**Introduction:** The Health Resources and Services Administration (HRSA) conducts site visits to assess awardee capability, performance, and compliance against the applicable statutory and regulatory programmatic requirements. Within HRSA's Bureau of Primary Health Care (BPHC), Operational Site Visits (OSVs) and Federal Tort Claims Act (FTCA) Site Visits are used to verify compliance for health centers. The information below outlines and contrasts high level thematic topics for FTCA Site Visits and OSVs. The purpose of this document is to assist health centers in preparing for HRSA conducted site visits by highlighting the differences between the two types of assessments.

**Operational Site Visits**: OSVs support BPHC's effective oversight of the Health Center Program. The most common type of site visit is an OSV, which provides an objective assessment and verification of the status of each Health Center Program awardee's compliance as outlined in the <u>Health Center</u> <u>Program Compliance Manual</u>.

**FTCA Site Visits:** FTCA site visits are conducted for health centers who have been FTCA deemed for the purposes of medical malpractice liability coverage. FTCA site visits are conducted to ensure programmatic compliance with FTCA statutory requirements found in <u>42 U.S.C. 233</u> sections (g) and (h), with respect to credentialing and privileging, risk management, claims management, and quality improvement/quality assurance (QI/QA), the FTCA Health Center Policy Manual, and the <u>Health Center Program Compliance Manual</u> Chapter 5 (Clinical Staffing), Chapter 10 (Quality Improvement/Assurance), and Chapter 21 (FTCA Deeming Requirements). Factors that may prompt a site visit include, but are not limited to: 1. Submission of an initial deeming application; 2. Documentation submitted that indicates possible non-compliance with deeming requirements during the review of the health center's FTCA application; 3. The need for follow-up based on prior site visit findings or other identified issues; 4. History of repeated conditions or current conditions placed by HRSA on the health center's Health Center Program grant, as documented on the health center's associated Notice of Award and/or through enforcement action; and/or 5. History of medical malpractice claims.

	Thematic Topics	Operational Site Visits	FTCA Site Visits	Similarities and Differences
Authority	Authority: Statutory and or Regulatory Requirements	<u>45 CFR 75</u> .342 and 75.364.	42 U.S.C. 233 sections (g) and (h), and 42 CFR part 6. Also, 42 U.S.C. 233(q).	
Pre- Site Visit	Health Center Notification	Health Center CEOs/Executive Directors may be notified at least 6-8 weeks in advance via standard email notification.	Health Center CEOs/Executive Directors may be notified at least 6-8 weeks in advance via standard email notification.	

	Thematic Topics	Operational Site Visits	FTCA Site Visits	Similarities and
				Differences
Pre-Site Visit, cont.	Site Visit Occurrence	HRSA conducts operational site visits for health centers at least once per period of performance. For health centers with a 1-year period of performance, the operational site visit generally takes place 2–4 months into the new period of performance. For health centers with a 3-year period of performance, the operational site visit takes place approximately 14–18 months into the new period of performance. However, HRSA may adjust the 14–18 month time period due to extenuating circumstances.	HRSA conducts FTCA Site Visits based on factors assessed each calendar year. FTCA site visits typically occur between the months of May and October but may be conducted at any time throughout the calendar year.	
	Site Visit Resources	CEOs/Executive Directors, other key management staff, and Board of Directors have access to relevant resources on the <u>BPHC Site Visit Resources webpage</u> to prepare for the site visit, including but not limited to scope of project pre-assessment tools, and the Site Visit Protocol outlining questions per chapter.	CEOs/Executive Directors, other key management staff, and board of directors have access to a range of targeted FTCA site visit resources and tools to prepare for a site visit. These tools are located on BPHC's webpage, under <u>FTCA Site Visit</u> protocol. Resources include a site visit training presentation, sample program forms, such as a document review checklist, sample agenda, sample site visit report, and other resources.	
	In-person or Virtual Site Visits	Health Center Operational Site Visits may be conducted in person, <u>virtually</u> , or in a hybrid format.	FTCA Site visits may be conducted in person, virtually, or in a hybrid format. Please review the supplement to the FTCA Health Center Program Site Visit Protocol: <u>Guidelines and Logistics for Virtual FTCA</u> <u>Site Visits</u> .	÷

	Thematic Topics	notes a Significant Difference; <u>Squares</u> connotes topics th Operational Site Visits	FTCA Site Visits	Similarities
				and
				Differences
	Pre-Site Visit call	Pre-OSV calls are co-scheduled by the designated	FTCA pre-site visit calls are co-scheduled by	
		HRSA staff and the consultant team lead. Pre-site visit	the designated HRSA staff and the	
		calls occur with Health Center key staff prior to the	consultant team lead. Pre-site visit calls	
		start of the site visit. Areas discussed include the site	occur with health center key staff prior to	
		visit purpose, expectations, logistics, required	the entrance conference. Areas discussed	
		documentation, access to the online portal to submit	include the site visit purpose, expectations,	
		documentation, site visit resources, and the timeline	logistics, required documentation, access	
I		for submissions of required documents.	to the online portal to submit	
1			documentation, site visit resources, and the	+
nt.		These calls occur approximately 4 weeks prior to the	timeline for submissions of required	
Pre-Site Visit, cont.		start of the site visit.	documents.	
isit,				
		(Please Note: If the health center would like the	These calls occur approximately 4 weeks	
Site		Primary Care Association to attend the pre-site visit	prior to the start of the FTCA site visit.	
re-		call, the health center is responsible for providing the		
д		PCA with the agenda and dial-in information.)		
	Role of Consultant	The OSV consultants will use their expertise, special	FTCA consultants will use their expertise,	
		knowledge, and training to assist BPHC in assessing	special knowledge, and training to assist	
		the health center's compliance with Health Center	BPHC in assessing the health center's	
		Program requirements and provide technical	compliance with, the Federal Tort Claims	
		Assistance as needed. They will record site visit	Act (FTCA) Health Center Policy Manual,	
		findings in the EHBs Structured Technical Assistance	the FTCA Health Center Deeming Program	
		Report (STAR) module.	Assistance Letter (PAL) for Deeming	
			Requirements, and requirements in the	
			following chapters of the Health Center	
			Program Compliance Manual:	
			Chapter 5: Clinical Staffing;	
			Chapter 10: Quality	
			Improvement/Assurance; and	
			Chapter 21: Federal Tort Claims Act	
			(FTCA) Deeming Requirements.	

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	Number of Site Visit Consultants	3 Consultants (Administrative, Clinical, and Fiscal).	2 Consultants (Clinical and Risk Management).	+
Pre-Site Visit, cont.	Allotted days required for Site Visit	Generally, between 1-3 business days.	Generally, 3 business days.	
	Days of the Week to conduct the Site Visit (SV)	Tuesdays through Thursdays are the three most frequently selected days of the week to conduct the site visit.	Tuesdays through Thursdays are the three most frequently selected days of the week to conduct the site visit.	
	HRSA Representative Opening Remarks	During the entrance conference, the HRSA Representative will provide an overview of the purpose of the site visit and may provide any relevant Health Center Program updates.	During the entrance conference, the HRSA Representative will provide an overview of the site visit and may provide any relevant FTCA updates.	÷
During the Site Visit	Health Center Opening Remarks	For the entrance conference, Health Center staff are encouraged to have prepared opening remarks (for example, a power point presentation or another format of their choosing) to provide high-level background details on the health center goals, patient population, services, sites, staffing, etc.	For the entrance conference, Health Center staff are encouraged to have prepared opening remarks (for example, a power point presentation or another format of their choosing) to provide a high-level overview of the health center. Presentation is limited to 10 minutes.	÷

	Thematic Topics	Operational Site Visits	FTCA Site Visits	Similarities and Differences
During the Site Visit, cont.	Site Visit (SV) Structure	Site visits will be conducted utilizing standardized questions, methods, and resources as outlined in the Health Center Program <u>Site Visit Protocol (SVP)</u> . HRSA designed the Site Visit Protocol (SVP) to gather necessary information to perform its oversight responsibilities. The SVP includes standard and transparent methodologies that support and align with the <u>Health Center Program Compliance Manual</u> .	The FTCA <u>Document Review Checklist</u> contains documents used to assess compliance with FTCA program requirements during the FTCA site visit. The <u>FTCA Health Center Site Visit Protocol</u> is an available reference for the on-site assessment. An FTCA site visit is composed of interviews, demonstrations, walk- throughs, policy reviews and confirmation	
	Compliance Areas Reviewed	Chapter 3 (Needs Assessment) through Chapter 21 (FTCA Deeming Requirements, if applicable) of the <u>Health Center Program Compliance Manual</u> .	of policy implementation. The FTCA Health Center Policy Manual, the FTCA Health Center Deeming Program Assistance Letter, and Chapters 5 (Clinical Staffing), 10 (Quality Improvement/Assurance) and 21 (FTCA Deeming Requirements) of the <u>Health</u> <u>Center Program Compliance Manual</u> . The areas of focus include Risk Management, Quality Improvement/Assurance, Credentialing and Privileging, Claims Management, and related patient safety activities.	•
	Entrance and Exit Conferences; CEO Debriefings	An entrance conference meeting will occur at the start of each site visit, coupled with end-of-the-day debriefs with the CEO, if applicable. The exit conference to review site visit findings occurs on the end of the site visit.	An entrance conference meeting will occur at the start of each site visit, coupled with end-of-the-day debriefs with the CEO. The exit conference to review site visit findings occurs on the last day of the visit.	

	Thematic Topics	notes a Significant Difference; <u>Squares</u> connotes topics th Operational Site Visits	FTCA Site Visits	Similarities and Differences
During the Site Visit, cont.	Tour Health Center Site(s)	Tours are generally conducted on day one. Designees selected by the health center will conduct an in- person or a live virtual tour of the service site (or, if the health center has multiple service sites, at least two service sites) for the site visit team. For virtual tours, the health center may use video-conferencing software and the health center's equipment (for example, phone, tablet, computer camera).	Tours are generally conducted on day one. Designees selected by the health center will conduct an in-person or a live virtual tour of at least one service site for the site visit team. For virtual tours, the health center may use video-conferencing software and the health center's equipment (for example, phone, tablet, computer camera).	
	Board of Directors Meeting and Participation	A Board of Directors (BOD) meeting will occur, generally on the second day of the site visit. These meetings are held without health center staff. BOD members also are encouraged to participate in the entrance and exit conferences.	A board of directors (BOD) meeting will occur, generally on the second day of the site visit. These meetings are held without health center staff. BOD members also are encouraged to participate in the entrance and exit conferences.	
	Site Visit Exit Conference	The operational site visit concludes on the last day with an exit conference. The site visit consultant team will summarize general findings from all aspects reviewed (e.g., Program Requirement Compliance Analysis, Promising Practices, and FTCA Deeming Requirements) with the health center staff and board members. Please see the Operational Site Visit (OSV) <u>Exit</u> <u>Conference Tracking Resource</u> , which may be used by consultants, the health center staff, board members and the HRSA Representative to track preliminary recommendations and site visit findings during the exit conference.	During the exit conference, the site team will provide preliminary findings during the exit conference. The FTCA <u>Document Review Checklist</u> contains the documents used to assess compliance with FTCA program requirements during the site visit. This checklist is used as a guide at the exit conference.	

	Thematic Topics	notes a Significant Difference; <u>Squares</u> connotes topics the <b>Operational Site Visits</b>	FTCA Site Visits	Similarities and Differences
Post- Site Visit	Site Visit Report Timeline and Performance Improvement	<ul> <li>Following the OSV, the health centers have an opportunity to address, as applicable, any preliminary compliance findings with the Correspondence</li> <li>Request Opportunity (CRO) before the report is finalized. Within 45 days from the end of the site visit, a final standardized report will be issued via the electronic handbook (EHB) to the Chief Executive Officer (CEO)/Program Director (PD).</li> <li>OSV consultants may provide verbal information regarding performance improvement during the site visit, but performance improvement details are not part of the final written site visit report.</li> <li>The report will include findings of non-compliance, if any.</li> </ul>	Following the FTCA site visit, the final report will be issued, typically within 4-6 weeks from the end of the site visit. The report will include findings of non- compliance, if any. The health center Chief Executive Officer (CEO)/Program Director (PD) will be notified via the EHBs and an action plan to demonstrate compliance will be provided. The health center should respond to the action plan, if applicable, by the due date in the EHBs.	
	Conditions on the Health Center's Notice of Award	The health center's designated staff (for example, CEO/PD) should thoroughly review the health center's site visit report and the Health Center Program Compliance Manual to understand any findings indicating that the health center did not demonstrate compliance. For all areas of non-compliance indicated in the final site visit report, HRSA will issue a corresponding condition to the health center through a Notice of Award. For more information and a full list of conditions, refer to the <u>Progressive Action Conditions</u> <u>Library</u> .	FTCA does not place conditions on health center awards. Findings of non-compliance may impact future FTCA deeming status. Findings may be shared with other programmatic monitoring offices which may result in corresponding condition(s) to the health center through a Notice of Award (NoA).	

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				and Differences
	Conditions on the Health Center's Notice of Award, cont.	(Please Note: In circumstances where the site visit report contains <u>FTCA risk and claims management</u> <u>findings that require follow-up</u> , the FTCA Program may share a Corrective Action Plan (CAP) with the health center. The health center is expected to respond to the CAP and address findings before the next FTCA deeming cycle.)		
Post- Site Visit, cont.	Point of Contact Prior to and Post the Final Site Visit Report	Between the pre-site visit call and the issuance of the site visit report, contact the HRSA Representative for site visit-related questions. Once the site visit report is sent to the health center, use the <u>BPHC Contact Form</u> to address any related questions. Additional information can be found on the <u>Health</u> <u>Center Program Compliance FAQs webpage</u> .	For questions that may arise prior to and after the FTCA site visit, health center staff may email <u>BPHCFTCASiteVisit@hrsa.gov</u> .	
	Technical Assistance (TA)	Health center staff may request technical assistance from the site visit team on various topic areas to help optimize health center operations. However, the information shared will not be recorded as part of the site visit report. It is important to note that the primary purpose of the OSV is to assess and verify compliance relative to Chapters 3 (Needs Assessment) through Chapter 21 (FTCA Deeming Requirements) of the <u>Health Center Program Compliance Manual</u> .	Technical Assistance may be provided throughout the site visit to health center staff. However, it is important to note that the primary purpose of the FTCA site visit is to assess and verify compliance with FTCA programmatic requirements.	÷
		(Please Note: TA may also be requested any time during the calendar year by submitting details using the <u>BPHC Contact Form</u> .)	(Please Note: TA may also be requested any time during the calendar year by submitting details using the <u>BPHC Contact Form</u> .)	