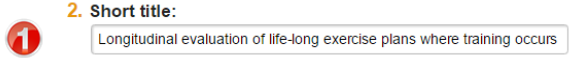
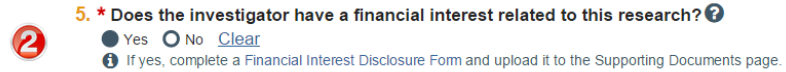
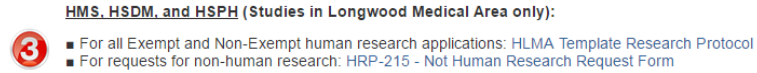
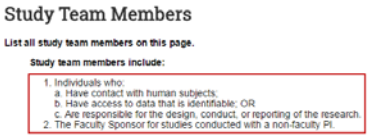
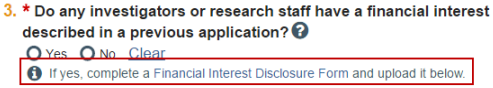
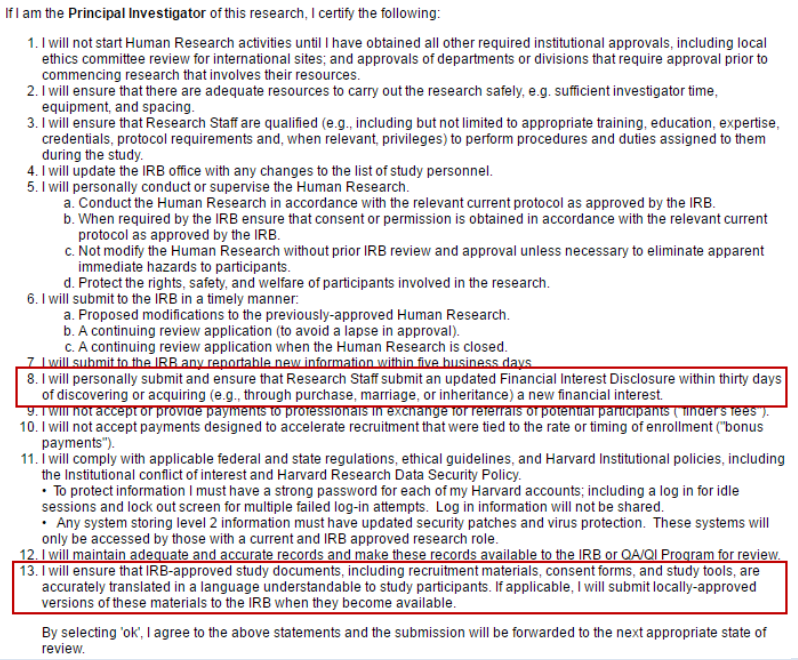
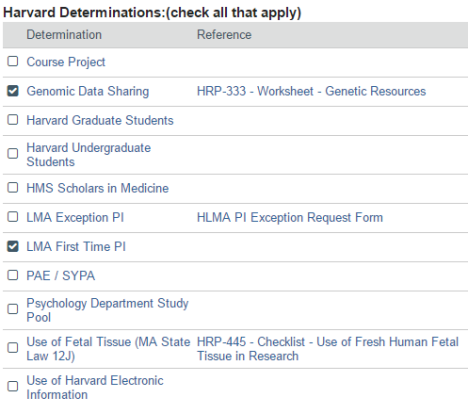
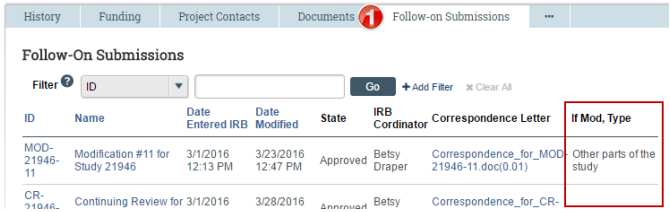
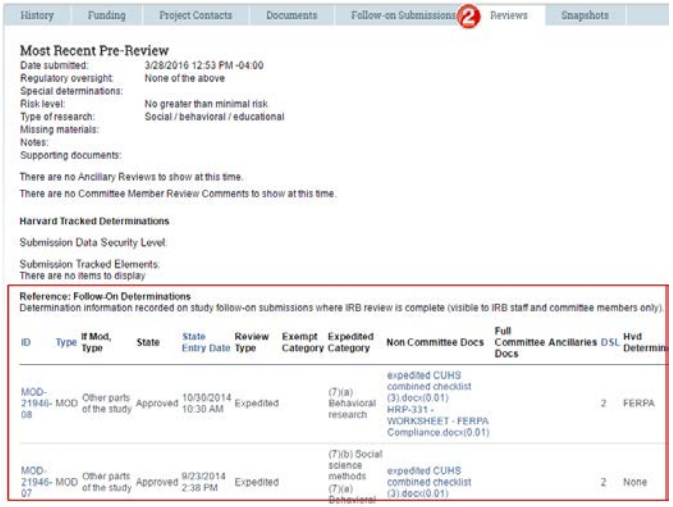
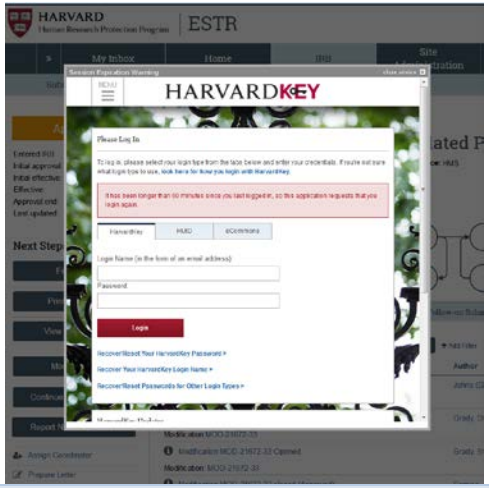
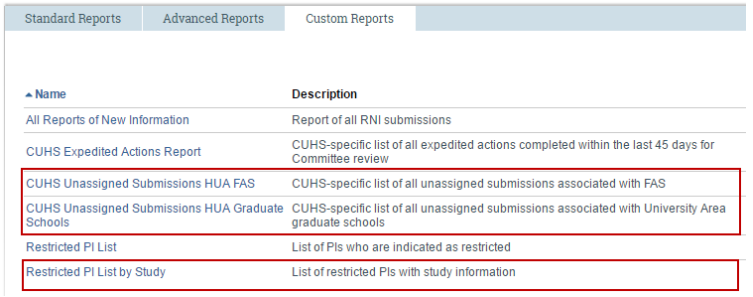
ESTR 1.22.1 Configuration Release Items: April 27 2017

This release includes instruction revisions, along with revisions to documents linked in the system, including forms, templates, determination letters, worksheets, and checklists.

What has changed…	What it means…	How it looks (as applicable)…
SmartForm Pages		
Basic Information 1. Short title now limits to 80 characters only	1. System support of text limits for short title to ensure "clean" view of submission short names throughout the system.	
2. Added instruction regarding positive disclosure	2. There is no change in policy. This is simply an on-screen reminder of submission requirements.	
3. Removed the description of the LMA Exemption Form	3. LMA has updated the single Protocol Template available such that separate submission templates are no longer necessary.	
Study Team Members Revised the instructions on the screen and in the non-Harvard team members form	There is no change in policy. This is to clarify the definition of a study team member.	
Supporting Documents Translation Attestation Form is removed.	Due to changes in process, the Translation Attestation form is no longer required when non-English versions of study materials are in use. Instead, the PI assurance that is confirmed when submitting materials to the IRB has been updated to confirm this attestation.	
Continuing Review/Closure Added instruction regarding positive disclosure	There is no change in policy. This is simply an on-screen reminder of submission requirements.	

What has changed…	What it means…	How it looks (as applicable)…
Activities		
Submit and Assign PI Proxy 1. Revised PI assurance language to clarify item 8 and add item 13. This is also updated in the text of the notice that is sent when the submit activity is completed. 2. Removed the VA language that appears on the Submit activity for continuing reviews on VA Projects.	1. From this point forward, the assurance provided by the PI includes a) confirmation of personal responsibility to ensure interest disclosure, and b) attestation that any translated materials are accurate. 2. There is no change in policy. System text was only visible under special circumstances and is removed.	 If I am the **Principal Investigator** of this research, I certify the following: 1. I will not start Human Research activities until I have obtained all other required institutional approvals, including local ethics committee review for international sites; and approvals of departments or divisions that require approval prior to commencing research that involves their resources. 2. I will ensure that there are adequate resources to carry out the research safely, e.g. sufficient investigator time, equipment, and spacing. 3. I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. 4. I will update the IRB office with any changes to the list of study personnel. 5. I will personally conduct or supervise the Human Research. a. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB. b. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB. c. Not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to participants. d. Protect the rights, safety, and welfare of participants involved in the research. 6. I will submit to the IRB in a timely manner: a. Proposed modifications to the previously-approved Human Research. b. A continuing review application (to avoid a lapse in approval). c. A continuing review application when the Human Research is closed. 7. I will submit to the IRB any reportable new information within five business days. 8. I will personally submit and ensure that Research Staff submit an updated Financial Interest Disclosure within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest. 9. I will not accept or provide payments to professionals in exchange for referrals of potential participants ("finder's fees"). 10. I will not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments"). 11. I will comply with applicable federal and state regulations, ethical guidelines, and Harvard Institutional policies, including the Institutional conflict of interest and Harvard Research Data Security Policy. • To protect information I must have a strong password for each of my Harvard accounts; including a log in for idle sessions and lock out screen for multiple failed log-in attempts. Log in information will not be shared. • Any system storing level 2 information must have updated security patches and virus protection. These systems will only be accessed by those with a current and IRB approved research role. 12. I will maintain adequate and accurate records and make these records available to the IRB or QA/QI Program for review. 13. I will ensure that IRB-approved study documents, including recruitment materials, consent forms, and study tools, are accurately translated in a language understandable to study participants. If applicable, I will submit locally-approved versions of these materials to the IRB when they become available. By selecting 'ok', I agree to the above statements and the submission will be forwarded to the next appropriate state of review.
Track Harvard Determinations Added new determinations, removed those unused, and revised the prompt for some existing.	In this IRB staff completed activity, determination listings have been updated to match current practices. Updated guidance for this activity is provided separately to IRB staff.	 **Harvard Determinations:(check all that apply)** Determination / Reference ☐ Course Project ☑ Genomic Data Sharing — HRP-333 - Worksheet - Genetic Resources ☐ Harvard Graduate Students ☐ Harvard Undergraduate Students ☐ HMS Scholars in Medicine ☐ LMA Exception PI — HLMA PI Exception Request Form ☑ LMA First Time PI ☐ PAE / SYPA ☐ Psychology Department Study Pool ☐ Use of Fetal Tissue (MA State Law 12J) — HRP-445 - Checklist - Use of Fresh Human Fetal Tissue in Research ☐ Use of Harvard Electronic Information

What has changed…	What it means…	How it looks (as applicable)…
Workspace		
Active and Archived Main Study 1. The Type of Modification displays on the Follow-on Submissions tab.	1. This is an additional column for at-a-glance view of the type of modification listed under the Follow-on Submissions tab.	
2. Follow-on Determinations submission list available to IRB staff (only) for reference during review.	2. A list visible only to IRB staff under the Reviews tab, this allows for single location reference into all determinations made on a project.	

What has changed…	What it means…	How it looks (as applicable)…
System When the system remains idle for more than 30 minutes, the displayed window has been re-sized.	The timeout period is the same. This just expands the window so that it is easy to log back in.	
Reports		
1. Added Restricted PI by Department report which includes a list of associated studies 2. Added Unassigned reports to support local team submission assignments	New reports are available to IRB staff only, to support submission assignment and review.	
Determination Letters, and Meeting Agenda and Minutes		
• Issues with funding source displaying properly have been corrected. • On Minutes and Agenda, document lists have been removed and formatting has been simplified to allow for easier edits before and after committee meetings.	When creating determination letters, agenda or minutes, IRB staff will have adjusted items available for further formatting.	

What has changed…	What it means…	How it looks (as applicable)…
Forms, Templates, Checklists, and Worksheets		
All of the forms, templates, checklists and worksheets (referred to as the HRPP Toolkit) were reviewed. Some have been revised, others added or removed. All updated documents are available in context and via the IRB Library in ESTR.	As of April 27, 2017, the IRBs will discontinue use of removed templates, forms and documents. • For new projects: new versions should be used or updated. • For existing projects: updates to previously approved versions can be proposed. If changes are substantive, the IRB may request that you complete a newer version of the form or template.	See below summary of HRPP Toolkit changes.

Release 1.22.1 Summary of HRPP Toolkit Changes

New Documents

Document Name	Type	Changes Summary
HRP-445-CHECKLIST-Use of Fresh Human Fetal Tissue in Research	Checklist	New checklist as per the addition of 12J suite of documents
HRP-202-FORM-IRB Member Information.docx	Form	Previously not in ESTR, added to the Library for reference
HRP-226-FORM-PI Exception Request Form	Form	Added to ESTR Library (LMA Specific)
HRP-545-Use of Human Fetal Tissue in Research and M G L ch 112 §12J_3-15-2017	Letter	New letter as per the addition of 12J suite of documents
HLMA Exempt Human Research Consent Script Template	Template	Added to the ESTR Library and on the SmartForm (LMA Specific)
HRP-332-WORKSHEET-NIH GDS Institutional Certification	Worksheet	Added to the ESTR Library

Document Name	Type	Changes Summary
HRP-335-WORKSHEET-Provost Review	Worksheet	Added to the ESTR Library

Revised Documents

Document Name	Type	Changes Summary
HRP-410-CHECKLIST-Waiver or Alteration of Consent Process	Checklist	Added newborn blood spot
HRP-411-CHECKLIST-Waiver of Written Documentation of Consent	Checklist	Added newborn blood spot
HRP-412-CHECKLIST-Pregnant Women	Checklist	Added N/A References
HRP-413-CHECKLIST-Non-Viable Neonates	Checklist	Added N/A where applicable
HRP-414-CHECKLIST-Neonates of Uncertain Viability	Checklist	Added N/A where applicable
HRP-415-CHECKLIST-Prisoners	Checklist	Prisoner and Unexpected Incarceration Checklists combined into a single doc
HRP-442-CHECKLIST-Information Security Level Determination	Checklist	Slight revision to description levels
HRP-221-FORM-Financial Interest Disclosure	Form	Removed 'IRB Use Only' section and signature line; moved definitions to the footnotes
HRP-213-FORM-Non-Human Subjects Research Request Determination Form	Form	Revised grammar and numbering, rephrased question 3 to include federal genomic data repositories and institutional certification.
HRP-220-FORM-Non-Harvard Study Personnel	Form	Revised to accurately reference the fCOI definitions, removed parenthetical phrase from Section B, namely "including data that is indirectly identifiable using a coding system or key".
HRP-224-FORM-IRB Cede Request	Form	Removed template guide reference and added faculty sponsor space for CUHS investigators
Chair's Agenda	Letter	Revision to reference items (LMA specific)

Document Name	Type	Changes Summary
HRP-501a-Meeting Minutes	Letter	Format changes, additional reference sections
HRP-501-Meeting Agenda	Letter	Format changes, additional reference sections
HRP-512a-Mods Required for Non-Human Research	Letter	Revised grammar regarding submission of response to required modifications
HRP-512-Mods Required to Secure Approval	Letter	Clarify that no human subjects research can occur until final approval secured
HRP-516-Deferral	Letter	Changes to provide greater instruction for investigators on next steps, fixed issue with how funding displays
HRP-517-Disapproval	Letter	Revised reference carbon copy list
HRP-519-Information Item	Letter	Content and format revision
HRP-520-External Report	Letter	Revised reference carbon copy list
HRP-526a-Mods Required for Human Research-Not Engaged	Letter	Document number change and revised grammar regarding submission of response to required modifications
HRP-541-External IRB	Letter	Slight revisions, including narrowing focus of the relying PI to receive only noncompliance determined to be serious/continuing.
LMA Investigator Manual	Other	Revised instruction, added appendices
CR Summary of Study Progress Template	Template	Adding clinicaltrials.gov related question
HLMA Adult Consent Form Template	Template	Minor grammar and reference revisions
HLMA Adult Surrogate Consent Form Template	Template	Minor grammar and reference revisions
HLMA Child Assent Form Template	Template	Minor grammar and reference revisions
HLMA Consent Template for HIPAA-covered entities	Template	Minor grammar and reference revisions

Document Name	Type	Changes Summary
HLMA Parental or Guardian Permission Template	Template	Minor grammar and reference revisions
HLMA Research Protocol	Template	Minor grammar and reference revisions, major section layout revisions
CUHS Adult Consent Form Template	Template	Minor revisions, remove reference to Template Guide
CUHS Child Assent Form Template	Template	Minor revisions, remove reference to Template Guide
CUHS Parental or Guardian Permission Template	Template	Minor revisions, remove reference to Template Guide
CUHS Protocol Template	Template	Minor revisions, remove reference to Template Guide
HRP-301-HUA-WORKSHEET-Review Materials	Worksheet	Split for HUA specific list of items to reference
HRP-301-LMA-WORKSHEET-Review Materials	Worksheet	Split for LMA specific list of items to reference
HRP-302-WORKSHEET-Approval Intervals	Worksheet	Updated guidance
HRP-303-WORKSHEET-Communication of Review Results	Worksheet	Removed reference to emergency research
HRP-306-WORKSHEET-Drugs	Worksheet	Updated regulatory references
HRP-307-WORKSHEET-Devices	Worksheet	Clarification regarding HUD
HRP-308-WORKSHEET-Pre-Review	Worksheet	Removed DOE checklist requirement
HRP-310-WORKSHEET-Human Research Determination	Worksheet	Added newborn blood spot information
HRP-311-WORKSHEET-Engagement	Worksheet	Title wording change
HRP-312-WORKSHEET-Exemption	Worksheet	Updated Section 2.1.

Document Name	Type	Changes Summary
HRP-313-WORKSHEET-Expedited Review	Worksheet	Removed reference to HUD CR
HRP-314-WORKSHEET-Criteria for Approval	Worksheet	Minor update to purpose paragraph
HRP-318-WORKSHEET-Additional Federal Agency Criteria	Worksheet	Updated DOE requirements
HRP-324-WORKSHEET-Contracts	Worksheet	Included timeframe per AAHRPP
HRP-333-WORKSHEET-Genetic Resources	Worksheet	Added text regarding Chinese resources

Removed Documents

Document Name	Type
HRP-415b-CHECKLIST-Unexpected Incarceration	Checklist (included within HRP-415-CHECKLIST-Prisoners)
CUHS Template Guide	Other (CUHS specific)
CUHS Investigator Scope of Work Template	Template (CUHS specific)
HRP-332-WORKSHEET-GCP	Worksheet
HRP-334-WORKSHEET-SIM Projects	Worksheet
HRP-223 - FORM - Translation Attestation	Form
HRP-203 - FORM - Exemption Request	Form (LMA specific)

Unchanged Documents

Document Name	Type

Document Name	Type
HRP-416-CHECKLIST-Children	Checklist
HRP-417-CHECKLIST-Cognitively Impaired Adults	Checklist
HRP-418-CHECKLIST-Non-Significant Risk Device	Checklist
HRP-441-CHECKLIST-HIPAA Waiver of Authorization	Checklist
HRP-217-FORM-Radiation Safety	Form
HRP-225-FORM-Individual Investigator Agreement	Form
HRP-510a-Approval CR or MOD Team	Letter
HRP-510a-Approval MOD Other	Letter
HRP-510-Approval	Letter
HRP-510c-Exemption Determination	Letter
HRP-510d-Modification Exemption Determination	Letter
HRP-511-Closure	Letter
HRP-513a-Modification NHSR Determination	Letter
HRP-513-NHSR Determination	Letter
HRP-515-Suspension or Termination	Letter
HRP-521-Significant Risk Device Determination	Letter

Document Name	Type
HRP-522-Certification of Approval of Prisoner Research	Letter
HRP-523-Request for Approval of Not Otherwise Approvable Research	Letter
HRP-526-Human Research-Not Engaged	Letter
HRP-528-NIH GDS Institutional Certification	Letter
HLMA IAA Template	Template
HLMA Short Form Consent Template	Template
HRP-304-WORKSHEET-IRB Composition	Worksheet
HRP-305-WORKSHEET-Quorum and Expertise	Worksheet
HRP-315-WORKSHEET-Advertisements	Worksheet
HRP-316-WORKSHEET-Payments	Worksheet
HRP-317-WORKSHEET-Short Form of Consent Documentation	Worksheet
HRP-320-WORKSHEET-Scientific or Scholarly Review	Worksheet
HRP-321-WORKSHEET-Review of Information Items	Worksheet
HRP-330-WORKSHEET-HIPAA Authorization	Worksheet
HRP-331-WORKSHEET-FERPA Compliance	Worksheet