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NIH System Support for the Mgmt of Human Subject a

Point of Contact	Dawn Corbett, NIH
Activities/Progress to Date	
Agenda/Discussion Points	
Pending Decisions	
Participation	
Key Risks/Issues	
Meeting Summary	NIH is developing a new system within the eRA Commons that will allow grantees to provide NIH updates to the human subject and clinical trial information provided through the Human Subject and Clinical Trial Information Form that comes in with grant applications for due dates on or after Jan 25, 2018. The system will streamline current processes, reduce duplicate entry, and improve data to enhance NIH's oversight of clinical trials. The system, to be released this summer, will replace the Inclusion Management System (IMS) in the eRA Commons. Typically recipients will update information via RPPR, but they will also be able to access the system through the eRA Commons Status Module. The module will allow for corrections after RPPR submission, off-cycle updates (e.g. delayed onset studies), and interim progress reports (e.g. recruitment). Users can add/update study information, update enrollment data, provide updates on adverse events, study milestones, Clinicaltrials.gov registration and reporting, etc. The system will be able to pull information on registered studies directly from ClinicalTrials.gov, and will allow initiation of ClinicalTrials.gov registration from within the eRA system. The system will support associating human subject studies across different grants as well as uploading individual-level data on sex/gender, race, ethnicity, and age of participants (.csv file) Attendees were asked for feedback on current plans.
Volunteer Opportunities	

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Agency Matrix Working Group

Point of Contact	Lynda Wolter (lynda.wolter@northwestern.edu)
Activities/Progress to Date	Working Group reviewed the prototypes of the Agency Matrix - a tableau public version built by Northwestern University in table format and the data base built by University of Wisconsin.
Agenda/Discussion Points	
Pending Decisions	1. Add feedback link on Matrix versions 2. Add functionality to sort agencies and systems 3. Make more visible the filtering options on Tableau version 4. Wisconsin database to become the source for the Tableau visualization 5. Make sure data is downloadable in excel like format 6. Make sure one can drill down from Tableau to the Wisconsin data base information
Participation	Added 3 new volunteers to the Working Group mailing list
Key Risks/Issues	Goal to have version 1 ready for community mid-February Need to have FDP on new website technology.
Meeting Summary	Working Group met on Tuesday morning at 8am. Demonstration of the 2 prototypes of the Agency Matrix: Tableau visualization in a table format and a data base version. Discussion of features to add include a feedback button (especially useful if data becomes out of date), downloadable format, filtering and sorting options. Determination that the database Wisconsin built will become source the Tableau version. Need to have FDP on new website technology
Volunteer Opportunities	Volunteers needed for QA/data integrity review on an ongoing basis

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Subawards

Point of Contact	Amanda Hamaker; Amanda Humphrey; Stephanie Scott
Activities/Progress to Date	Subcontract sample template - will be posted for discussion this week. Walked through the sample subcontract template. Intentionally less prescriptive than the subaward template. With some modification it could be used with non-federal subs. Document has been designed to be flexible and this should be considered in review and use of the document.
Agenda/Discussion Points	
Pending Decisions	Subcontract Template Discussion: 1. Structure: we are planning to release this as a word document. Since it is a sample and not a template, it is not prescriptive like the subaward template is, there is guidance in the brackets, but this document is intended for PTEs to have more flexibility in drafting than a standard subaward. a. In fact, with some minor modifications by any entity, this could be used for non-federal subs as well. 2. Just wanted to point out that because this is broadly flexible, there are simply options for cost reimbursement and fixed price as appropriate, but it is up to the PTE to select / delete the right one. a. Confirming we want to leave as a single document versus separating out. If we have separate ones, it may speed up drafting time for manual drafting, but will hard for programmers to maintain on the back end and for us as well. 3. The template doesn't reference any specific federal provisions around costing / finance information, including and especially FAR 31.3 and 2 CFR 200, this provides flexibility for different PTE and sub types such as for-profit non-profit mixes. a. Again gives flexibility for use with non-federal awards b. These should principles should still be articulated via the inclusion of the final contract and/or applicable FARs. 4. Change from subcontract to subaward nomenclature Multiple votes to remove the word "research" - not always research projects David Mayo - contracts under UG versus contracts under FAR. UG does not refer to these as subcontracts. May consider leaving the nomenclature up to the institution. A point to consider. Removal of word "Research" may raise less questions. Subaward versus Subcontract could raise audit concern. Subaward is from the UG perspective so this is the preferred term. Ken - title was an attempt at a compromise; agrees with removal of the word "research" 5. Use of PTE and subrecipient versus contractor / subcontractor
Participation	Certificates of Confidentiality: (see slides) How does the FDP Subawards committee assist with this? • Discussion: options for incorporating into FDP subawards: Update the template (concerns re: planning IT resources if we have another release in

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2018)
- Providing optional language for the additional terms section of Attachment 2 and incorporating fully in 2019
- Relying on the NIHGPS and creating FAQs / guidance
- Additional Option: Leave it up to the institutions to have their own policy and if the IRB handles it, great.

Draft language from partners shared - see slides. Written as "if applicable" and includes a certification.

What are your institutions doing? Other discussion?
• Part of the IRB process - between IRB and PI, part of the protocol - how do we ensure the subrecipient is doing this?
• Have we considered doing this as a certification?
• Who sets the criteria to determine if this is criteria has been met for CoC? NIH policy
• Understanding is that the CoC will not be specifically identified in the NOA.
• Institutions seeing inconsistencies in how these are being issued.
• Five questions - specific to the SOW - who should be answering these?
• Argument toward relying on the grants policy statement - echoed by others
• Specific language in the policy that the PTE must ensure compliance - explicitly state this
• Can we add a certification to the Expanded Clearinghouse?

Key Risks/Issues

Questions for the subcontracts group to consider:
Question - Is there a reason that the new payment language from the subaward template wasn't included? To be addressed with the working group. The subcontract group doesn't need to add more payment language per se, but that we want the community to agree that the broadness of the payment language and underlying cost principles is best left broad so as to be flexible depending on the contract type and situation.

Question - Have the contracting officers at any of the institutions been asked how they feel about this? HHS typically reviews the subs sent under their contracts. However these are specific to the project/contract and not to the general terms of the subcontract. Agreement that most contracting officers won't want to review these.

Question - Will there be guidance for what changes to make when using this sample for a non-federal subcontract? Yes, should be in FAQs. If not, will add.

Reminder - this is not meant to be an FDP template, but a tool you can use to start from when issuing a subcontract.

Question for discussion - should this be a single document to include both the FP and CR or should they be separated into two documents?
- Pamela - Increase in people trying to do hybrids between CR and FP. Would like to discourage that. Seeing this in general not necessarily with just the subcontracts.

Research Integrity - OSTP policy from 2000 surrounding research integrity. Should be

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	included in each agencies general policies. Could add a reference to the templates if the membership desires… What do people think? Grants policy statement is sufficient. Add an FAQ to address. FAQ should address where reports should be made. Could make it more general to capture more things. RAQ scoring - see if we can get talking notes. • Scoring based assessment versus judgment based assessment • Important to make the distinction between entity based risk and project based risk. • How much does quantification help or hurt? • Opportunity in front of us is to simplify
Meeting Summary	What's next? • Additional FAQs as discussed at this meeting. • Foreign Template FAQs - specific to foreign template items. • Subcontract for comments - mid-February, ready by May meeting • Fixed Price Subawards - Evaluation of FDP role • New guidance to write. Watch for emails sent to the listerv in late January/early February requesting your feedback. Reminder: Templates created to make things easier – don't change them! Let us know if you get one with changes, we'll contact the institution.
Volunteer Opportunities	Guidance Group - This group is always looking for new contributors to assist in revising existing guidance documents and creating new. This group will soon begin to work on new FAQs to be added and to initiate the one-page/checklist for use in talking about the FDP templates with institution legal counsel. ERA Focus Group (Spring 2018) this would be a 2-hour focus group discussion on programming and the use of the FDP templates by institutions that pre-populate their templates. We want to hear what the barriers are to a streamlined update process for your institutions. Please contact the co-chairs if you have any interest in participating in these or other groups.

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FDP/SMART IRB Reliance Agreement Taskforce

Point of Contact	Lynette Arias/Alexandra Albinak
Activities/Progress to Date	The purpose of the Taskforce it to obtain FDP member feedback on the SMART IRB to ensure that the agreement, along with documents, tools and resources associated with the agreement, can be used by a broad spectrum of institutions and that they reflect FDP member feedback.
Agenda/Discussion Points	
Pending Decisions	The key decisions include to what extent FDP feedback will be incorporated into the SMART and at what version; how will we address the issues highlighted; and whether there might be an FDP pilot or demonstration using some version of SMART reliance agreement and tools.
Participation	Human Subjects Subcommittee members, other compliance and faculty attendees, and the guest speakers (see presentation slides for names and affiliations).
Key Risks/Issues	Top three topics for discussion and resolution include the requirement for an FWA, QA and clarification of agreement terms. Other broader issues include the need to use SMART for both federal and non-federal and in minimal risk studies. The Task Force will continue to work on these issues. There was a suggestion that FDP and/or SMART should look into developing a local context database for use by FDP and SMART institutions that would include local and state laws. SMART is working on it so perhaps that could be a fruitful collaboration. How sIRB works in terms of COI also came up and could be addressed from a procedural standpoint. Regarding QA, UC System is looking at creating a system-wide certification for QA as an alternative to AAHRP and will be based on regulations only. FDP will investigate this as a model.
Meeting Summary	The Task Force discussion centered around the need for clarity on the terminology and language used in the SMART reliance agreement and the specific requirements and responsibilities, including the need to have an FWA and quality assurance (QA) program. Non-accredited IRBs do not have a formal QA program so discussions revolved around what is an acceptable program. It can be said that many non-accredited IRBs do, in fact, have undergone a process of quality assessment that would be acceptable. An FWA is required for all institutions conducting human subjects research using federal funds so SMART uses this as a form of assurance that the IRB will follow acceptable standards. Discussion centered around alternative ways to obtain these assurances.
Volunteer Opportunities	Opportunities for participation include signing on to the SMART IRB, exploring some of the ideas listed here.

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Membership Committee Meeting

Point of Contact	Katherine V. Kissmann
Activities/Progress to Date	• Registration desk – provide assistance to FDP staff at each meeting • Institutional mentoring – match new attendee institutions with mentors, as requested • ERI activities – work with ERI to facilitate their efforts • Member attendance and feedback – work with FDP staff to monitor attendance and provide feedback • Annual report - review, analyze and summarize for Executive Committee • Election – Gather candidate statements and photos for website for voting
Agenda/Discussion Points	
Pending Decisions	• Institutional vs. System Memberships for future phases
Participation	In attendance at this meeting: Charisse, Katherine and Larry; Webb Brightwell – Harvard University; Andrea Deaton – University of Oklahoma; Michael Eads – Northern Illinois University; Jeremy Hamlin – University of New Mexico; Jeanne Hermann – University of Tennessee Health Science Center; Karen Jarvis-Thorne – Boston College; Michael Kusiak - University of California; Jackie Lucas – Beckman Research Institute City of Hope
Key Risks/Issues	• Summarize annual report data for presentation at May meeting • Distribute, analyze data and summarize new attendee survey • Assist with website construction/maintenance • Plan to engage more federal agency participation • Provide assistance to ERA committee
Meeting Summary	• September 2017 Meeting Minutes/Summary – Motion made and passed to approve minutes from September 2017 meeting • Registration Table - recommendation made to have registration table open from 4:30 – 6:30 p.m. on the first day of the meeting to allow for attendees arriving during the reception to obtain their name badge and reduce traffic on Monday morning. Will discuss with FDP staff. • New Attendee Reception – Reception held immediately prior to the general Welcome Reception. Need to ensure that EC and MC members interact more with the new attendees. Recommend to have reception host, greeters at the door and a brief welcome and introduction like the one at the September meeting as a permanent part of the reception. • New Attendee Orientation – 31 people attended the orientation. Feedback received that the content regarding how to get involved was helpful. • New Attendee Experience Survey – Survey was reviewed and approved by the Executive Committee and will be distributed to first time attendees after each meeting. Feedback will be used to improve communication and events for future meetings. • Annual Report – Jeanne Hermann analyzed and summarized the report data. There was

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an overwhelming amount of data collected. The summary was provided to the Executive Committee. The EC requested that a brief summary be provided to the members at the May meeting and that the information should be made available to the members. Discussion regarding future report content was discussed. The report content will be used for strategic planning and future action items for the EC.

- Member Participation Guide – Table of contents and medium for the guide were discussed. The table of contents will continue to be discussed through conference calls with a goal to have the draft finalized for review and approval by the EC at the May meeting.

Volunteer Opportunities

Registration desk volunteers are needed for each meeting.

Member Participation Guide Working Group – This group is tasked with creating a guidance document for participation in FDP. The group is currently working on a draft table of contents, glossary and format for the document for review by the Membership Committee which will then be proposed to the Executive Committee. The guide will serve as a resource for participation in FDP, working groups, pilots, demonstrations, etc. as well as to more fully define roles and expectations for each representative, attendee, etc.

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Costing and Procurement Updates

Point of Contact	Sara Bible, Stanford University and Jim Luther, Duke University
Activities/Progress to Date	The Administrative Cost Working Group continues to work on and discuss several important topics related to implementation of the Uniform Guidance, including implementation of the Procurement Standards. During the past year the implementation of NIH's Single Institutional Review Board (sIRB) requirements has become critical. Work on these topics has been ongoing between meetings through discussions with Federal and university representatives. More recently the implementation of the public data access requirements has been a focus for the working group. The working group is focused on efficient and effective implementation of the Uniform Guidance, sIRB, the public data access requirements and other costing and regulatory issues.
Agenda/Discussion Points	
Pending Decisions	•Costing for public data access requirements •Clinical Trials definition •Procurement: Procedure for review and approval of a micro-purchase threshold over $10,000
Participation	Federal representatives, University faculty and administrative representatives.
Key Risks/Issues	•Increased cost of the IRB process •Costs of commercial IRB is not known at this time •Increased workload for IRB staff and panels •Need for updated or new electronic IRB systems to accommodate use by multiple sites •Time to prepare for sIRB implementation was extended by four months to January 25, 2018. However, institutions of higher education (IHEs) are still concerned about the amount of work and systems updates that need to be made prior to the January 2018 deadline. •Direct charging sIRB costs will reduce other costs that can be direct charged to sponsored projects •Definition of Clinical Trials: The administrative burden associated with applicability to Social and/or Behavioral research is significant without associated benefits. •Readiness of institutions to function as the sIRB. Implications include adequate personnel and technology resources. Procurement: There has been no decision on which agency/agencies has authority for review and approval of a micro-purchase threshold over $10,000.
Meeting Summary	The topics and key risks described above were discussed during this session. Links to the following FAQs are below: sIRB Costing FAQs June 2017: https://osp.od.nih.gov/clinical-research/nih-policy-on-the-

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	use-of-a-single-irb-for-multi-site-research-faqs-on-costs/
Volunteer Opportunities	

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Expanded Clearinghouse

Point of Contact	Lynette Arias and Pamela Webb – Co-Chairs
Activities/Progress to Date	See below and session slides at http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_184135.pdf
Agenda/Discussion Points	
Pending Decisions	Decisions pending at this time include: decision whether to add non FDP members to the Clearinghouse, allow the API to eventually be available for request by public, specific communication and marketing avenues for Pilot Report; and long range planning for the Clearinghouse.
Participation	The session was attended by well over 100 individuals. The session included very active audience participation and feedback on the ongoing use and development of the Clearinghouse.
Key Risks/Issues	The Expanded Clearinghouse Working Group is actively pursuing encouraging all FDP member organizations to join the Clearinghouse at this time. We hope to have all FDP member organizations either included or information provided by them regarding reasons for not joining, by the end of February. This will help provide information to the FDP Executive Committee regarding potential future mandatory use of the Clearinghouse and also provide the Working Group the ability to help address any concerns in order to achieve full FDP participation.
Meeting Summary	In addition to the information covered in the slides, there was a good discussion of the options for encouraging and potentially adding non FDP members in the Clearinghouse in the future. This discuss included such options as: charging a fee for non FDP orgs, surveying current participating organizations for their top list of frequent collaborating institutions, utilizing public information about large research institutions to include on an invitation list, etc. These options will be more fully fleshed out in the coming months and discussed at future FDP meeting sessions. A demonstration of sorts was provided related to how the API is intended to work and rough timeline was provided related to the development of and roll out of the API.
Volunteer Opportunities	Voluntary participation in the Expanded Clearinghouse is still encouraged by all FDP member organizations. As we move towards long range planning there will likely be opportunities for joining topic specific working groups. Interested parties can contact the co-chairs at fdpechelp@gmail.com

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FDP/SMART IRB Reliance Agreement Task Force

Point of Contact	Lynette Arias/Alexandra Albinak
Activities/Progress to Date	The purpose of the Taskforce is to partner with SMART IRB related to the SMART IRB Reliance Agreement; to obtain FDP member feedback on Agreement; and to ensure that the agreement, along with associated documents, tools and resources can be used by a broad spectrum of institutions and reflect FDP member feedback.
Agenda/Discussion Points	
Pending Decisions	The key decisions include to what extent FDP feedback will be incorporated into the SMART IRB Agreement and at what version and what timeline; how will issues highlighted be addressed; and how FDP can best partner with SMART IRB, potentially via a pilot or demonstration using some version of SMART Reliance Agreement and tools.
Participation	Human Subjects Subcommittee members, other compliance and faculty attendees, and the guest speakers (see presentation slides for names and affiliations).
Key Risks/Issues	Top three topics for discussion and resolution include the requirement for an FWA, QA and clarification of agreement terms. Other broader issues include the need to use SMART IRB Reliance Agreement for both federal and non-federal and in minimal risk studies. The Task Force will continue to work on these issues. There was a suggestion that FDP and/or SMART should look into developing a local context database for use by FDP and SMART institutions that would include local and state laws. SMART is working on it so perhaps that could be a fruitful collaboration. How sIRB works in terms of COI also came up and could be addressed from a procedural standpoint. Regarding QA, UC System is looking at creating a system-wide certification for QA as an alternative to AAHRP and will be based on regulations only. FDP will investigate this as a model.
Meeting Summary	The Task Force discussion centered around the need for clarity on the terminology and language used in the SMART reliance agreement and the specific requirements and responsibilities, including the need to have an FWA and quality assurance (QA) program. Non-accredited IRBs do not have a formal QA program so discussions revolved around what is an acceptable program. It can be said that many non-accredited IRBs do, in fact, have undergone a process of quality assessment that would be acceptable. An FWA is required for all institutions conducting human subjects research using federal funds so SMART uses this as a form of assurance that the IRB will follow acceptable standards. Discussion centered on alternative ways to obtain these assurances.
Volunteer Opportunities	Opportunities for participation include signing on to SMART IRB, exploring all of the information and resources listed there and providing feedback to the Task Force.

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Faculty Administrator Collaboration Team (FACT)

Point of Contact	Mark Haselkorn and Dave Reed – Co-Chairs
Activities/Progress to Date	See below and session slides at: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_184136.pdf
Agenda/Discussion Points	
Pending Decisions	Determination to be made relative to FACTs specific placement in the FDP structure and specific project, pilots or demonstrations that FACT will undertake.
Participation	The session was attended by approximately 80 individuals who included a mix of faculty and administrators. The session included very active audience participation
Key Risks/Issues	The area of faculty and administrator collaboration is a large one and at this time FACT is still in its conception and infancy stage, fleshing out the landscape, areas that are ripe for discussion and action and how this group can best be formed to address and how best to approach the many possible activities.
Meeting Summary	Summary items from discussion on initial FACT project relations to Qualitative and Quantitative assessment of faculty and administrator collaboration at institutions: Suggestions for Qualitative surveys 1. How do faculty and administration work together to improve proposal success rate? 2. Can we measure faculty satisfaction? a. Partially covered in “probe questions” such as “which procedures work, which don’t”, and “how do you measure research success” 3. A primary concern is finding the best way for faculty and administration to communicate 4. Younger more energetic faculty may have greater expertise in setting animal care/human subject policies 5. What is the best model for faculty and administration collaboration on compliance? 6. How do faculty and administration collaborate to optimize a training program? Could training faculty and administrators in teams be an option? 7. Ask admins: What are faculty doing right/wrong; ask faculty: What are admins doing right/wrong? 8. There is a third party involved: how do research admins and faculty feel about finance office?? 9. To what degree does fear of consequences guide decisions of faculty (e.g. changing research direction) and administrators (e.g. retaining mediocre workers for fear of hiring somebody worse) 10. Do faculty administrators collaborate better with other faculty than non-faculty administrators?

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Suggestions for Quantitative surveys
1. Can we capture the degree of variability in research support at different levels? (e.g. college, center, or department)
2. Are there any metrics to measure the turnover of research administrators at different levels?
3. Can we capture the degree of training/certification of research administrators at different levels?
4. Can we measure the level of industrial engagement of each institution?
5. Is there a way to measure how faculty admins perform regular to non-faculty admins?
6. Are institutions centralized or de-centralized? (is this a qualitative question?)

General comments
1. Can the surveys developed by FACT be made available?
2. Johns Hopkins agreed to provide questions used in their recent survey
3. FACT should not overlook nonacademic research institutes

Volunteer Opportunities

Volunteers for the Working Group are no longer being accepted at this time, but a listserv/email group is planned and will be used to collect ongoing feedback and solicit volunteers for specific projects, once determined.

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Compliance Unit Standard Procedure (CUSP)

Point of Contact	Aubrey Schoenleben, University of Washington and Sally Thompson-Iritani, University of W
Activities/Progress to Date	The goal of this working group is to develop an online resource for sharing standard procedures used in animal care protocols. See below and session slides for progress to date. Slides can be found at: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_184132.pdf
Agenda/Discussion Points	
Pending Decisions	• Determine how data will be organized within the site (how granular of an organizational system is needed/preferred) • Define scope and system requirements for the first phase of the project
Participation	This session was attended by approximately 50 individuals, either in person or via web conference.
Key Risks/Issues	See Key Decisions Pending above.
Meeting Summary	The Data Import/Export team provided background on how procedure types can be further broken down in to sub-categories using pick lists. Discussion included the pros/cons of using pick lists, a top 20 list, and search capabilities (or a combination of the three). The team will survey working group members over the next month to determine how many sub-categories and what grouping criteria should be used when defining a procedure or substance. Additional feedback during the meeting included institutions wanting their IT groups to weigh in on the difficulty/time requirement for preparing procedures to be uploaded to the database, an emphasis to reduce burden and keep this as simple as possible, and the possibility that some institutions will not want to share all their procedures, e.g., primate research information. Other key decisions made during the working session include: (1) each individual will be required to have a unique account, and (2) the name of the contributing institution will be collected as part of the metadata for a given procedure, however, the institution can decide if this information is displayed to all users. The federal sponsor for this project also noted the CUSP project will be included in a Request for Information (RFI) that will be issued in response to the 21st Century Cures Act. The purpose of this RFI is to seek input from the wider scientific community and the public on potential measures that may be taken to reduce regulatory burden.
Volunteer Opportunities	Please contact Aubrey (aubreys@uw.edu) or Sally (sti2@uw.edu) if you are interested in

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joining this working group. The working group meets monthly.