AAHRPP®

Association for the Accreditation of Human Research Protection Programs, Inc.®

Instructions to Apply for Initial Accreditation and Reaccreditation

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Introduction

Accreditation uses a set of objective Standards to evaluate the quality of an organization's Human Research Protection Program (HRPP). Through accreditation, an organization can demonstrate the overall excellence of its HRPP.

Steps to Get Accredited

Accredited organizations renew their accreditations three years after initial accreditation and every five years thereafter. Whether your organization is applying for initial accreditation or reaccreditation, the application process is the same.

For an overview of the accreditation process, see https://www.aahrpp.org/accreditation/get-accredited/overview.

Conduct a Self-Assessment

The first step in the accreditation process is to conduct a self-assessment where you evaluate your HRPP and make improvements as needed to ensure your organization meets the AAHRPP Standards.

Below is guidance for conducting a self-assessment. A key to getting started is to download and review the Evaluation Instrument for Accreditation. Read through the entire document before tackling any of the steps in earnest. Familiarize yourself with the Standards and Elements. If you have an internal IRB or ethics committee (EC), you may want to start with Domain II because this Domain might be most familiar to you and, therefore, easiest to complete.

When reviewing an Element or Standard in the Evaluation Instrument for Accreditation, consider the following questions, and if needed, take steps to improve your HRPP:

- Does your organization have policies and procedures that address the information described in the Required Written Materials?
- Does your organization follow the practices described in the Required Written Materials?
- Do the activities of your organization achieve the Outcomes?

During your self-assessment, you will create a list of your organization's supporting documents, which will later become Section C of your application (Application for Accreditation or Reaccreditation: Section C Template). You will then assemble copies of those supporting documents to form Section D. As you are conducting the self-assessment, revise your policies and procedures as needed so that they meet the Standards and Elements, and implement any necessary changes so that your written materials match your practice.

The success of your application is dependent on the accuracy and completeness of your organization's self-assessment and on the actions your organization takes to improve its HRPP.

MAKE A LIST OF SUPPORTING DOCUMENTS

Collect written materials (e.g., policies and procedures) that describe the practices your HRPP follows to meet each Standard and Element, or indicate that the Standard or Element is not applicable to your organization's HRPP. When available, collect and provide documents that verify your organization follows your HRPP's practices.

For each document, identify which Standard(s) or Element(s) the document meets/addresses. Indicate if there are certain sections or pages of the document that are responsive to the requirements of a particular Standard of Element. This list of documents will become part of your organization's Application for Accreditation or Application for Reaccreditation, specifically the Section C Element-by-Element Index of Supporting Documents.

Section D is comprised of your HRPP's supporting documents. Provide one copy of each document cited in the Section C Element-by-Element index. If a document is cited for more than one Standard or Element, you will still only include one copy of the relevant document(s) in your application. Assign a reference number to each document.

SELECTING POLICIES AND PROCEDURES

AAHRPP uses the generic term "policies and procedures" to refer to many types of written materials that may describe and prescribe the activities an HRPP performs.

Policies and procedures include any written materials your organization uses to define and communicate its practices, such as standard operating procedures, policy statements, procedure descriptions, checklists, guidelines, educational materials, job descriptions, memoranda, forms, templates, strategic plans, screenshots of websites pages, charters, by-laws, mission statements, and other forms that are used to administer the HRPP. Policies and procedures are not limited to IRB/EC policies and procedures; other organizational procedures may be relevant, such as some policies related to financial disclosures, position descriptions, pharmacy, contracting, corporate compliance, or corporate ethics.

INCLUDE AMONG SUPPORTING DOCUMENTS:

- Application forms
- Reviewer checklists
- Informed consent templates
- Organizational chart for the HRPP
- Organizational chart for the overall organization
- Template letters (e.g., approvals, contingent approvals, disapprovals, lapse of approval)
- IRB/EC/HRPP manuals for investigators and research teams

DO NOT INCLUDE AS SUPPORTING DOCUMENTS:

- Budgets
- Employee manuals
- Faculty handbooks or by-laws
- Medical staff handbooks or by-laws
- Policies, procedures, and forms related to HIPAA
- Publicly available documents (e.g., Belmont Report, federal regulations, OHRP guidance)
- Resumes and curriculum vita
- Slide presentations
- Software manuals
- Websites or materials created by another organization
- Websites that duplicate documents provided in another form

For additional tips on conducting a self-assessment see: Part 1: Conduct a Self-Assessment (aahrpp.org)

Build and Develop an Application

OVERVIEW

Once you have completed your self-assessment, it is time to start putting together a formal Application for Accreditation or Reaccreditation. If you are unfamiliar with preparing PDF files, obtain software early in the process, become familiar with it, and allow at least one week to assemble the application. Please visit the Part 2: Build and Develop an Application section of our website for required application materials (described below) and detailed formatting instructions. Contact AAHRPP staff at reporting@aahrpp.org with questions.

There are two steps to the application process. Step 1 involves the initial submission of an Application for Accreditation or Reaccreditation to AAHRPP. An application reviewer (Step 1 reviewer) assesses the written materials to determine if they meet AAHRPP Standards and provides feedback about any revisions that may be required to allow the materials to meet AAHRPP Standards.

Once the Step 1 process is complete, the organization provides a final set of written materials (Step 2 Application) in preparation for a site visit.

PREPARE A STEP 1 APPLICATION FOR ACCREDITATION OR REACCREDITATION

Organizations must submit an Application for Accreditation or Reaccreditation (Step 1 Application) for AAHRPP to conduct a review of their written materials for its HRPP.

The Step 1 Application is comprised of the following:

ONE PDF FILE CONTAINING:

- Section A – Application for Accreditation or Reaccreditation
- Section B – Overview of the HRPP
- Section C – Element-by-Element Index to Supporting Documents
- Section D – Supporting Documents (e.g., HRPP policies and procedures)

ONE EXCEL SPREADSHEET CONTAINING:

- Section E – IRB/EC Roster(s)

An application reviewer (Step 1 reviewer) will review your application. Application reviewers are experienced AAHRPP representatives who currently work or have worked at accredited organizations. Following review, AAHRPP staff and the application reviewer will communicate any requested changes in the Application (Step 1) Review report and by email if needed. This report identifies any Standards and Elements that are not met and provides specific instructions on what is required to address the Standard or Element satisfactorily.

Once you receive the Application (Step 1) Review, you will work with the application reviewer to update your written materials so that all Standards and Elements are satisfactorily addressed in preparation for a site visit. You should include all revised materials in your Step 2 Application.

PREPARE A STEP 2 APPLICATION FOR ACCREDITATION OR REACCREDITATION

Once the application reviewer determines that the organization's policies and procedures are consistent with the Accreditation Standards, AAHRPP staff will reach out to request additional materials

relevant to a site visit (Step 2 Application) and will provide you with any needed additional instructions and guidance.

The Step 2 Application is comprised of the following (additional details on each section can be found below or on the AAHRPP website using the links provided for each section):

ONE PDF FILE CONTAINING:

- Section A – Application for Accreditation or Reaccreditation
- Section B – Overview of the HRPP
- Section C – Element-by-Element Index to the Supporting Documents
- Section D – Supporting Documents (e.g., HRPP policies and procedures)

ONE EXCEL SPREADSHEET CONTAINING:

- Section E – IRB/EC Roster(s)

ONE PDF FILE CONTAINING:

- Section F – Minutes, Government Correspondence, and Audits

ONE EXCEL SPREADSHEET CONTAINING:

- Section G – List of Active Studies including names of researchers

ONE WORD DOCUMENT CONTAINING:

- Section H – Key Personnel and Research Team List

Application Sections

SECTION A: APPLICATION FOR ACCREDITATION OR REACCREDITATION

Use the Application for Accreditation or Reaccreditation: Section A form and guidance to submit the application.

For the Step 2 Application, review the information in Section A provided with your Step 1 Application and update as needed or if changes were requested by AAHRPP. If no changes are needed or were requested, it is acceptable to resubmit the same Section A form you completed for Step 1.

SECTION B: OVERVIEW OF YOUR HUMAN RESEARCH PROTECTION PROGRAM

Maximum length: Seven pages. Please see a template with the list of sections to include on our website: Application for Accreditation or Reaccreditation: Section B – Overview of the HRPP Template

SECTION C: ELEMENT-BY-ELEMENT INDEX TO THE SUPPORTING DOCUMENTS

Section C is an Element-by-Element index to the supporting documents (to be provided in Section D) that allows AAHRPP staff, the application reviewer, and site visitors to locate information that supports your organization meeting each AAHRPP Standard and Element. The AAHRPP website includes a template you can use to create Section C (Element-by-Element Index of Supporting Documents.)

Generate Section C using the list of your organization's policies and procedures created during your self-assessment. Reference the document number, and provide a brief explanation of what the document is and how it meets the Standard or Element. Use combinations of page numbers, paragraph numbers, line numbers, item numbers, chapter titles, and section headings to pinpoint the supporting information.

For example, if you wish to point out information in your researcher manual that addresses financial conflicts of interest, provide the page numbers, section numbers, and section titles as appropriate, rather than referencing the researcher manual in its entirety.

As another example:

Element I.1.C. The organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.	• Board of Directors Policy "Research Involving Humans" (**Document 10, Section V on page 3**) grants the IRB authorities as required by the regulations, and outlines the IRB's independence. • IRB Policies and Procedures (**Document 15, page 10, Item XI, "Undue Influence of IRB members"**) describes what IRB members should do if they believe they are being coerced or unduly influenced. • Compliance Policy (**Document 14, 4th bullet on page 2**) identifies the Senior Vice President for Research as the individual with the responsibility to investigate allegations of coercion and undue influence and take corrective action.

Additional brief narratives to orient the application reviewer and site visitors may be included in Section C but are not required. AAHRPP does not consider procedural details described in Section C to be written policies and procedures.

You should not use more than one page for each Standard or Element, and you should not separate Standards and Elements by page breaks. While not required, if you have the capability

to create a hyperlink from the Element-by-Element index to the policy or procedure (or revised and new policies for a Step 2 application) in the PDF file, you may do so.

SECTION D: SUPPORTING DOCUMENTS

AAHRPP staff, application reviewers, and site visitors use the information from your organization's policies and procedures in Section D, along with observations made during the site visit, to conduct an evaluation of your organization's HRPP.

Section D is comprised of one copy of each supporting document ordered by a unique reference number. Include only one copy even when the document is used to support more than one Standard or Element. All supporting materials must be included in the application. Therefore, instead of including hyperlinks to external webpages or other materials, please include the actual documents (or screenshots of the webpage) in Section D.

You can find further details about formatting your PDF for Sections A-D, including bookmarking and pagination requirements, in AAHRPP's Instructions for Submitting Materials in Support of Accreditation.

SECTION E: IRB/EC ROSTER(S)

If your organization's HRPP includes one or more internal IRB/EC, include the roster for each IRB/EC; you may either list each IRB/EC in a separate worksheet within the Excel file or list the IRB(s)/EC(s) to which the member belongs in the first column of the spreadsheet. Assemble a list of IRB/EC members in a single Microsoft Excel file.

Format the spreadsheet with the following columns (you may also use AAHRPP's optional Section E Template):

- IRB/EC (include only if there is more than one IRB/EC)
    - Indicate the name/number of the IRB(s)/EC(s) to which the individual is a member.
- Name of IRB/EC member (separate columns for first name and last name)
- Earned degree(s)
- Scientific status (i.e., scientist or non-scientist)
- Representative capacity
    - Indicate the population(s) about which the member is knowledgeable or experienced in working with, such as children, pregnant women, prisoners, economically disadvantaged, educationally disadvantaged, cognitively impaired adults, or indigenous peoples.

- Indications of experience
    - Provide a description of all relevant experience that describes each member's chief anticipated contributions to IRB/EC deliberations, such as current/past professions, life experiences as a research participant or with vulnerable populations, research experience, IRB/EC experience, certifications and licensures, or other information as appropriate.
- Relationship of the IRB/EC member to the organization (e.g., current or former employee, consultant, board of directors, volunteer, trainee, or student)
    - If the organization has multiple entities, include both the relationship and the entity with which the member has a relationship (e.g., faculty of ABC University or medical staff of DEF Hospital.)
- Affiliation status
    - Indicate whether the IRB/EC member or any immediate family member is affiliated with the organization. (Note that an IRB/EC member may have no individual relationship with the organization, but may be affiliated because an immediate family member of the IRB/EC member has a relationship with the organization.)
- Office position on the IRB/EC (e.g., chair or vice chair)
- Membership status (e.g., member, alternate, or non-voting. If a member is *ex officio*, indicate whether the member is also a voting member)
- Alternate status (e.g., list the member(s) or class of members for whom the alternate member may substitute, or otherwise leave blank)

SECTION F: MINUTES AND CORRESPONDENCE

Section F consists of a single PDF file that contains the following:

- A recent set of minutes for each IRB/EC, if your organization has an internal IRB(s)/EC(s) or is an independent IRB/EC. If your organization has more than 3 internal IRB(s)/EC(s), please contact reporting@aahrpp.org to discuss the number of sets of minutes to provide.
- Any **negative** actions by a government oversight office and follow-up by your organization, such as restrictions placed on IRB(s)/EC(s) or researchers, or other compliance actions related to the oversight of human participants research. Include correspondence with relevant regulatory agencies. Negative actions by a government oversight office include, but are not limited to:
    - Compliance actions taken by non-US government authorities related to human research protections

- Compliance actions taken by US Federal government authorities related to human research protections, such as:
    - US Office for Human Research Protections (OHRP) Determination Letters
    - US Food and Drug Administration (FDA) Warning Letters
    - FDA 483 Inspection Reports

  Do not include government office or agency inspection reports with no findings or concerns.

  For organizations undergoing initial accreditation, these actions should be limited to those that occurred in the last year before submission of the Step 2 application.

  For organizations undergoing reaccreditation, these actions include:

  - those that have occurred since the last Annual Report to AAHRPP
  - any actions that were not resolved as of the last Annual Report to AAHRPP, and
  - any actions not previously reported to AAHRPP since the last reaccreditation.

  If your organization has not received any such communication from government offices during the period specified above, please note this in a separate, bookmarked page of your Section F PDF.

- A list of internal audits or reviews your organization conducted of research teams or IRBs/ECs in the past year. The list should include: the approximate date(s) of the audit, audit focus (e.g., research team informed consent documents, IRB/EC minutes), whether it was a routine or for-cause audit, and the results and/or actions taken. An optional template is available on AAHRPP's website: Application for Accreditation or Reaccreditation: Section F Minutes, Audits, and Government Correspondence

You can find further details about formatting your PDF for Section F, including bookmarking and pagination requirements, in AAHRPP's Instructions for Submitting Materials in Support of Accreditation.

SECTION G: LIST OF ACTIVE STUDIES

Section G consists of a list of active open studies in a single Microsoft Excel file. Format the spreadsheet with the following columns (you may also use AAHRPP's optional Section G template):

- Title
- IRB/EC tracking number (when used)
- IRB/EC name or number
- Name of researcher (or researcher code number)

- Degrees of researcher
- Date of initial approval
- Name of sponsor or funding entity (e.g., National Institutes of Health, Department of Defense, Environmental Protection Agency, American Diabetes Association, Greenwall Foundation, or General Motors Foundation)
- Type of initial review (i.e., full, expedited, or exempt)
    - For studies reviewed by an external IRB/EC, it is acceptable to simply write "external" if you are unsure of the type of initial review.
- Indicate whether the research is biomedical or social/behavioral/education research (SBER). Alternatively, if an IRB/EC reviews only a specific type of research (biomedical or SBER), you may indicate at the top of the list the type of research the IRB/EC reviews.

Include all active open studies reviewed under expedited procedures or by the convened IRB(s)/EC(s), regardless of whether they were internally or externally reviewed. Open studies are those studies that have not been reported as closed or complete to your IRB(s)/EC(s) or that your IRB(s)/EC(s) has not closed (e.g., due to lack of action on the part of a sponsor or study team, such as failure to submit a closure report). Include all exemption determinations made in the most recent year (i.e., the period from January 1 through December 31).

If your organization has multiple locations (e.g., different campuses or hospitals), add a column to the spreadsheet indicating at which of your organization's locations the study is conducted.

SECTION H: KEY PERSONNEL AND RESEARCH TEAMS

Please use the Section H form provided on AAHRPP's website to allow your organization to identify a) the appropriate individuals who are knowledgeable about the HRPP and the specific roles and functions that will be assessed through interviews during site visits; and b) researchers and research team members based on their roles, the type of studies they conduct, experience working with IRBs/ECs, and participants they enroll in studies.

For each category listed, provide the title and name of the individual or individuals who fulfill that role. Please follow the instructions listed at the beginning of the form.

Application Assembly and Submission

Please refer to the Instructions for Submitting Materials in Support of Accreditation on our website for detailed information on the assembly and formatting of an Application for Accreditation or Reaccreditation.

Contact AAHRPP staff at reporting@aahrpp.org if you have questions related to submitting an Application for Accreditation or Reaccreditation.

*****Please do not change your written materials between the submission of your Step 2 Application and the site visit. Contact AAHRPP staff if any written materials must change during this time.*****

Evaluation of Practice

Once you have submitted your Step 2 Application, AAHRPP staff will work with you to schedule your site visit.

Site Visit

You will receive information in preparation for the site visit, including a Draft Site Visit Agenda and list of Documents to Pull. Please see Documents to Pull Frequently Asked Questions (FAQs) on our website for additional guidance.

During the site visit, a team of AAHRPP peer reviewers will evaluate how your HRPP policies and procedures are operationalized at your organization through document review and interviews with HRPP key personnel and research teams.

Please see our website for further information about the site visit: Part 4: Evaluation of Practice.

Draft Site Visit Report

The site visit team will provide written feedback via a Draft Site Visit Report noting any Areas of Concern that need to be addressed by your organization in order to meet the Accreditation Standards. Your organization will have an opportunity to respond to the Observations and Areas of Concern (if applicable) presented in the Draft Site Visit Report.

Approximately 30 calendar days after the site visit, you will receive a copy of your Draft Site Visit Report. You will then have 30 calendar days to respond to any Areas of Concern noted in your Draft Site Visit Report. If there are no Areas of Concern noted in your Draft Site Visit Report, no additional action is required from your organization and the report will be reviewed by the Council on Accreditation to make a determination regarding accreditation/reaccreditation status.

Please see Instructions for Responding to the Draft Site Visit Report on AAHRPP's website for further information and materials to respond to your Draft Site Visit Report.

Council on Accreditation Review

AAHRPP staff, along with the site visit team leader, will review your response to the Draft Site Visit Report and prepare a preliminary version of the final report (known as the Final Site Visit Report) for the AAHRPP Council on Accreditation (Council) to review.

At one of its quarterly meetings, the Council will review the Application for Accreditation or Reaccreditation, Draft Site Visit Report, your response to the Draft Site Visit Report, and the written evaluation of your response in the preliminary Final Site Visit Report. The Council will then make a determination of accreditation status, and this decision is communicated to your organization in writing in the Final Site Visit Report.

For more details on the determinations regarding an organization's accreditation status the AAHRPP Council may make, please see: Part 5: Council on Accreditation Review and AAHRPP's Accreditation Procedures.

Response to Council Review

In some cases, the Council may determine that a Status Report or Improvement Plan is needed. Should the Council request a Status Report and/or an Improvement Plan, you will be alerted to this (along with submission due dates) in the Required Reporting section of your Final Site Visit Report.

Please see the guidance on AAHRPP's website about submitting Status Reports and Improvement Plans: Part 6: Response to Council Review. For more detailed information on Status Reports and Improvement Plans, you may also refer to AAHRPP's Accreditation Procedures.

Timeline for Accreditation and Reaccreditation

Please note that the time frames listed are ***approximate*** and will be unique to each organization.

Initial Accreditation	Reaccreditation
Organizations can submit an initial Application for Accreditation at **any time**.	Organizations are assigned to a Council cohort (March, June, September, or December).

<table>
<tr><td></td><td>All Applications for Reaccreditation are due on the following dates one year prior to your assigned Council review date:

<table><tr><th>Council Cohort:</th><th>Due Date:</th></tr><tr><td>March</td><td>March 15</td></tr><tr><td>June</td><td>June 15</td></tr><tr><td>September</td><td>September 15</td></tr><tr><td>December</td><td>December 15</td></tr></table></td></tr>
<tr><td>Within approximately 60 calendar days of receiving a complete Step 1 Application, AAHRPP will send a written Step 1 Review of Application Materials.</td><td>Within approximately 60 calendar days of receiving a complete Step 1 Application, AAHRPP will send a written Step 1 Review of Application Materials.</td></tr>
<tr><td>Organization responds in a separate email for each Standard and Element until all revisions are completed. This should begin as soon as the review is received and should ideally be completed within one year of receipt of the Step 1 Review of Application Materials.</td><td>Organization responds in a separate email for each Standard and Element until all revisions are completed. This should begin as soon as the review is received.
Organizations have 30 calendar days to respond to all Standards and Elements that require revision.</td></tr>
<tr><td>Once all revisions have been completed and approved by the Step 1 reviewer, AAHRPP staff sends instructions on submitting the Step 2 Application.
The Step 2 Application, which includes the revised policies and procedures, must then be submitted within 14 calendar days of AAHRPP requesting the submission.</td><td>Once all revisions have been completed and approved by the Step 1 reviewer, AAHRPP staff sends instructions on submitting the Step 2 Application.
The Step 2 Application, which includes the revised policies and procedures, must then be submitted within 14 calendar days of AAHRPP requesting the submission.</td></tr>
<tr><td>The site visit is scheduled to occur approximately 60-90 calendar days after receiving the Step 2 Application.</td><td>The site visit is scheduled after receiving the Step 2 Application.
See Accreditation Timeline table below for the deadline by which a site visit must occur to be reviewed at the assigned Council date.</td></tr>
<tr><td>AAHRPP will send a written Draft Site Visit Report approximately 30 calendar days after the site visit has ended.</td><td>AAHRPP will send a written Draft Site Visit Report approximately 30 calendar days after the site visit has ended.</td></tr>
</table>

<table>
<tr><th>Initial Accreditation</th><th>Reaccreditation</th></tr>
<tr><td>After receiving the Draft Site Visit Report, the organization has 30 calendar days to provide a written response to the report.</td><td>After receiving the Draft Site Visit Report, the organization has 30 calendar days to provide a written response to the report.</td></tr>
<tr><td>The Final Site Visit Report is prepared and reviewed by the Council on Accreditation.</td><td>The Final Site Visit Report is prepared and reviewed by the Council on Accreditation.</td></tr>
<tr><td>The Council on Accreditation may request a Status Report and/or an Improvement Plan from your organization.
Improvement Plans are due in approximately one month for review at the following Council meeting. Status Reports are due in approximately four months.

See table below for specific due dates:</td><td>The Council on Accreditation may request a Status Report and/or an Improvement Plan from your organization.
Improvement Plans are due in approximately one month for review at the following Council meeting. Status Reports are due in approximately four months.

See table below for specific due dates:</td></tr>
</table>

Council at Which SR or IP Requested:	Improvement Plan Due:	Status Report Due:
March	May 1	August 1
June	August 1	November 1
September	November 1	February 1
December	February 1	May 1

REACCREDITATION TIMELINE BY ASSIGNED COUNCIL DATE:

The reaccreditation process lasts one year; thus, the Council dates in the chart below will occur one year ***after*** the year the Step 1 Application is due.

> Example: An organization whose Step 1 Application is due in **March 2025** would be reviewed at the **March 2026** Council on Accreditation meeting.

Below are the last possible dates by which each step of the reaccreditation process must be completed in order for an organization to remain on track for their scheduled Council on Accreditation meeting.:

March	June	September	December	Last Day to Complete Event / Task
15-Mar	**15-Jun**	**15-Sep**	**15-Dec**	**Step 1 Application Due**
26-May	26-Aug	26-Nov	25-Feb	Step 1 Review Sent to Organization
25-Jun	25-Sep	26-Dec	27-Mar	Step 1 Response Due from Organization
3-Aug	3-Nov	3-Feb	5-May	Step 2 Submission Due from Organization

28-Sep	29-Dec	31-Mar	30-Jun	Earliest Potential Day for a Site Visit*
31-Oct	**31-Jan**	**3-May**	**2-Aug**	**Last Day to Complete a Site Visit**
7-Dec	9-Mar	9-Jun	8-Sep	Draft Site Visit Report (DSVR) Sent to Organization
6-Jan	8-Apr	9-Jul	8-Oct	DSVR Response Due from Organization
15-Mar	**15-Jun**	**15-Sep**	**15-Dec**	**COUNCIL ON ACCREDITATION MEETING***

- *Approximate date
- Application and Response due dates for organizations that fall on weekends or US holidays will be delayed until the next business day.