordinator assigned to your submission.