THE PRIVACY, CONFIDENTIALITY AND SECURITY ASSESSMENT TOOL: WORKBOOK



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Foreword

With the scale-up of HIV and other health services in low- and middle-income countries, an increasing amount of personally identifiable health information is being collected at health facilities and in data repositories at regional and national levels. Countries need to protect the confidentiality and security of identifiable and de-identified personal health information, and this can be accomplished in part through the existence and implementation of relevant privacy laws.

An UNAIDS and PEPFAR workshop with multi-stakeholder input that was held in Geneva in 2006 led to the development of country guidelines to protect the confidentiality and security of HIV-information. These Guidelines on protecting the confidentiality and security of HIV information (Interim guidelines) can be used by countries to adapt, adopt and implement their own guidelines.¹

In 2008, 96 low- and middle-income countries were surveyed to determine whether or not they had developed and implemented their own guidelines. Very few countries had developed comprehensive guidelines on protecting the confidentiality and security of HIV information.²

Based on the *Interim guidelines*, an Assessment Tool was drafted in 2011 to help national stakeholders assess the existence and implementation of national country policies on protecting the confidentiality and security of personal health information collected and held at the facility and data warehouse levels.

This draft was reviewed at a workshop of health-care professionals and community members in Lusaka, Zambia, in 2012. The suggestions were compared and combined with existing data security and confidentiality guidelines and in June 2014, a penultimate version of the Assessment Tool was produced. This draft was field tested in Kingston, Jamaica, in September 2014. The feedback resulted in the production of the UNAIDS/PEPFAR privacy, confidentiality and security Assessment Tool protecting personal health information³, which provides guidance for countries to facilitate the assessment of the security of the collection, storage and use of data in order to maintain privacy, confidentiality and security.

For those unfamiliar with the use of this Assessment Tool and its three modules, the UNAIDS/PEPFAR privacy, confidentiality and security Assessment Tool: user manual (user manual) has been produced. This User Manual^{4,5} provides guidance for health professionals who want to use the Assessment Tool to gather the information required to assess the extent to which the confidentiality and security of identifiable and de-identified personal health information are protected. This publication is a workbook that relevant professionals can download and perform their assessment with. For those unfamiliar how to use the Tool, please refer to the Privacy, confidentiality and security assessment tool: user manual. 4,5

¹ UNAIDS/PEPFAR Guidelines on protecting the confidentiality and security of HIV information. Geneva: UNAIDS; 2007 (http://www.unaids.org/en/resources/documents/2016/confidentiality_security_assessment_tool).

² Beck EJ, Mandalia S, Harling G, Santas X, Mosure D, Delay P. Protecting HIV-Information in Countries Scaling Up HIV Services, Journal of the International AIDS Society 2011, 14:6. http://www.biomedcentral.com/content/pdf/1758-2652-14-6.pdf

³ UNAIDS/PEPFAR privacy, confidentiality and security Assessment Tool: protecting personal health information. Geneva. UNAIDS; 2016 (http://www.unaids.org/en/resources/documents/2016/confidentiality_security_assessment_tool).

⁴ The Privacy, confidentiality and security assessment tool user manual (http://www.unaids.org/en/resources/documents/2016/confidentiality_security_tool_user_manual).

⁵ Privacy, confidentiality and security assessment tool: a user manual (http://onusidalac.org/1/images/2016/user-manual. pdf).

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Acronyms

AIDS acquired immunodeficiency syndrome

ART antiretroviral therapy
ARV antiretroviral medicine

CDC Centers for Disease Control and Prevention

CSO confidentiality and security officer

ePAS Electronic Patient Administration System

HIV human immunodeficiency virus IRB institutional review board

MOH Ministry Of Health

NCHHSTP National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

NGO nongovernment organizations

PEPFAR President's Emergency Plan For AIDS Relief

UNAIDS The Joint United Nations Programme on HIV/AIDS

Concepts relevant to the protection of data

Three interrelated concepts affect the protection of data: privacy, confidentiality and security.

- Privacy is both a legal and an ethical concept. The legal concept refers to the legal protection that has been accorded to an individual to control both access to and use of personal information. Privacy provides the overall framework within which both confidentiality and security are implemented. Privacy protections vary between jurisdictions and are defined by law and regulations.
- Confidentiality relates to the right of individuals to the protection of their data during its storage, transfer and use in order to prevent unauthorized disclosure of that information. Confidentiality policies and procedures should include discussion of the appropriate use and dissemination of health data, with systematic consideration of ethical and legal issues (as defined by privacy laws and regulations).
- Security is a collection of technical
 approaches that address issues covering
 physical, electronic and procedural
 protection for information collected.
 Security discussions should include
 identification of potential threats to systems
 and data, and they must address both the
 protection of data from inadvertent or
 malicious inappropriate disclosure and the
 non-availability of data due to system failure
 and user errors.

While all data have confidentiality and security requirements, there are important differences

in terms of their sensitivity and the potential impact if confidentiality is breached. Five main types of information exist.

- Personally identifiable health information is individual-level information that includes personal identifiers (such as names and addresses) that are generally obtained at the point of service delivery. This also includes national identification numbers, such as social security numbers in the United States of America.
- 2. Pseudo-anonymized or de-identified health information is individual-level information that has been stripped of certain identifiers (such as names and addresses). In many cases, the identifying information has been replaced with a randomized identifier or key value that can be used (if necessary) to link it with a person's record that is being maintained at a service facility.
- Anonymized or non-identified health information is information that has been stripped of all identifiers. Since no keys are kept, these data can no longer be linked to the person's record that is being maintained at a service facility.
- 4. Aggregated health information are data based on aggregating individual-level information into an indicator. They may be obtained from communities, health facilities or data warehouses. These data are usually managed at the level of regional or national databases and also are collected by many international organizations.
- Non-personal health information is information on facilities, geographic data, information on drugs and drug supplies, and other logistics.

1.0 Aim of the Assessment Tool

This Assessment Tool comprises three modules that provide health-care professionals with a set of standardized questions that will enable them to gather country-based information to assess whether the privacy, confidentiality and security of personal health information are protected throughout the service delivery and data management settings in a particular country.

These three modules in this tool are as follows:

- Facility-level Assessment Tool
- 2. Data warehouse-level Assessment Tool
- 3. Policy-level Assessment Tool.

2.0 Main points: how to use the Assessment Tool

A detailed User Manual on how to apply the Assessment Tool and its three modules has been prepared. The Assessment Tool and the User Manual complement one another, and those unfamiliar with the Assessment Tool should consult the User Manual.

This section of the Assessment Tool provides a brief description of the content of the modules and a summary of how the assessment should be applied at the health facility, data warehouse and policy levels, respectively. For more detailed guidance, please consult the User Manual.

Each of the three modules contains a set of questions under the following major headings:

Governance and policy

Data collection (not included at the policy level)

Data storage

Data backup (not included at the policy level)

Authorization and access control Data release Transmission security

Data disposal

These headings, in turn, have a number of subheadings and relevant questions, as can be seen in the following example of **Governance** and policy:

1. Governance and policy

- 1.1 Policy
- 1.2 Governance structure
- 1.3 Review of security practices
- 1.4 Responsibilities and training
- 1.5 Monitoring, detecting and responding to security breaches
- 1.6 Conducting risk assessments
- 1.7 Connectivity to other networks

Box 1 Checklist for administering the Assessment Tool

- The Ministry of Health—specifically the office of the Permanent Secretary of Health—should lead and coordinate this initiative, and it could be co-managed by the Director of Health Informatics.
- A steering committee must be created with membership from Ministry of Health and key stakeholders (including other government ministries, donors and members of civil society).
- A terms of reference and a selection process must be developed for the selection of an external professional (the Assessor) to conduct the assessment.
- A work plan needs to be developed based on discussions between members
 of the steering committee. The work plan outlines the process for administering
 the Assessment Tool and lists relevant members of the Ministry of Health, other
 government officials, health and legal professionals, and members of civil society
 who will participate in the process.
- An entry meeting provides the launching point to start the assessment and an opportunity to agree on the process and the logistics of administering the Assessment Tool. The Permanent Secretary needs to send out an invitation letter to entry meeting participants.
- The entry meeting should be led by the Director of Health Informatics, along with members of the Records Department of the Ministry of Health. The Assessor and the Ministry of Health present the draft work plan.
- Prior to each site visit, the Records Department of the Ministry of Health must designate a meeting coordinator at each site. The meeting coordinator should identify and contact those who should be present at the meeting and brief them on the reason for the meeting.
- At the onset of the meeting at each site, hard copies of the Assessment Tool need to be distributed to the participants. The Ministry of Health or the Assessor shall introduce the reason for the meeting and describe the Assessment Tool to the participants.
- Data collection uses the paper-based or electronic version of the Assessment Tool.
- Following the completion of the assessment process at all levels, an exit meeting should be held where the results of the assessment are presented to a wider audience (including members of civil society). The results should then be discussed with this broader group of stakeholders.
- The Assessor and member of the Ministry of Health review the results of the assessment, incorporating issues raised through the feedback process and developing a report based on the findings. This report will inform the way forward in terms of developing and implementing guidelines for protecting the confidentiality and security of personal health information.

3.0 The Privacy, Confidentiality and Security Assessment Tool

3.1 Facility-level Assessment Tool and questions

The following facility-level questions are set to determine the security, confidentiality and appropriate use (including sharing) of data collected by health programs at the primary, secondary and tertiary levels.

The questions are grouped into eight sections:

- 1. Governance and policy
- 2. Data collection
- 3. Data storage
- 4. Data backup
- 5. Authorization and access control
- 6. Data release
- 7. Transmission security
- 8. Data disposal.

A brief purpose statement introduces each section, followed by a set of questions.

	RECOMMENDED FACILITY-LEVEL QUESTIONS	
Category	Question	Instruction

1. GOVERNANCE AND POLICY

1.1 Policy

Purpose: to determine the existence, accessibility, distribution, development and review of a written policy document that ensures the confidentiality and security of personally identifiable health data.

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1	Do you have clearly defined roles and access levels for all persons with authorized access to personally identifiable data? 1. Yes 2. No	
2	Do you have clearly defined standard procedures or methods that must be followed when accessing personally identifiable data? 1. Yes 2. No	
3	Does a written policy document regarding the requirements for ensuring the confidentiality and security of personally identifiable health data exist in this facility (referred to as the "Data Confidentiality and Security Policy" or "the Policy")? 1. Yes (if written documentation is determined to exist, identify the appropriate staff to answer this module) 2. No, but a policy is in the process of development 3. No, but various informal policies exist 4. No, we do not have any policy or written guidelines	IF "2," "3" OR "4," GO TO QUESTION 6.
4	Is the Data Confidentiality and Security Policy readily accessible to all staff members in this facility who have access to confidential, individual-level data? (By "readily accessible," we mean that staff can easily access the policy online or in hard copy while at work.) 1. Yes 2. No	
5	To which stakeholders and organizations is the Data Confidentiality and Security Policy document distributed? (Please select all that apply.) 1. All staff with access to medical records or confidential health program information 2. Staff who request it 3. Medical practitioners 4. Nursing practitioners 5. Public health specialists 6. Health-care volunteers 7. Other health professionals 8. Information technology staff (including data entry staff, analysts, managers and programmers) 9. Administrative staff 10. Cleaners, security guards and other providers of support services 11. Policy document is not distributed 12. Health records staff 99. Other (please specify):	

	In which of the following formats is the Data Confidentiality and Security Policy document available to staff for reference? (Please select all that apply.)	
6	Printed hard copies Electronic, distributed via e-mail	
	3. Electronic, distributed via CD or other media4. Electronic, available on the Internet (please specify the	
	URL): 99. Other (please specify):	

1.2 Governance structure

Purpose: to determine the governance structure that is in place to provide oversight for the appropriate collection, use and dissemination of data, including regular review of the policy document and security practices.

7	Is there a local governance structure (e.g. steering committee/ advisory board) in place to provide oversight for the appropriate collection, use and dissemination of data, including regular review of the policy document and security practices? 1. Yes 2. No 99. Other (please specify):	IF "2," GO TO QUESTION 9.
8	How often does the steering committee or advisory board meet? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years 6. No regular meeting schedule	
9	Which uses of personally identifiable information are covered by your local guidelines on the security and confidentiality of data? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Not specified 99. Other (please specify):	
10	Is information security and its management reviewed at regular intervals? 1. Yes 2. No	

1.3 Review of security practices

Purpose: to determine the security practice and review as documented in the Policy.

11	Are security practices reviewed by independent auditors? 1. Yes 2. No	IF "2," GO TO QUESTION 13.
12	How often do independent auditors review security practices? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Not specified 99. Other (please specify):	

1.4 Responsibilities and training Purpose: to determine the security practice and review as documented in the Policy.

	Policy.	
13	Are staff explicitly informed of their individual responsibilities for protecting the systems (paper-based or electronic) that are used to access and utilize personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 15
14	How are staff informed of their individual responsibilities for protecting the systems (paper-based or electronic) that are used to access and utilize personally identifiable health data? (Please select all that apply.) 1. Policy documents distributed to staff 2. Informal on-the-job training received by staff 3. Formal training received by staff 99. Other (please specify):	
15	Do policies state that staff are personally responsible for protecting paper records, computer workstations, laptop computers or other devices associated with confidential public health information or data? 1. Yes 2. No	
16	Are all persons authorized to access personally identifiable health data trained on the organization's information security policies and procedures? 1. Yes 2. No	IF "2," GO TO QUESTION 20
17	How often must staff repeat the training on confidentiality and security measures? 1. Every year 2. Every 1–2 years 3. Every 2+ years 99. Other (please specify):	
18	Which of the following is the format of the training on confidentiality and security measures? (Please select all that apply.) 1. Material read by staff from printed document 2. Material read by staff on a website 3. Instructor-led web training at scheduled intervals 4. Instructor-led training in a classroom setting 5. One-on-one training with another staff member (peer-led model) 99. Other (please specify):	
19	Is the date of the training or test documented in the employee's personnel file? 1. Yes 2. No	
20	Do all newly hired staff members sign a confidentiality agreement before they are given authorization to access personally identifiable health data? 1. Yes 2. No	

21	Which of the following authorized staff members in your program sign a confidentiality agreement? (Please select all that apply.) 1. All staff with access to medical records or confidential health program information 2. Medical practitioners 3. Nursing practitioners 4. Public health specialists 5. Health-care volunteers 6. Other health professionals 7. Information technology staff (including data entry staff, analysts, managers and programmers) 8. Administrative staff 9. Professional service providers 10. Cleaners, security guards and other providers of support services 11. Staff are not required to sign an agreement 99. Other (please specify):	IF "11," GO TO QUESTION 24
22	Do staff have to repeat the review and signing of the confidentiality statement indicating they understand the policies and agree to implement them? 1. Yes 2. No	IF "2," GO TO QUESTION 24
23	How often must staff repeat the review and signing of the confidentiality statement indicating they understand the policies and agree to implement them? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Never 99. Other (please specify):	
24	Are staff explicitly informed of the possible consequences of failing to properly protect personally identifiable health data? 1. Yes 2. No	
25	Depending on the severity of the breach, which of the following are possible consequences for members of staff who fail to protect personally identifiable health data? (Please select all that apply.) 1. Education or counselling to prevent repeat minor breaches 2. Reduction or loss of security clearance 3. Reduction or loss of data access privileges 4. Demotion 5. Suspension 6. Dismissal/termination of employment 7. Civil legal action 8. Criminal legal action 9. Not specified 99. Other (please specify):	IF "9," GO TO QUESTION 28

26	How are staff informed of the possible consequences of failing to protect personally identifiable health data? (Please select all that apply.) 1. Policy documents distributed to staff 2. Informal on-the-job training received by staff 3. Formal training received by staff 4. Confidentiality statement signed by staff 99. Other (please specify):	
27	When a staff member's employment is terminated, when are data access privileges revoked? 1. Immediately upon termination 2. Within a specified period of time after termination (e.g. 30 days) 3. Not automatically revoked 99. Other (please specify):	
28	Is it a requirement that the Data Confidentiality and Security Policy is shared with patients in facilities that are collecting personally identifiable data? 1. Yes 2. No	IF "2," GO TO QUESTION 30.
29	How is the Data Confidentiality and Security Policy shared with patients? 1. Available on website, but not explicitly shared 2. Provided only upon request 3. Provided to all patients as a hard copy or a link to the website as a matter of practice 4. Provided only verbally to patients 99. Other (please specify):	
30	Is there a designated information security manager at the facility? 1. Yes 2. No	IF "2," GO TO QUESTION 33
31	Is there a written description of the information security manager's responsibilities? 1. Yes 2. No	IF "2," GO TO QUESTION 33
	Which of the following tasks are part of the information security manager's responsibilities? (Please select all that apply.) 1. Identify and review all applicable guidelines 2. Advocate for the resources needed for information confidentiality and security 3. Ensure that information confidentiality and security goals are identified, that they meet organizational requirements, and that they are initiated and integrated into relevant processes 4. Improve confidentiality and security awareness by initiating appropriate plans and programs 5. Test, review and validate the effectiveness of the implementation of the information confidentiality and security policy 6. Provide clear direction and visible management support for confidentiality and security initiatives 7. Approve assignment of specific roles and responsibilities for information confidentiality and security across the organization 8. All of the above 99. Other (please specify):	

1.5	1.5 Monitoring, detecting and responding to security breaches			
	to identify and manage security breaches as documented in			
33	Do written guidelines exist for managing security breaches for both electronic and paper-based systems? 1. Yes 2. No	IF "2," GO TO QUESTION 35.		
34	Which of the following procedures for responding to security breaches for both electronic and paper-based systems are included in written procedures? (Please elect all that apply.) 1. Roles and responsibilities of staff for managing security breaches 2. Preparing to handle security breaches by rehearsing potential responses 3. Detecting security breaches when they occur and determining the type of incident and appropriate response 4. Analyzing available information related to the security breach to determine the type of incident and the appropriate response 5. Prioritizing the response to the security breach based on criticality of the affected resources (including notifying appropriate individuals) 6. Containing the security breach (e.g. shutting down a system, disconnecting it from a wired or wireless network, disconnecting its modem cable or disabling certain functions) 7. Eradicating the security breach and removing the effects of the cause (such as disabling compromised user accounts) 8. Recovering from the security breach and restoring systems to normal operations 9. Acquiring, preserving, securing and documenting evidence related to the security breach 10. Creating additional security checks to prevent similar security breaches 99. Other (please specify):			
35	Are electronic systems monitored to detect potential or actual security breaches? 1. Yes 2. No	IF "2," GO TO QUESTION 38		
37	How often are electronic systems monitored? 1. Real time, continuous 2. Daily 3. Weekly 4. When a security breach is suspected 99. Other (please specify):			
1.6 Conducting risk assessments Purpose: to determine the presence and scheduling of risk assessments documented in the Policy.				
38	Are risk assessments conducted? 1. Yes 2. No	IF "2," GO TO QUESTION 41		

39	How often are risk assessments performed? 1. Every year 2. Every 1–2 years 3. Every 2+ years 99. Other (please specify):		
40	Which of the following steps are performed during the risk assessment process? (Please select all that apply.) 1. System characterization: identify the boundaries of the IT system, along with the resources and information that constitute the system. 2. Threat identification: identify the potential threat sources and compile a threat statement that lists the potential threat sources that are applicable to the IT system being evaluated. 3. Vulnerability identification: develop a list of the system flaws or weaknesses that could be exploited by the potential threat sources. 4. Control analysis: analyze the controls that have been implemented (or are planned for implementation) by the organization as part of efforts to minimize or eliminate the likelihood of an exploitation of a system vulnerability. 5. Likelihood determination: derive an overall likelihood rating that indicates the probability that a potential vulnerability may be exploited. 6. Impact analysis: determine the adverse impact resulting from the successful exploitation of a vulnerability. 7. Risk determination: assess the level of risk to the IT system. 8. Control recommendations: provide controls that could mitigate or eliminate the identified risks. 9. Results documentation: document results in an official report or briefing. 99. Other (please specify):		
1.7 Connectivity to other networks			

1.7 Connectivity to other networks Purpose: to determine if the Policy sufficiently details connectivity to other networks.

neworks.		
41	Are computers permitted to be connected to more than one network? 1. Yes 2. No	IF "2," GO TO QUESTION 44
42	Which of the following methods are used to connect computers to more than one network? (Please select all that apply.) 1. Virtual private network (VPN) 2. Remote desktop software that uses virtual network computing (VNC) or remote frame buffer protocol (RFB) 3. Remote desktop software that uses remote desktop protocol (RDP) 4. Remote desktop software that uses another protocol (AIP, NX, X11 or proprietary) or the protocol is unknown 5. Multiple network interface cards (NIC) 6. Network bridge 99. Other (please specify):	

43	Is there built-in encryption on the methods used to connect to other networks? 1. Yes 2. No	
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2. DATA COLLECTION

2.1 Data collection mechanisms

Purpose: to determine data collection methods, content and quality regarding personally identifiable health data.

	personally identifiable health data.	
44	Which of the following data are received? (Please select all that apply.) 1. Personally identifiable health data 2. De-identified health data 3. Non-identifiable health data 4. Aggregated data 5. Non-personal data 99. Other (please specify):	
45	What types of data collection methods are used? 1. Paper-based only 2. Computer-based only 3. Both 99. Other (please specify):	
46	Do you have an updated list of databases containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 48
47	Do you have an updated inventory of computers and mobile devices containing these databases or any other personally identifiable health data? 1. Yes 2. No	
48	Which of the following personally identifiable health data elements are collected as part of providing individual health care? (Please select all that apply.) 1. Name 2. Date of birth 3. Government-issued identification number (such as national identification number, welfare number, driver's license number or passport number) 4. Facility-issued identification number (including medical record numbers) 5. Photographic identifiers (such as photos on a driver's license or passport) 6. Biometric identifiers (such as a fingerprint) 7. Mailing address 8. Phone numbers 9. Medical notes 10. E-mail address 11. Employment information 12. None 99. Other (please specify):	

49	Which of the following personally identifiable health data elements are collected for public health practice? (Please select all that apply.) 1. Name 2. Date of birth 3. Government-issued identification number (such as national identification number, welfare number, driver's license number or passport number) 4. Facility-issued identification number (including medical record numbers) 5. Photographic identifiers (such as photos on a driver's license or passport) 6. Biometric identifiers (such as a fingerprint) 7. Mailing address 8. Phone numbers 9. Medical notes 10. E-mail address 11. Employment information 12. None 99. Other (please specify):	
50	When data are collected or shared, do they contain only the minimum information necessary to achieve the stated public health purpose? 1. Yes 2. No	
51	Do the data collection methods capture the origin of how, when and by whom data were collected, modified or deleted in order to protect against improper modification (falsification) or destruction? (Please select all that apply.) 1. How data were collected, modified or deleted 2. When data were collected, modified or deleted 3. Who collected, modified or deleted data 4. No 99. Other (please specify):	
52	How often are data reviewed for accuracy? 1. Daily 2. Weekly 3. Monthly 4. Annually 5. Never 99. Other (please specify):	IF "5," GO TO QUESTION 55
53	What methods are used to review data for accuracy? (Please select all that apply.) 1. Computerized verification during data entry 2. Computerized verification during data collection 3. Computerized analysis of data files (i.e. outlier analysis) 4. Manual review of individual data records 5. No method in place to review data 99. Other (please specify):	IF "5," GO TO QUESTION 55
54	Are there documented processes for handling data inaccuracies? 1. No 2. Yes, for reporting inaccuracies 3. Yes, for correcting inaccuracies 4. Yes, for both reporting and correcting inaccuracies	

55	For personally identifiable health data that will be transferred, are personal identifiers removed before transfer for any of the following purposes? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Public use 5. Not specified 99. Other (please specify):	IF "2," GO TO QUESTION 60
56	When data are transferred, where are personal identifiers removed from the data? 1. At the data collection site before transferring 2. At the data warehouse before further transfer 99. Other (please specify):	
57	How are the personal identifiers removed? 1. By removing a specified list of identifiable fields 2. By creating a non-identifiable key that is constructed from identifiable data 3. Other (please specify):	
58	How are the keys for the personal identifiers stored? 1. Electronically 2. Hard copy 99. Other (please specify):	
59	Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted 99. Other (please specify):	

2.2 Physical security measures at site Purpose: to determine the physical precautions taken to secure personally identifiable health data.

60	Which of the following physical measures are used for protecting patient privacy while collecting information? (Please select all that apply.) 1. Minimize exchange of information verbally 2. Use a partition or curtain in open rooms 3. Use of a separate room with a soundproof barrier 4. Use of window films that provide visual privacy 5. Use of cover sheets on paper documents to provide visual privacy 6. Use of a computer screen guard that provides visual privacy 7. Use of a work space only accessible to authorized staff 8. No measures in place 99. Other (please specify):	
61	What other physical precautions are taken to secure personally identifiable health data? (Please select all the apply.) 1. Workspaces, cabinets, paper copies and computers with personally identifiable information are located within a secure area with no public access. 2. Sensitive documents are stored in cabinets and locked. 3. Only authorized personnel can access these cabinets and computers. 99. Other (please specify):	

3. DATA STORAGE

3.1 Policy

Purpose: to determine if there are clear guidelines on data archiving within the Policy.

	,	
62	Do you have written guidelines or standard operating procedures (SOPs) on archiving data ? 1. Yes 2. No	IF "2," GO TO QUESTION 64
63	Which of the following are included in the guidelines/ SOPs on archiving data? (Please select all that apply.) 1. How often data must be archived 2. Approved storage locations of archived data 3. Approved media for archiving data 4. Roles that are responsible for archiving data 99. Other (please specify):	

3.2 Physical security storage measures Purpose: to determine the physical precautions taken to secure personally identifiable health data in storage.

	identiliable health data in storage.	
64	Are buildings and rooms containing personally identifiable health data locked for both electronic and paper documents? 1. Yes 2. No	
65	What physical security controls are in place to prevent unauthorized access to buildings and rooms containing personally identifiable health data? 1. Window locks 2. Security guard or other authorized staff control access 3. Video monitoring 4. Bars/grills for doors or windows 5. Alarm system 6. No physical security control measures are in place 99. Other (please specify):	
66	Are records maintained that indicate which staff are authorized to access buildings and rooms containing personally identifiable health data? 1. Yes 2. No	
67	Do staff need a user identifier and password to gain access to databases and documents containing personally identifiable health data? 1. Yes 2. No	
68	Are staff required to wear identification badges when accessing and working in rooms containing personally identifiable health data? 1. Yes 2. No	
69	Are records maintained that indicate the date and time that staff accessed rooms containing personally identifiable health data? 1. Yes 2. No	

70	The location used for storing paper-based confidential information is safe from the following (please select all that apply): 1. Risk of fire 2. Risk of flooding 3. Risk of animal or insect damage (such as mice or termites) 4. Power interruptions 5. Natural disasters 6. Theft 7. None of the above	
71	The location used for storing computers containing confidential information is safe from the following (please select all that apply): 1. Risk of fire 2. Risk of flooding 3. Risk of animal damage (such as rodents) 4. Power interruptions 5. Natural disasters 6. Theft 7. None of the above	
72	Are persons who are not authorized to access personally identifiable health data allowed to access rooms that contain the records or data? 1. Yes 2. No	IF "2," GO TO QUESTION 74
73	Are persons who are not authorized to access personally identifiable health data required to provide proper identification to authorized staff before being granted access to rooms containing personally identifiable health data? 1. Yes 2. No	
Purposo	3.3 Inventory management	rogarding

Purpose: to determine if there is clear guidance within the Policy regarding the migration of data to newer technologies.

74	What types of identification tags are applied to equipment? (Please select all that apply.) 1. Temporary adhesive labels that are not tamper-proof or tamper-evident 2. Permanent or semi-permanent adhesive labels that are tamper-proof or tamper-evident 3. Engraved metal plates attached to equipment 4. Identification is engraved directly on the equipment surface 5. None	
75	99. Other (please specify): How are the facility's inventory records for equipment maintained? (Please select all that apply.) 1. Handwritten or typed paper documents 2. Spreadsheet software 3. Database software 4. Asset management software 5. No inventory records are maintained 99. Other (please specify):	IF "5," GO TO QUESTION 77

99. Other (please specify):

4. DATA BACKUP

4.1 Computers and laptops Purpose: to determine the physical precautions taken to backup personally identifiable health data on computers.

	identinable fleatiff data off computers.	
77	Are patient data on desktop and laptop computers backed up? 1. Yes 2. No	IF "2," GO TO QUESTION 85
78	How often are patient data on desktop and laptop computers backed up? 1. Immediately when the data are revised 2. Daily 3. Weekly 4. As needed or requested 99. Other (please specify):	
79	Where are backup copies stored? (Please select all that apply.) 1. On the same computer on which data are collected 2. On a central server 3. In cloud-based storage 4. On removable media	
80	Are backup patient data from desktop and laptop computers encrypted? 1. Yes, during the backup process 2. Yes, before backup process 3. No 99. Other (please specify):	
81	When removable media are used for backup, are the removable media encrypted? 1. Yes 2. No	
82	How often are backup media for desktop and laptop computers containing patient data transferred to an off-site storage facility? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Annually 6. Never 99. Other (please specify):	
83	Are your backups rotated: ie. are you backing up the backup? 1. Yes 2. No	

	How often are stored data migrated when newer storage media become available? 1. Monthly	
84	2. Quarterly3. Every 6 months4. Annually	
	5. Every 2 years6. No regular migration schedule	
	7. Never	

4.2 Servers

Purpose: to determine the physical precautions taken to secure personally identifiable health data in storage on servers.

85	Are patient data on servers backed up? 1. Yes, by the system administrator as needed or requested 2. Yes, by the system administrator on a regular schedule 3. Yes, using an automated, scheduled process 4. No 99. Other (please specify):	IF "4," GO TO QUESTION 90
86	Are data periodically migrated to newer backup media as technology changes provide newer methods of storage? 1. Yes 2. No	IF "2," GO TO QUESTION 89
87	Are data backups migrated when newer storage media become available? 1. Yes 2. No	IF "2," GO TO QUESTION 89
88	How often are stored data migrated when newer storage media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years 6. No regular migration schedule 7. Never	
89	Are backup media regularly tested to ensure that they can be relied upon in case of emergencies? 1. Yes 2. No	

4.3 Audit logs

Purpose: to determine the use, review and backup of audit logs.

90	Are audit logs created to assist in recording all system transactions? 1. Yes 2. No	IF "2," GO TO QUESTION 100
91	Are audit logs stored separately from the rest of the system that they are monitoring? 1. Yes 2. No	

92	Which of the following data elements are recorded in the audit log? (Please select all that apply.) 1. IP address or MAC address of computer from which action originated 2. User identifier 3. Dates, times and details of key events (e.g. log on and log off) 4. Records of successful and rejected system access attempts 5. Activation and de-activation of protection systems (such as antivirus systems and intrusion detection systems) 6. Files accessed and the kind of access 7. Record identifier 99. Other (please specify)	
93	How often is the audit log reviewed? 1. Real-time, continuous 2. Daily 3. Weekly 4. Only when needed or requested 5. Never 99. Other (please specify):	IF "5," GO TO QUESTION 95
94	Who reviews the audit log? (Please select all that apply.) 1. Data management staff 2. Clinical staff 3. Confidentiality and security officer/information security manager 4. Database administrator 5. Independent auditor 99. Other (please specify):	
95	Are audit logs backed up? 1. Yes 2. No	IF "2," GO TO QUESTION 100
96	How are audit logs backed up? 1. By the system administrator as needed or requested 2. By the system administrator on a regular schedule 3. Using an automated, scheduled process 99. Other (please specify):	
97	How often are audit logs backed up? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 99. Other (please specify):	
98	How often are audit logs of backup data transferred to an off-site storage facility? 1. Daily 2. Weekly 3. As needed or requested 4. Never 99. Other (please specify):	IF "4," GO TO QUESTION 100
99	Are the off-site storage facilities for backup media for audit logs locked? 1. Yes 2. No	

5. AUTHORIZATION AND ACCESS CONTROL

5.1 Policy

Purpose: to determine if access to data is clearly defined within the Policy and if security controls are independently validated.

100	Access to data has been defined for the following staff members (please select all that apply): 1. Staff access not defined 2. Medical practitioners 3. Nursing practitioners 4. Public health specialists 5. Other health professionals 6. Information technology staff (including data clerks, analysts, managers and programmers) 7. Administrative staff 8. Professional service providers 9. Volunteers 10. Academic or other researchers 11. Cleaners, security guards and other providers of support services 12. Bilateral donor staff 13. Multilateral institution staff (e.g. staff from the Global Fund to Fight AIDS, Tuberculosis and Malaria) 99. Other (please specify):	IF "1," GO TO QUESTION 103
101	Are system security controls independently tested and validated? 1. Yes 2. No	

5.2 User access

Purpose: to determine if levels of access are specified for using data for different purposes.

	• •	
102	Which of the following types of data have specified levels of access for those professionals with defined access roles? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Public use 6. Not specified 99. Other (please specify):	

5.3 Passwords

Purpose: to determine if the Policy requires user sessions to be locked after certain periods of inactivity.

Do staff need a year identifier and necessard to gain		•	
access to a computer? 1. Yes 2. No 3. Not applicable (no computer available) IF "3," GO TO QUESTION 120	103	1. Yes 2. No	GO TO QUESTION

104	How are user identifiers generated? 1. By the computer operating system 2. By the computer software application 3. By a system administrator, with user identifier composition rules 4. By a system administrator, without user identifier composition rules 5. By information security manager 99. Other (please specify):	
105	Is the password file encrypted? 1. Yes 2. No	
106	Are there established procedures for verifying the identity of a user prior to providing a new, replacement or temporary password? 1. Yes 2. No	
107	How are user identifiers and passwords issued to users? (Please select all that apply.) 1. In person 2. By telephone 3. Through e-mail 99. Other (please specify):	
108	After what period of inactivity are user identifiers disabled? 1. 14 days 2. 30 days 3. 60 days 4. 90 days 5. 180 days 6. 360 days 7. Not disabled 99. Other (please specify):	
109	When a staff member's employment is terminated, are there procedures for revoking access to personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 111
110	When a staff member's employment is terminated, when are data access privileges revoked? 1. Immediately upon termination via an automated process 2. Within a week 3. Within a month 4. Never 99. Other (please specify):	
111	Are user sessions automatically locked after a certain specified period of inactivity for software applications that contain personally identifiable health data? 1. Yes 2. No	
112	What is the minimum password length? 1. 6 or fewer characters 2. 7–8 characters 3. 9 or more characters 4. No minimum password length	

120	policy? 1. Yes 2. No	GO TO QUESTION 122
Purpo	6.1 Policy se: to determine if the Policy contains a detailed release Do you have written guidelines for the data release	section.
	6. DATA RELEASE	
119	Are biometrics or other technologies (e.g. fingerprint verification, signature verification, hardware tokens or smart cards) being used for user identification and authentication? 1. Yes 2. No	
118	Is reusing passwords prohibited for a specific number of generations (i.e. a certain number of previous passwords cannot be reused)? 1. Yes 2. No	
117	How is the reset password provided to the user? (Please select all that apply.) 1. Through e-mail 2. By telephone 3. In person 99. Other (please specify):	
116	Is a password reset mechanism established for computers and computer software applications that contain personally identifiable health data? 1. Yes—upon password expiration only 2. Yes—can be initiated by the user before the password expires (such as at the first indication of a possible security breach) 3. No	IF "3," GO TO QUESTION 119
115	Which of the following is the minimum time that you change passwords? 1. Less than 1 day 2. 1–7 days 3. 8–14 days 4. 15–30 days 5. More than 30 days 6. No minimum time	
114	Are passwords masked when entered into computer applications? 1. Yes 2. No	
113	Does the system enforce specifications for passwords, such as a combination of a minimum number of lower-case letters, upper-case letters, numbers and special characters? 1. Yes 2. No	

121	Which of the following information is included in the data release policy? (Please select all that apply.) 1. Class of use for which data may be released (e.g. individual health care or public health practice) 2. Specific data elements that may be released 3. Entities and organizations to whom data may be released 4. Requirements for how recipients will protect the confidentiality of received data 5. Specifications for time limitations on use of released data 6. Data quality standards that must be met prior to data release 7. Clearly defined individual(s) who are authorized to release data 8. Clear procedures for handling data requests that are not covered under the data release policy 99. Other (please specify):	

6.2 Mandatory requirements for data release Purpose: to determine the extent to which the Policy covers requirements and conditions in terms of the release of data.

122	According to the Data Confidentiality and Security Policy, for what purpose may personally identifiable health data be released? (Please select all that apply.) 1. Not specified in the Data Confidentiality and Security Policy 2. Individual health care 3. Public health practice (including monitoring and evaluation) 4. Human subject research (with consent) 5. Exceptional statutory purposes 6. Public use 99. Other (please specify):	IF "1," GO TO QUESTION 135. IF "2," GO TO QUESTION 123. IF "3," GO TO QUESTION 126. IF "4," GO TO QUESTION 129.
123	Under what circumstances is the release of personally identifiable health data for individual health care permitted? (Please select all that apply.) 1. Authorized transfer of a patient across facilities 2. Authorized transfer between clinical services 3. Request from patient 4. Not specified 99. Other (please specify):	ANSWER ONLY IF #2 WAS CHOSEN FOR QUESTION 122

124	Which of the following conditions must be met before releasing personally identifiable health data for individual health care? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify that the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	
125	Which of the following conditions must be met by the organization receiving personally identifiable health data in order for data to be release for individual health care? (Please select all that apply.) 1. Signed confidentiality statements from recipient facility staff 2. Documentation of security training of recipient facility staff 3. Evidence of security assessment (eg. review of procedural, electronic or physical security controls) 4. Documentation of internal steering group review and approval 5. Agreement by the recipient to destroy information after the purpose of the data release has been fulfilled 6. Assurance that the minimum amount of data needed to satisfy the purpose is being requested 7. Not specified 99. Other (please specify):	
126	Under what circumstances is the release of personally identifiable health data for public health practice permitted? (Please select all that apply.) 1. Not specified 2. Regulation of public health policy 3. Public health program planning 4. National reporting 99. Other (please specify):	ANSWER ONLY IF #3 WAS CHOSEN FOR QUESTION 122
127	Which of the following conditions must be met before releasing personally identifiable health data for public health practice? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify that the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	

128	What requirements must be met by the organization receiving personally identifiable health data in order for data release to be authorized for public health practice? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (review of procedural, electronic and physical security controls) 4. Review and approval by the internal steering group 5. Agreement to destroy information after purpose of data release has been fulfilled 6. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 7. Not specified 99. Other (please specify):	
129	When is the release of personally identifiable health data for human subject research (with consent) permitted? (Please select all that apply.) 1. Ethics committee or IRB review and approval 2. Not specified 99. Other (please specify):	ANSWER ONLY IF #4 WAS CHOSEN FOR QUESTION 122
130	Which of the following conditions must be met before releasing personally identifiable health data for human subject research (with consent)? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Acquisition of formal approval for the data release 5. Not specified 99. Other (please specify):	
131	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for human subject research (with consent)? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (review of procedural, electronic, and physical security controls) 4. Proof of ethics or IRB research review and approval 5. Review of a scientific protocol by an internal steering group 6. Agreement to destroy information after purpose of data release has been fulfilled 7. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 8. Not specified 99. Other (please specify):	

132	When is the release of personally identifiable health data for exceptional statutory purposes permitted? (Please select all that apply.) 1. Court order 2. Subpoena 3. Request from law enforcement agency 4. Request from prosecuting attorneys 5. Request from defense attorneys 6. Request from a health-care practitioner providing treatment for a health-care worker or a law enforcement officer because of a medically significant exposure to blood or body fluids 7. Not specified 99. Other (please specify):	ANSWER ONLY IF #5 WAS CHOSEN FOR QUESTION 122
133	Which of the following conditions must be met before releasing personally identifiable health data for exceptional statutory purposes? (Please select all that apply.) 1. Review of data for accuracy 2. Removal of direct patient identifiers from released records 3. Acquisition of formal approval for the data release 4. Not specified 99. Other (please specify):	
134	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for exceptional statutory purposes? (Please select all that apply.) 1. Review and approval of request by legal counsel 2. Review and approval of request by confidentiality and security officer (or equivalent official) 3. Review and approval by internal steering group 4. Signed confidentiality statements from persons receiving data 5. Documentation of security training 6. Medical record release signed by patient 7. Medical record release signed by the patient's attorney 8. Security assessment (review of procedural, electronic and physical security controls) 9. Agreement to destroy information after purpose of data release has been fulfilled 10. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 11. Not specified 99. Other (please specify):	

7. TRANSMISSION SECURITY

7.1 Routers

Purpose: to determine the extent to which the policy covers router usage	Purpose: to dete	ermine the exte	nt to which the	policy covers	router usage.
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135	Is a router that controls information flow between the local area network and the Internet or other networks installed? 1. Yes 2. No	IF "2," GO TO QUESTION 139
136	Which of the following are characteristics of the router configuration? (Please select all that apply.) 1. Enables password protection 2. Limits router access to named users or user groups through command privilege levels 3. Displays banner indicating ownership of the system and that unauthorized access is prohibited 4. Disables unnecessary services 5. Prevents internal IP addresses from being revealed 6. Enables logging of access, including source IP address and the date, time and description of access 7. Accesses lists that contain information to deny or allow traffic by IP address or group 8. Turns off incoming IP-directed broadcasts (IP packets that are sent to a particular network or group of networks) 99. Other (please specify):	
137	How often are router logs reviewed? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Never 6. As needed or requested 99. Other (please specify):	
138	Who reviews and provides oversight of router logs? (Please select all that apply.) 1. Internal IT staff, manually 2. Internal IT staff, using log analysis software 3. Independent auditor 99. Other (please specify):	

7.2 Firewalls

Purpose: to determine the extent to which the policy covers procedures for protecting data through the use of firewalls.

protecting data through the use of methans.			
139	Are firewalls installed on computers, servers and networks? 1. Yes 2. No	IF "2," GO TO QUESTION 144	
140	Which characteristics do the installed firewalls possess? (Please select all that apply.) 1. Apply a security level in accordance with the type of network 2. Block intrusion attempts (from wireless networks [Wi-Fi], hackers, etc.) 3. Specify which software application can access the network or the Internet 4. Block access of specified software applications 5. Offer outbound protection to control information that leaves the computer 6. Others (please specify):		

141	How often are computers, servers and network firewall logs reviewed? 1. Real-time, continuous 2. Daily 3. Weekly 4. Monthly 5. Quarterly 6. As needed or requested 7. Never 99. Other (please specify):	
142	Who reviews computer, server or network firewall logs? (Please select all that apply.) 1. Internal IT staff, manually 2. Internal IT staff, using log analysis software 3. Independent auditor 4. No one is assigned to review firewall logs 99. Other (please specify):	
143	Which of the following are included in computer, server or network firewall audits? (Please select all that apply.) 1. Review rule sets 2. Review accounts 3. Ensure that logging is enabled and that the logs are reviewed periodically 4. Ensure that the latest patches and updates are tested and installed 5. Ensure that specific IP addresses are blocked 6. Ensure that specific ports are blocked 7. Perform vulnerability and penetration testing 8. No firewall audits are performed 99. Other (please specify):	

7.3 Antivirus on computers
Purpose: to determine the extent to which the policy requires electronic systems containing personally identifiable health data to use antivirus software.

144	Is antivirus software installed on desktop and laptop computers containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 146
145	How often is antivirus software updated on desktop or laptop computers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. Never 99. Other (please specify):	
146	When are individual files scanned on desktop or laptop computers containing personally identifiable health data? (Please select all that apply.) 1. As scheduled 2. When moved, copied, opened or saved 3. When downloaded 4. Only as part of a scheduled system scan 99. Other (please specify):	

147	How often is the operating system scanned by antivirus software on desktop and laptop computers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	
148	How often are removable media connected to desktop or laptop computers that contain personally identifiable health data scanned by antivirus software? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	

7.4 Antivirus on servers

Purpose: to determine the extent to which the policy requires servers containing personally identifiable health data to use antivirus software.

149	Is antivirus software installed on servers? 1. Yes 2. No	IF "2," GO TO QUESTION 154		
150	How often is antivirus software updated on servers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):			
151	When are individual files scanned on servers containing personally identifiable health data? 1. As scheduled 2. When moved, copied, opened or saved 3. When downloaded 4. Only as part of a scheduled system scan 99. Other (please specify):			
152	How often is the operating system on servers containing personally identifiable health data scanned by antivirus software? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):			

	How often are all drives containing personally identifiable health data and connected to server(s) scanned by	
	antivirus software?	
	1. Real-time, continuous	
153	2. Daily	
	3. Weekly	
	4. As needed or requested	
	5. At computer start-up	
	6. Never	
	99. Other (please specify):	

7.5 Transfer of paper data

Purpose: to determine the physical precautions taken to store and secure personally identifiable health data in paper format.

154	Does your site store paper records containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 156
155	How often are data on paper transferred to an off-site storage facility? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Annually 6. Never 99. Other (please specify):	
156	Which of the following security controls are implemented to ensure the security of paper-based data when they are being transferred within a facility or to an off-site storage facility? (Please select all that apply.) 1. A list of approved transport providers (such as site staff, courier services, and government and private postal services) 2. A locked container for transferring or transporting the paper-based data 3. A tamper-proof seal for the container used for transferring or transporting paper-based data 4. A transfer log that identifies the records being transferred, the sender, the recipient, the delivery person, and all relevant dates and times 5. Authentication of the identity of the recipient on delivery 6. Verification of successful delivery 99. Other (please specify):	

7.6 Transmission of electronic data

Purpose: to determine the physical precautions taken to transfer personally identifiable health data electronically.

157	Does your site store electronic records containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 164
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158	What methods or media are used to transfer electronic data within a site? (Please select all that apply.) 1. Intranet, local area network or wide area network 2. E-mail 3. Internet (via web browser) 4. File transfer protocol (FTP) 5. Tape 6. Optical media (CD or DVD) 7. Flash drive or memory stick 8. External hard drive 9. Smart card 99. Other (please specify):	
159	What controls are implemented to ensure the security of electronic data when they are being moved within a site? (Please select all that apply.) 1. Authentication of the identities of the sender and receiver before information transfer 2. Password-protected data files (with or without encryption) 3. Encryption of the information during transfer 4. Post-transfer verification of the appropriate and successful transfer of information 5. None of the above 99. Other (please specify):	
160	What methods or media are used to transfer electronic data between sites? 1. Intranet, local area network and wide area network 2. E-mail 3. Internet (via web browser) 4. File transfer protocol (FTP) 5. Tape 6. Optical media (CD or DVD) 7. Flash drive or memory stick 8. External hard drive 9. Smart card 10. None of the above 99. Other (please specify):	
161	For which of the following transfer methods or media and transfer types is encryption used when data are in transit within the site? (Please select all that apply.) 1. Not used 2. Intranet, local area network and wide-area network 3. E-mail 4. Internet (via web browser) 5. File transfer protocol (FTP) 6. Tape 8. Optical media (CD or DVD) 9. Flash drive or data stick 10. External hard drive 11. Smart card 99. Other (please specify)	

162	Which controls are implemented to ensure the security of electronic data when they are being moved between sites? (Please select all that apply.) 1. Authentication of the identities of the sender and receiver before information transfer 2. Password-protected data files (with or without encryption) 3. Encryption of the information during transfer (such as SSLs) 4. Post-transfer verification of the appropriate and successful transfer of information 99. Other (please specify):	
163	When transferring data within and between sites, which methods are used to authenticate sending and receiving parties? (Please select all that apply.) 1. Sending and receiving parties are not authenticated 2. Two-factor authentication (TFA) 3. Public key infrastructure (PKI) 99. Other (please specify):	

7.7 Mail handling Purpose: to determine the procedures used for handling incoming mail at sites involved with personally identifiable health data.

	involved with personally recirculable neutrin data.	
	Which of the following procedures are used for handling incoming mail at sites involved with personally identifiable health data? (Please select all that apply.) 1. All mail marked "confidential" must be checked by authorized personnel only and kept in a secured location until it is processed. 2. Mail marked "confidential" should only be opened by the addressee.	
164	3. The person in charge of receiving the confidential mail must record the receipt of all mail into a log book by the end of each day; each log entry must note the name of the sender, what was received and the date of receipt. 4. The person in charge of receiving the confidential mail must contact the sender on the day of receipt with notification that the mail was received. 5. No procedures are in place. 99. Other (please specify):	

8. DATA DISPOSAL

8.1 Data disposal

Purpose: to determine the extent to which the policy covers secure retirement and disposal of paper-based data.

and disposal of paper-based data.		
165	Do you have written guidelines for the secure disposal and destruction of data? 1. Yes 2. No	
166	Do you maintain a data retirement schedule for destroying records when they are no longer needed? 1. Yes 2. No	IF "2," GO TO QUESTION 168
167	Which types of records are addressed in the data retirement schedule? (Please select all that apply.) 1. Paper records 2. Backup copies of paper records 3. Electronic records 4. Backup copies of electronic records 99. Other (please specify):	
168	Which method(s) of destruction or disposal are used? (Please select all that apply.) 1. Burning 2. Demagnetizing 3. Overwriting 4. Pulping 5. Pulverizing, crushing or grinding 6. Reformatting 7. Shredding 99. Other (please specify):	
169	Do you maintain documentation of the secure destruction or disposal of records (such as a certification or verification of destruction)? 1. Yes 2. No	IF "2," THE FACILITY- LEVEL ASSESSMENT IS COMPLETE.
170	What information must be included in documentation of the secure destruction or disposal of records? (Please select all that apply.) 1. Organization 2. Organization contact 3. Date of destruction or disposal 4. Name and signature of person who authorized the destruction or disposal of data 5. Description of information destroyed or disposed of, including type (paper or electronic) 6. Time period covered by the records to be destroyed 7. Method of destruction or disposal (e.g. burning, demagnetizing, overwriting, pulping, pulverizing, reformatting or shredding) 8. Name and signature of person who destroyed or disposed of data 9. Name and signature of person who witnessed destruction or disposal of data 10. Copy of contract with outside firm handling the destruction or disposal of data 99. Other (please specify):	

3.2 Data warehouse-level Assessment Tool

The following data warehouse-level questions are set to determine the security, confidentiality and appropriate use (including sharing) of data collected by health programs.

The questions are grouped into eight sections:

- 1. Governance and policy
- 2. Data collection
- 3. Data storage
- 4. Data backup
- 5. Authorization and access control
- 6. Data release
- 7. Transmission security
- 8. Data disposal.

A brief purpose statement introduces each section. It is followed by a set of questions to be answered.

	RECOMMENDED WAREHOUSE-LEVEL QUESTIONS	
Category	Question	Instruction

1. GOVERNANCE AND POLICY

1.1 Legislation

Purpose To determine the existence, accessibility, distribution, development process and review, of a written policy document ensuring the confidentiality and security of personally identifiable health data

	and security of personally identifiable health data Do you have clearly defined roles and access levels for all	
1	persons with authorized access to personally identifiable data? 1. Yes 2. No	
2	Do you have clearly defined standard procedures or methods that must be followed when accessing personally identifiable data? 1. Yes 2. No	
3	Does a written policy document regarding the requirements for ensuring the confidentiality and security of personally identifiable health data exist in this country (referred to as the "Data Confidentiality and Security Policy" or "the Policy")? 1. Yes (If written documentation is determined to exist, identify the appropriate staff to answer this module) 2. No, but a policy is in the process of development 3. No, but various informal policies exist 4. No, we do not have any policy or written guidelines	IF "2," "3" OR "4," GO TO QUESTION 6.
4	Is the Data Confidentiality and Security Policy readily accessible to all staff members who have access to confidential individual-level data? (By "readily accessible," we mean that they can easily access the policy online or in hard copy while at work.) 1. Yes 2. No	
5	To which stakeholders or organizations is the Data Confidentiality and Security Policy document distributed? (Please select all that apply.) 1. All staff with access to medical records or confidential health program information 2. Staff who request it 3. Medical practitioners 4. Nursing practitioners 5. Public health specialists 6. Health-care volunteers 7. Other health professionals 8. Information technology staff (including data entry staff, analysts, managers and programmers) 9. Administrative staff 10. Cleaners, security guards and other providers of support services 11. Policy document is not distributed 12. Health records staff 99. Other (please specify):	

In which of the following formats is the Data Confidentiality and Security Policy document available for reference by staff? 1. Printed hard copies 2. Electronic, distributed via e-mail 3. Electronic, distributed via CD or other media 4. Electronic, available on the Internet (please specify the URL): 99. Other, specify:	

1.2 Governance structure

Purpose – To determine the governance structure that is in place to provide oversight for the appropriate collection, use, and dissemination of data, including regular review of the policy document and security practices.

7	Is there a local governance structure (e.g. steering committee/advisory board) in place to provide oversight for the appropriate collection, use and dissemination of data, including regular review of the policy document and security practices? 1. Yes 2. No 99. Other (please specify):	IF "2," GO TO QUESTION 9
8	How often does the steering committee or advisory board meet? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years 6. No regular meeting schedule	
9	Which uses of personally identifiable information are covered by your local guidelines on the security and confidentiality of data? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Not specified 99. Other (please specify):	
10	Is information security and its management reviewed at regular intervals? 1. Yes 2. No	

1.3 Review of security practices Purpose – To determine the security practice and review as documented in the policy

in the poney		
11	Are security practices reviewed by independent auditors? 1. Yes 2. No	IF "2," GO TO QUESTION 13
12	How often do independent auditors review security practices? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Not specified 99. Other (please specify):	

1.4 Responsibilities and training Purpose – To determine the responsibilities and training required as documented in the policy.

	in the policy.	
13	Are staff explicitly informed of their individual responsibilities for protecting the systems used to access and utilize personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 15
14	How are staff informed of their individual responsibilities for protecting the systems used to access and utilize personally identifiable health data? (Please select all that apply.) 1. Policy documents distributed to staff 2. Informal on-the-job training received by staff 3. Formal training received by staff 99. Other (please specify):	
15	Do policies state that staff are personally responsible for protecting paper records, computer workstations, laptop computers or other devices associated with confidential public health information or data? 1. Yes 2. No	
16	Are all persons authorized to access personally identifiable health data trained on the organization's information security policies and procedures? 1. Yes 2. No	IF "2," GO TO QUESTION 20
17	How often must staff repeat the training on confidentiality and security measures? 1. Every year 2. Every 1–2 years 3. Every 2+ years 99. Other (please specify):	
18	Which of the following is the format of the training on confidentiality and security measures? (Please select all that apply.) 1. Material read by staff from printed document 2. Material read by staff on website 3. Instructor-led web training at scheduled intervals 4. Instructor-led training in a classroom setting 5. One-on-one training with another staff member (peer-led model) 99. Other (please specify):	
19	Is the date of the training or test documented in the employee's personnel file? 1. Yes 2. No	
20	Do all newly hired staff members sign a confidentiality agreement before they are given authorization to access personally identifiable health data? 1. Yes 2. No	

21	Which of the following authorized staff members in your program sign a confidentiality agreement? (Please select all that apply.) 1. All staff with access to medical records or confidential health program information 2. Medical practitioners 3. Nursing practitioners 4. Public health specialists 5. Health-care volunteers 6. Other health professionals 7. Information technology staff (including data entry staff, analysts, managers and programmers) 8. Administrative staff 9. Professional service providers 10. Cleaners, security guards and any other providers of support services 11. Staff are not required to sign an agreement 99. Other (please specify):	
22	Do the staff have to repeat the review and signing of the confidentiality statement indicating they understand the policies and agree to implement them? 1. Yes 2. No	IF "2," GO TO QUESTION 24
23	How often must staff repeat the review and signing of the confidentiality statement indicating they understand the policies and agree to implement them? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Never 99. Other (please specify):	
24	Are staff explicitly informed of the possible consequences of failing to properly protect personally identifiable health data? 1. Yes 2. No	
25	Depending on the severity of the breach, which of the following are possible consequences for members of staff who fail to protect personally identifiable health data? (Please select all that apply.) 1. Education or counselling to prevent repeat minor breaches 2. Reduction or loss of security clearance 3. Reduction or loss of data access privileges 4. Demotion 5. Suspension 6. Dismissal/termination of employment 7. Civil legal action 8. Criminal legal action 9. Not specified 99. Other (please specify):	IF "9," GO TO QUESTION 28

26	How are staff informed of the possible consequences of failing to protect personally identifiable health data? (Please select all that apply.) 1. Policy documents distributed to staff 2. Informal on-the-job training received by staff 3. Formal training received by staff 4. Confidentiality statement signed by staff 99. Other (please specify):	
27	When a staff member's employment is terminated, when are data access privileges revoked? 1. Immediately upon termination 2. Within a specified period of time after termination (e.g. 30 days) 3. Not automatically revoked	
28	Is there a designated confidentiality information security manager at the data warehouse/repository? 1. Yes 2. No	IF "2," GO TO QUESTION 31
29	Is there a written description of the information security manager's responsibilities? 1. Yes 2. No	IF "2," GO TO QUESTION 31
30	Which of the following tasks are part of the information security manager's responsibilities? (Please select all that apply.) 1. Identify and review all applicable guidelines 2. Advocate for the resources needed for information confidentiality and security 3. Ensure that information confidentiality and security goals are identified, that they meet organizational requirements, and that they are initiated and integrated into relevant processes 4. Improve confidentiality and security awareness by initiating appropriate plans and programs 5. Test, review and validate the effectiveness of the implementation of the information confidentiality and security policy 6. Provide clear direction and visible management support for confidentiality and security initiatives 7. Approve assignment of specific roles and responsibilities for information confidentiality and security across the organization 8. All of the above 99. Other (please specify):	
1.5 Monitoring, detecting and responding to security breaches Purpose: to identify and manage security breaches as documented		

1.5 Monitoring, detecting and responding to security breaches Purpose: to identify and manage security breaches as documented in the Policy.

Do writ breach 1. Yes 2. No	ten guidelines exist for managing security es?	IF "2," GO TO QUESTION 33
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32	Which of the following procedures for responding to security breaches are included in written procedures? (Please select all that apply.) 1. Roles and responsibilities of staff for managing security breaches 2. Preparing to handle security breaches by rehearsing potential responses 3. Detecting security breaches when they occur and determining the type of incident and appropriate response 4. Analyzing available information related to the security breach to determine the type of incident and the appropriate response 5. Prioritizing the response to the security breach based on criticality of the affected resources (including notifying appropriate individuals) 6. Containing the security breach (e.g. shutting down a system, disconnecting it from a wired or wireless network, disconnecting its modem cable or disabling certain functions) 7. Eradicating the security breach and removing the effects of the cause (such as disabling compromised user accounts) 8. Recovering from the security breach and restoring systems to normal operations 9. Acquiring, preserving, securing and documenting evidence related to the security breach 10. Creating additional security checks to prevent similar security breaches 99. Other (please specify):	
33	Are systems monitored to detect potential or actual security breaches? 1. Yes 2. No	IF "2," GO TO QUESTION 35
34	How often are electronic systems monitored? 1. Real time, continuous 2. Daily 3. Weekly 4. When a security breach is suspected 99. Other (please specify):	

1.6 Conducting risk assessments Purpose – To determine the presence and scheduling of risk assessments documented in the policy.

	· · ·	
35	Are risk assessments mandated under the Data Confidentiality and Security Policy? 1. Yes 2. No	IF "2," GO TO QUESTION 38
36	How often are risk assessments performed? 1. Every year 2. Every 1–2 years 3. Every 2+ years 99. Other (please specify):	

37	Which of the following steps are performed during the risk assessment process? (Please select all that apply.) 1. System characterization: identify the boundaries of the IT system, along with the resources and the information that constitute the system. 2. Threat identification: identify the potential threat sources and compile a threat statement that lists the potential threat sources that are applicable to the IT system being evaluated. 3. Vulnerability identification: develop a list of the system flaws or weaknesses that could be exploited by the potential threat sources. 4. Control analysis: analyze the controls that have been implemented (or are planned for implementation) by the organization as part of efforts to minimize or eliminate the likelihood of an exploitation of a system vulnerability. 5. Likelihood determination: derive an overall likelihood rating that indicates the probability that a potential vulnerability may be exploited. 6. Impact analysis: determine the adverse impact resulting from a successful exploitation of a vulnerability. 7. Risk determination: assess the level of risk to the IT system. 8. Control recommendations: provide controls that could mitigate or eliminate the identified risks. 9. Results documentation: document results in an official report or briefing. 99. Other (please specify):	

1.7 Connectivity to other networks Purpose – To determine if the policy sufficiently details connectivity to other networks.:

38	Are computers permitted to be connected to more than one network? 1. Yes 2. No	IF "2," GO TO QUESTION 41
39	Which of the following methods are used to connect computers to more than one network? (Please select all that apply.) 1. Virtual private network (VPN) 2. Remote desktop software that uses virtual network computing (VNC) or remote frame buffer protocol (RFB) 3. Remote desktop software that uses remote desktop protocol (RDP) 4. Remote desktop software that uses another protocol (AIP, NX, X11 or proprietary) or the protocol is unknown 5. Multiple network interface cards (NIC) 6. Network bridge 99. Other (please specify):	
40	Is there built-in encryption on the methods used to connect to other networks? 1. Yes 2. No	

2.DATA COLLECTION

2.1 Data collection mechanisms

Purpose – To determine data collection methods, content and quality regarding personally identifiable health data.

	ding personally identifiable health data.	
41	Which of the following data are received? (Please select all that apply.) 1. Personally identifiable health data 2. De-identified health data 3. Non-identifiable health data 4. Aggregated data 5. Non-personal data 99. Other (please specify):	
42	In what form are data received? 1. Paper-based only 2. Computer-based only 3. Both 99. Other (please specify):	
43	Do you have an updated list of databases containing personally identifiable health data? 1. Yes 2. No	
44	Do you have an updated inventory of computers and mobile devices containing these databases or any other personally identifiable health data? 1. Yes 2. No	
45	Which of the following personally identifiable health data elements are received for public health practice? (Please select all that apply.) 1. Name 2. Date of birth 3. Government-issued identification number (such as a national identification number welfare number, driver's license number or passport number) 4. Facility-issued identification number (including medical record numbers) 5. Photographic identifiers (such as photos on a driver's license or passport) 6. Biometric identifiers (such as a fingerprint) 7. Mailing address 8. Phone numbers 9. Medical notes 10. E-mail address 11. Employment information 12. None 99. Other (please specify):	
46	When data are collected or shared, do they contain only the minimum information necessary to achieve the stated public health purpose? 1. Yes 2. No	

Do the data collection methods capture the origin of how, when and by whom the data were collected, modified or deleted in order to protect against improper modification (falsification) or destruction? (Please select all that apply.) 1. How data were collected, modified or deleted 2. When data were collected, modified or deleted 3. Who collected, modified or deleted data 3. No 99. Other (please specify): For personally identifiable health data that will be transferred, are personal identifiers removed before transfer? 1. Yes 2. No When data are transferred, where are personal identifiers removed from the data? 1. At the data collection site before transferring 2. At the data warehouse before further transfer 99. Other (please specify): How are the personal identifiers removed? 1. By removing a specified list of identifiable fields 2. By creating a non-identifiable key that is constructed from identifiable data 3. Other (please specify): How are the keys for the personal identifiers stored? 1. Electronically 2. Hard copy 99. Other (please specify): Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted 99. Other (please specify):			
transferred, are personal identifiers removed before transfer? 1. Yes 2. No When data are transferred, where are personal identifiers removed from the data? 49 1. At the data collection site before transferring 2. At the data warehouse before further transfer 99. Other (please specify): How are the personal identifiers removed? 1. By removing a specified list of identifiable fields 2. By creating a non-identifiable key that is constructed from identifiable data 3. Other (please specify): How are the keys for the personal identifiers stored? 1. Electronically 2. Hard copy 99. Other (please specify): Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted	47	when and by whom the data were collected, modified or deleted in order to protect against improper modification (falsification) or destruction? (Please select all that apply.) 1. How data were collected, modified or deleted 2. When data were collected, modified or deleted 3. Who collected, modified or deleted data 3. No	
removed from the data? 1. At the data collection site before transferring 2. At the data warehouse before further transfer 99. Other (please specify): How are the personal identifiers removed? 1. By removing a specified list of identifiable fields 2. By creating a non-identifiable key that is constructed from identifiable data 3. Other (please specify): How are the keys for the personal identifiers stored? 1. Electronically 2. Hard copy 99. Other (please specify): Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted	48	transferred, are personal identifiers removed before transfer? 1. Yes	GO TO QUESTION
1. By removing a specified list of identifiable fields 2. By creating a non-identifiable key that is constructed from identifiable data 3. Other (please specify): How are the keys for the personal identifiers stored? 1. Electronically 2. Hard copy 99. Other (please specify): Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted	49	removed from the data? 1. At the data collection site before transferring 2. At the data warehouse before further transfer	
1. Electronically 2. Hard copy 99. Other (please specify): Is access restricted to the files containing keys? 1. Yes, with user identification and password or lock and key 2. No, access is not restricted	50	By removing a specified list of identifiable fields By creating a non-identifiable key that is constructed from identifiable data	"3" GO TO QUESTION
1. Yes, with user identification and password or lock and key2. No, access is not restricted	51	 Electronically Hard copy 	
2.2 Physical acceptate management site	52	 Yes, with user identification and password or lock and key No, access is not restricted Other (please specify): 	

2.2 Physical security measures at site Purpose – To determine the physical precautions taken to secure personally identifiable health data

Secure area with no public access. Sensitive documents are stored in cabinets and locked. Only authorized personnel can access these cabinets d computers.
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3. DATA STORAGE

3.1 Policy

Purpose – To determine if there are clear guidelines in terms of data archival within the policy.

54	Do you have written guidelines or standard operating procedures (SOPs) on archiving data? 1. Yes 2. No	IF "2," GO TO QUESTION 56
55	Which of the following are included in the guidelines/ SOPs on archiving data? (Please select all that apply.) 1. How often data must be archived 2. Approved storage locations of archived data 3. Approved media for archiving data 4. Roles responsible for archiving data 99. Other (please specify):	

3.2 Physical security storage measures

Purpose – To determine the physical precautions taken to secure personally identifiable health data in storage.

	thable health data in storage.	
56	Are buildings and rooms containing personally identifiable health data locked for both electronic and paper documents? 1. Yes 2. No	
57	What physical security controls are in place to prevent unauthorized access to buildings and rooms containing personally identifiable health data? 1. Window locks 2. Security guard or other authorized staff control access 3. Video monitoring 4. Bars/grills for doors or windows 5. Alarm system 6. No physical security control measures are in place 99. Other (please specify):	
58	Are records maintained that indicate which staff are authorized to access buildings and rooms containing personally identifiable health data? 1. Yes 2. No	
59	Do staff need a user identifier and password to gain access to databases and documents containing personally identifiable health data? 1. Yes 2. No	
60	Are staff required to wear identification badges when accessing and working in rooms containing personally identifiable health data? 1. Yes 2. No	
61	Are records maintained that indicate the date and time that staff accessed rooms containing personally identifiable health data? 1. Yes 2. No	

62	The location used for storing paper-based confidential information is safe from the following (please select all that apply): 1. Risk of fire 2. Risk of flooding 3. Risk of animal or insect damage (such as rodents or insects) 4. Power interruptions 5. Natural disasters 6. Theft	
	7. None of the above The location used for storing computers containing	
63	confidential information is safe from the following (please select all that apply): 1. Risk of fire 2. Risk of flooding 3. Risk of animal damage (such as rodents) 4. Power interruptions 5. Natural disasters 6. Theft 7. None of the above	
64	Are persons who are not authorized to access personally identifiable health data allowed to access rooms that contain the records or data? 1. Yes 2. No	IF "2," GO TO QUESTION 66
65	Are persons who are not authorized to access personally identifiable health data required to provide proper identification to authorized staff before being granted access to rooms containing personally identifiable health data? 1. Yes 2. No	
Purpose	3.3 Inventory management – To determine if there is clear guidance within the policy	regarding

To determine if there is clear guidance within the policy regarding the migration of data to newer technologies

	the inigration of data to newer technologies	
66	What types of identification tags are applied to equipment? (Please select all that apply.) 1. Temporary adhesive labels that are not tamper-proof or tamper-evident 2. Permanent or semi-permanent adhesive labels that are tamper-proof or tamper-evident 3. Engraved metal plate attached to equipment 4. Identification is engraved directly on the equipment surface 5. None 99. Other (please specify):	
67	How are the facility's inventory records for equipment maintained? (Please select all that apply.) 1. Handwritten or typed paper documents 2. Spreadsheet software 3. Database software 4. Asset management software 5. No inventory records are maintained 99. Other (please specify):	IF "5," GO TO QUESTION 69

the cord	How often are the facility's in 1. Continuously—items are inventory record immediate 2. Items are tagged and entitle within 1 month of receipt. 3. Items are tagged and entitle more than 1 month after receipt. 4. Regularly, but not on a second to the second temperature in the
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4. DATA BACKUP

4.1 Computers and laptops Purpose – To determine the physical precautions taken to backup personally identifiable health data on computers

	· · · · · · · · · · · · · · · · · · ·	
69	Are patient data on desktop and laptop computers backed up? 1. Yes 2. No	IF "2," GO TO QUESTION 77
70	How often are patient data on desktop and laptop computers backed up? 1. Immediately when the data are revised 2. Daily 3. Weekly 4. As needed or requested 99. Other (please specify):	
71	Where are backup copies stored? (Please select all that apply.) 1. On the same computer on which data are collected 2. On a central server 3. In cloud-based storage 4. On removable media	
72	Are backup patient data from desktop and laptop computers encrypted? 1. Yes, during the backup process 2. Yes, before creation of the backup 3. No 99. Other (please specify):	
73	When removable media are used for the backup process, are the removable media encrypted? 1. Yes 2. No	
74	How often are backup media for desktop and laptop computers containing patient data transferred to an off-site storage facility? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Annually 6. Never 99. Other (please specify):	IF "6," GO TO QUESTION 77.
75	Are your backups rotated ie. are you backing up the backup? 1. Yes 2. No	

	11 6 11 1 1	
	How often are stored data migrated when newer storage media become available?	
	1. Monthly	
	2. Quarterly	
76	3. Every 6 months	
	4. Annually	
	5. Every 2 years	
	6. No regular migration schedule	
	7. Never	

4.2 Servers

Purpose – To determine the physical precautions taken to secure personally identifiable health data in storage on servers.

3. Yes, using an automated, scheduled process 4. No 99. Other (please specify): Are data periodically migrated to newer backup media as technology changes provide newer methods of storage? 1. Yes 2. No Are data backups migrated when newer storage media become available? 1. Yes 2. No How often are stored data migrated when newer storage media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years		racinimation reality data in storage on servers.	
technology changes provide newer methods of storage? 1. Yes 2. No Are data backups migrated when newer storage media become available? 1. Yes 2. No How often are stored data migrated when newer storage media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years	77	 Yes, by the system administrator as needed or as requested Yes, by the system administrator on a regular schedule Yes, using an automated, scheduled process No 	GO TO QUESTION
become available? 1. Yes 2. No How often are stored data migrated when newer storage media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years	78	technology changes provide newer methods of storage? 1. Yes	GO TO QUESTION
media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years	79	become available? 1. Yes	GO TO QUESTION
7. Never	80	media become available? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years 6. No regular migration schedule	
Are backup media regularly tested to ensure that they can be relied upon in case of emergencies? 1. Yes 2. No	81	be relied upon in case of emergencies? 1. Yes	

4.3 Audit logs

Purpose – To determine the use, review and backup of audit logs

82	Are audit logs created to assist in recording all system transactions? 1. Yes 2. No	IF "2," GO TO QUESTION 92
83	Are audit logs stored separately from the rest of the system that they are monitoring? 1. Yes 2. No	

84	Which of the following data elements are recorded in the audit log? (Please select all that apply.) 1. IP address or MAC address of computer from which action originated 2. User identifier 3. Dates, times and details of key events (e.g. log on and log off) 4. Records of successful and rejected system access attempts 5. Activation and de-activation of protection systems (such as antivirus systems and intrusion detection systems) 6. Files accessed and the kind of access 7. Record identifier 99. Other (please specify):	
85	How often is the audit log reviewed? 1. Real-time, continuous 2. Daily 3. Weekly 4. Only when needed or requested 5. Never 99. Other (please specify):	IF "5," GO TO QUESTION 87
86	Who reviews the audit log? (Please select all that apply.) 1. Data management staff 2. Clinical staff 3. Confidentiality and security officer/information security manager 4. Database administrator 5. Independent auditor 99. Other (please specify):	
87	Are audit logs backed up? 1. Yes 2. No	IF "2," GO TO QUESTION 92
88	How are audit logs backed up? 1. By the system administrator as needed or requested 2. By the system administrator on a regular schedule 3. Using an automated, scheduled process 99. Other (please specify):	
89	How often are audit logs backed up? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 99. Other (please specify):	
90	How often are audit logs of backup data transferred to an off-site storage facility? 1. Daily 2. Weekly 3. As needed or requested 4. Never 99. Other (please specify):	IF "4," GO TO QUESTION 92
91	Are the off-site storage facility for backup media for audit logs locked? 1. Yes 2. No	

5.AUTHORIZATION AND ACCESS CONTROL

5.1 Policy

Purpose – To determine if access to data is clearly defined within the policy and that if security controls are independently validated.

92	Access to data has been defined for the following staff members (please select all that apply): 1. Staff access not defined 2. Medical practitioners 3. Nursing practitioners 4. Public health specialists 5. Other health professionals 6. Information technology staff (including data clerks, analysts, managers and programmers) 7. Administrative staff 8. Professional service providers 9. Volunteers 10. Academic or other researchers 11. Bilateral donor staff 12. Multilateral institution staff (e.g. staff from the Global Fund to Fight AIDS, Tuberculosis and Malaria) 99. Other (please specify):	IF "1," GO TO QUESTION 94
93	Are system security controls independently tested and validated? 1. Yes 2. No	

5.2 User access

Purpose – To determine if levels of access are specified for using data for different purposes.

Which of the following types of data have specified levels			
of access for those professionals with defined access roles? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Public use 6. Not specified 99. Other (please specify):	94	of access for those professionals with defined access roles? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Public use 6. Not specified	

5.3 Passwords

Purpose – To determine if the policy requires user sessions to be locked after certain periods of inactivity

95	Do staff need a user identifier and password to gain access to a computer? 1. Yes 2. No	IF "2," GO TO QUESTION 112
96	How are user identifiers generated? 1. By the computer operating system 2. By the computer software application 3. By a system administrator, with user identifier composition rules 4. By a system administrator, without user identifier composition rules 5. By information security manager 99. Other (please specify):	

97	Is the password file encrypted? 1. Yes 2. No	
98	Are there established procedures to verify the identity of a user prior to providing a new, replacement or temporary password? 1. Yes 2. No	
99	How are user identifiers and passwords issued to users? (Please select all that apply.) 1. In person 2. By telephone 3. Through e-mail 99. Other (please specify):	
100	After what period of inactivity are user identifiers disabled? 1. 14 days 2. 30 days 3. 60 days 4. 90 days 5. 180 days 6. 360 days 7. Not disabled 99. Other (please specify):	
101	When a staff member's employment is terminated, are there procedures for revoking access to personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 103.
102	When a staff member's employment is terminated, when are data access privileges revoked? 1. Immediately upon termination via an automated process 2. Within a week 3. Within a month 99. Other (please specify):	
103	Are user sessions automatically locked after a certain specified period of inactivity for software applications that contain personally identifiable health data? 1. Yes 2. No	
104	What is the minimum password length? 1. 6 or fewer characters 2. 7–8 characters 3. 9 or more characters 4. No minimum password length	
105	Does the system enforce specifications for passwords, such as a combination of a minimum number of lower-case letters, upper-case letters, numbers and special characters? 1. Yes 2. No	
106	Are passwords masked when entered into computer applications? 1. Yes 2. No	

107	Which of the following is the minimum time that you change passwords? 1. Less than 1 day 2. 1–7 days 3. 8–14 days 4. 15–30 days 5. More than 30 days 6. No minimum time	
108	Is a password reset mechanism established for computers and computer software applications that contain personally identifiable health data? 1. Yes—upon password expiration only 2. Yes—can be initiated by the user before the password expires (such as at the first given indication of a possible security breach) 3. No	If "3," GO TO QUESTION 110
109	How is the reset password provided to the user? (Please select all that apply.) 1. Through e-mail 2. By telephone 3. In person 99. Other (please specify):	
110	Is reusing passwords prohibited for a specific number of generations (i.e. a certain number of passwords cannot be reused)? 1. Yes 2. No	
111	Are biometrics or other technologies (e.g. fingerprint verification, signature verification, hardware tokens or smart cards) being used for user identification and authentication? 1. Yes 2. No	

6. DATA RELEASE

6.1 Policy

Purpose – To determine if the policy contains a detailed release section.

112	Do you have written guidelines for the data release policy? 1. Yes 2. No	IF "2," GO TO QUESTION 114
113	Which of the following information is included in the data release policy? (Please select all that apply.) 1. Class of use for which data may be released (e.g. individual health care or public health practice) 2. Specific data elements that may be released 3. Entities and organizations to whom data may be released 4. Requirements for how recipients will protect the confidentiality of received data 5. Specifications for time limitations on use of released data 6. Data quality standards that must be met prior to data release 7. Clearly defined individual(s) who are authorized to release data 8. Clear procedures for handling data requests that are not covered under the data release policy 99. Other (please specify):	

6.2 Mandatory requirements for data release Purpose – To determine the extent to which the policy covers requirements and conditions in terms of the release of data.

114	According to the Data Confidentiality and Security Policy, for what purpose may personally identifiable health data be released? (Please select all that apply.) 1. Not specified in the Data Confidentiality and Security Policy 2. Individual health care 3. Public health practice (including monitoring and evaluation) 4. Human subject research (with consent) 5. Exceptional statutory purposes 6. Public use 99. Other (please specify):	IF "1,"GO TO QUESTION 127. IF "2," GO TO QUESTION 115. IF "3," GO TO QUESTION 118. IF "4," GO TO QUESTION 121.
115	When is the release of personally identifiable health data for individual health care permitted? (Please select all that apply.) 1. Authorized transfer of patient across facilities 2. Authorized transfer between clinical services 3. Request from patient 4. Not specified 99. Other (please specify):	ANSWER ONLY IF #2 WAS CHOSEN FOR QUESTION 114

116	Which of the following conditions must be met before releasing personally identifiable health data for individual health care? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify that the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	
117	Which of the following conditions must be met by the organization receiving personally identifiable health data in order for data to be release for individual health care? (Please select all that apply.) 1. Signed confidentiality statements by recipient facility staff 2. Documentation of security training of recipient facility staff 3. Evidence of security assessment (eg. review of procedural, electronic and physical security controls) 4. Documentation of internal steering group review and approval 5. Agreement by the recipient to destroy information after the purpose of the data release been fulfilled 6. Assurance that the minimum amount of data needed to satisfy the purpose is being requested 7. Not specified 99. Other (please specify):	
118	When is the release of personally identifiable health data for public health practice permitted? (Please select all that apply.) 1. Not specified 2. Regulation of public health policy 3. Public health program planning 4. National reporting 99. Other (please specify):	ANSWER ONLY IF #3 WAS CHOSEN FOR QUESTION 114
119	Which of the following conditions must be met before releasing personally identifiable health data for public health practice? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify that the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	

120	What requirements must be met by the organization receiving personally identifiable health data in order for data release to be authorized for public health practice? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (review of procedural, electronic and physical security controls) 4. Review and approval by the internal steering group 5. Agreement to destroy information after purpose of data release has been fulfilled 6. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 7. Not specified 99. Other (please specify):	
121	When is the release of personally identifiable health data for human subject research (with consent) permitted? (Please select all that apply.) 1. Ethics committee or IRB review and approval 2. Not specified 99. Other (please specify):	ANSWER ONLY IF #4 WAS CHOSEN FOR QUESTION 114
122	Which of the following conditions must be met before releasing personally identifiable health data for human subject research (with consent)? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Acquisition of formal approval for the data release 5. Not specified 99. Other (please specify):	
123	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for human subject research (with consent)? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (review of procedural, electronic and physical security controls) 4. Proof of ethics or IRB research review and approval 5. Review of a scientific protocol by an internal steering group 6. Agreement to destroy information after the purpose of the data release has been fulfilled 7. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 8. Not specified 99. Other (please specify):	

124	When is the release of personally identifiable health data for exceptional statutory purposes permitted? (Please select all that apply.) 1. Court order 2. Subpoena 3. Request from law enforcement agency 4. Request from prosecuting attorneys 5. Request from defense attorneys 6. Request from a health-care practitioner providing treatment for a health-care worker or a law enforcement officer because of a medically significant exposure to blood or body fluids 7. Not specified 99. Other (please specify):	ANSWER ONLY IF #5 WAS CHOSEN FOR QUESTION 114
125	Which of the following conditions must be met before releasing personally identifiable health data for exceptional statutory purposes? (Please select all that apply.) 1. Reviews of data for accuracy 2. Removal of direct patient identifiers from released records 3. Acquisition of formal approval for data release 4. Not specified 99. Other (please specify):	
126	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for exceptional statutory purposes? (Please select all that apply.) 1. Review and approval of request by legal counsel 2. Review and approval of request by Confidentiality Security Officer (or equivalent official) 3. Review and approval by internal steering group 4. Signed confidentiality statements from persons receiving data 5. Documentation of security training 6. Medical record release signed by patient 7. Medical record release signed by the patient's attorney 8. Security assessment (review of procedural, electronic and physical security controls) 9. Agreement to destroy information after purpose of data release has been fulfilled 10. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 11. Not specified 99. Other (please specify):	

7. TRANSMISSION SECURITY

7.1 Routers

Purpose - To determine the extent to which the policy covers router usage.

127	Is a router that controls information flow between the local area network and the Internet or other networks installed? 1. Yes 2. No	IF "2," GO TO QUESTION 131
128	Which of the following are characteristics of the router configuration? (Please select all that apply.) 1. Enables password protection 2. Limits router access to named users or user groups through command privilege levels 3. Displays banner indicating ownership of the system and that unauthorized access is prohibited 4. Disables unnecessary services 5. Prevents internal IP addresses from being revealed 6. Enables logging of access, including source IP address and the date, time and description of access 7. Accesses lists that contain information to deny or allow traffic by IP address or group 8. Turns off incoming IP-directed broadcasts (IP packets that are sent to a particular network or group of networks) 99. Other (please specify):	
129	How often are router logs reviewed? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. As needed or requested 6. Never 99. Other (please specify):	
130	Who reviews and provides oversight of the router logs? (Please select all that apply.) 1. Internal IT staff, manually 2. Internal IT staff, using log analysis software 3. Independent auditor 99. Other (please specify):	

7.2 Firewalls

Purpose – To determine the extent to which the policy covers procedures for protecting data in terms of firewalls.

	i	
131	Are firewalls installed on computers, servers and networks? 1. Yes 2. No	
132	Which of the following are characteristics of the installed firewalls? (Please select all that apply.) 1. Apply a security level in accordance with the type of network 2. Block intrusion attempts (from wireless networks [Wi-Fi], hackers, etc.) 3. Specify which software application can access the network or the Internet 4. Block access of specified software applications 5. Offer outbound protection to control information that leaves the computer 6. Others (please specify):	

133	How often are computers, servers and network firewall logs reviewed? 1. Real-time, continuous 2. Daily 3. Weekly 4. Monthly 5. Quarterly 6. As needed or requested 7. Never 99. Other (please specify):	
134	Who reviews computer, server or network firewall logs? (Please select all that apply.) 1. Internal IT staff, manually 2. Internal IT staff, using log analysis software 3. Independent auditor 4. No one is assigned to review firewall logs 99. Other (please specify):	
135	Which of the following are included in computer, server or network firewall audits? (Please select all that apply.) 1. Review rule sets 2. Review accounts 3. Ensure that logging is enabled and that the logs are reviewed periodically 4. Ensure that the latest patches and updates are tested and installed 5. Ensure that specific IP addresses are blocked 6. Ensure that specific ports are blocked 7. Perform vulnerability and penetration testing 8. No firewall audits are performed 99. Other (please specify):	

7.3 Antivirus on computers Purpose – To determine the extent to which the policy requires electronic systems containing personally identifiable health data, to use antivirus software.

136	Is antivirus software installed on desktop and laptop computers containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 141
137	How often is antivirus software updated on desktop and laptop computers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. Never 99. Other (please specify):	
138	When are individual files scanned on desktop or laptop computers containing personally identifiable health data? (Please select all that apply.) 1. As scheduled 2. When moved, copied, opened or saved 3. When downloaded 4. Only as part of a scheduled system scan 99. Other (please specify):	

139	How often is the operating system scanned by antivirus software on desktop and laptop computers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	
140	How often are removable media connected to desktop or laptop computers that contain personally identifiable health data scanned by antivirus software? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	

7.4 Antivirus on servers

Purpose – To determine the extent to which the policy requires servers containing personally identifiable health data, to use antivirus software.

	, , , , , , , , , , , , , , , , , , , ,	
141	Is antivirus software installed on servers? 1. Yes 2. No	IF "2," GO TO QUESTION 146
142	How often is antivirus software updated on servers containing personally identifiable health data? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	
143	When are individual files scanned on servers containing personally identifiable health data? 1. As scheduled 2. When moved, copied, opened or saved 3. When downloaded 4. Only as part of a scheduled system scan 99. Other (please specify):	
144	How often is the operating system on servers containing personally identifiable health data scanned by antivirus software? 1. Real-time, continuous 2. Daily 3. Weekly 4. As needed or requested 5. At computer start-up 6. Never 99. Other (please specify):	

5. At computer start-up	145	How often are all drives containing personally identifiable health data and connected to server(s) scanned by antivirus software? 1. Real-time, continuous 2. Daily 3. Weekly	
·	145		
0.110.0.		5. At computer start-up6. Never	
99. Other (please specify):		99. Other (please specify):	

7.5 Transfer of paper data

Purpose – To determine the physical precautions taken to store and transfer personally identifiable health data in paper format.

How often are data on paper transferred to an off-site storage facility? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Annually 6. Never 99. Other (please specify): Which of the following security controls are implemented to ensure the security of paper-based data when they are being transferred within a facility or to an off-site storage facility? (Please select all that apply.) 1. A list of approved transport providers (such as site staff, courier services, and government and private postal services) 2. A locked container for transferring or transporting the paper-based data 3. A tamper-proof seal for the container used for transferring or transporting paper-based data 4. A transfer log that identifies the records being transferred, the sender, the recipient, the delivery person, and all relevant dates and times 5. Authentication of the identity of the recipient on delivery 6. Verification of the success of delivery 99. Other (please specify):		La caracteristic de la car	
to ensure the security of paper-based data when they are being transferred within a facility or to an off-site storage facility? (Please select all that apply.) 1. A list of approved transport providers (such as site staff, courier services, and government and private postal services) 2. A locked container for transferring or transporting the paper-based data 3. A tamper-proof seal for the container used for transferring or transporting paper-based data 4. A transfer log that identifies the records being transferred, the sender, the recipient, the delivery person, and all relevant dates and times 5. Authentication of the identity of the recipient on delivery 6. Verification of the success of delivery	146	storage facility? 1. Daily 2. Weekly 3. Monthly 4. Quarterly 5. Annually 6. Never	
	147	Which of the following security controls are implemented to ensure the security of paper-based data when they are being transferred within a facility or to an off-site storage facility? (Please select all that apply.) 1. A list of approved transport providers (such as site staff, courier services, and government and private postal services) 2. A locked container for transferring or transporting the paper-based data 3. A tamper-proof seal for the container used for transferring or transporting paper-based data 4. A transfer log that identifies the records being transferred, the sender, the recipient, the delivery person, and all relevant dates and times 5. Authentication of the identity of the recipient on delivery 6. Verification of the success of delivery	

7.6 Transmission of electronic data

Purpose - To determine the physical precautions taken to transfer personally identifiable health data electronically

148	Does your site store electronic records containing personally identifiable health data? 1. Yes 2. No	IF "2," GO TO QUESTION 154
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149	What methods or media are used to transfer electronic data within sites? (Please select all that apply.) 1. Intranet, local area network and/or wide area network 2. E-mail 3. Internet (via web browser) 4. File transfer protocol (FTP) 5. Tape 6. Optical media (CD or DVD) 7. Flash drive or memory stick 8. External hard drive 9. Smart card 10. None of the above 99. Other (please specify):	
150	What controls are implemented to ensure the security of electronic data when they are being moved within a site? (Please select all that apply.) 1. Authentication of the identities of the sender and receiver before information transfer 2. Password-protected data files (with or without encryption) 3. Encryption of the information during transfer 4. Post-transfer verification of the appropriate and successful transfer of information 5. None of the above 99. Other (please specify):	
151	What methods or media are used to transfer electronic data between sites? 1. Intranet, local area network or wide area network 2. E-mail 3. Internet (via web browser) 4. File transfer protocol (FTP) 5. Tape 6. Optical media (CD or DVD) 7. Flash drive or memory stick 8. External hard drive 9. Smart card 99. Other (please specify):	
152	For which of the following transfer methods or media and transfer types is encryption used when data are in transit within the site? (Please select all that apply.) 1. Not used 2. Intranet, local area network or wide-area network 3. E-mail 4. Internet (via web browser) 5. File transfer protocol (FTP) 6. Tape 8. Optical media (CD or DVD) 9. Flash drive or data stick 10. External hard drive 11. Smart card 99. Other (please specify):	
153	When transferring data, which methods are used to authenticate sending and receiving parties? (Please select all that apply.) 1. Sending and receiving parties are not authenticated 2. Two-factor authentication (TFA) 3. Public key infrastructure (PKI) 99. Other (please specify):	

8. DATA DISPOSAL

Purpose - to determine the extent to which the policy covers secure retirement and disposal of data

	ment and disposal of data	
154	Do you have written guidelines for the secure disposal and destruction of data? 1. Yes 2. No	
155	Do you maintain a data retirement schedule for destroying records when they are no longer needed? 1. Yes 2. No	IF "2," THE DATA WAREHOUSE SECTION IS COMPLETE
156	Which types of records are addressed in the data retirement schedule? (Please select all that apply.) 1. Paper records 2. Backup copies of paper records 3. Electronic record 4. Backup copies of electronic records 99. Other (please specify):	
157	Which method(s) of destruction or disposal are used? (Please select all that apply.) 1. Burning 2. Demagnetizing 3. Overwriting 4. Pulping 5. Pulverizing, crushing or grinding 6. Reformatting 7. Shredding 99. Other (please specify):	
158	Do you maintain documentation of the secure destruction or disposal of the records (such as a certification or verification of destruction)? 1. Yes 2. No	IF "2," THE DATA WAREHOSE ASSESSMENT IS COMPLETE
159	What information must be included in the documentation of the secure destruction or disposal of the records? (Please select all that apply.) 1. Organization 2. Organization contact 3. Date of destruction or disposal 4. Name and signature of person who authorized destruction or disposal of data 5. Description of information destroyed or disposed of, including type (paper or electronic) 6. Time period covered by the records to be destroyed 7. Methods of destruction or disposal (e.g. burning, demagnetizing, overwriting, pulping, pulverizing, reformatting or shredding) 8. Name and signature of person who destroyed or disposed of data 9. Name and signature of person who witnessed destruction or disposal of data 10. Copy of contract with outside firm handling the destruction or disposal of data 99. Other (please specify):	

3.3 Policy-level Assessment Tool

The following policy–level questions will help determine the security, confidentiality and appropriate use (including sharing) of data that are collected by health programs.

The questions are grouped into the following six areas:

- 1. Governance and policy
- 2. Data storage
- 3. Authorization and access control
- 4. Data release
- 5. Transmission security
- 6. Data disposal

	RECOMMENDED POLICY-LEVEL QUESTIONS	
Category	Question	Instruction

1. GOVERNANCE AND POLICY

1.1. Legislation

Purpose – To determine the existence and extent of legislation covering the use of personally identifiable health data for public health practice and research.

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Does legislation exist that covers the use of personally identifiable health data for public health practice? 1. Yes 2. No	IF "2," GO TO QUESTION 3	
Does this legislation indicate the circumstances under which explicit individual consent is required when using personally identifiable health data for public health practice? 1. Yes 2. No		
Does legislation exist that covers the use of personally identifiable health data for human subject research? 1. Yes 2. No	IF "2", GO TO QUESTION 5	
Does this legislation indicate the circumstances under which explicit individual consent is required when using personally identifiable health data for human subject research? 1. Yes 2. No		
	Does legislation exist that covers the use of personally identifiable health data for public health practice? 1. Yes 2. No Does this legislation indicate the circumstances under which explicit individual consent is required when using personally identifiable health data for public health practice? 1. Yes 2. No Does legislation exist that covers the use of personally identifiable health data for human subject research? 1. Yes 2. No Does this legislation indicate the circumstances under which explicit individual consent is required when using personally identifiable health data for human subject research? 1. Yes	

1.2 Policy

Purpose - To determine the existence, accessibility, distribution, development process and review, of a written policy document ensuring the confidentiality and security of personally identifiable health data.

	and security of personally factionable ficultificates.	
5	Does a written policy document regarding the requirements for ensuring the confidentiality and security of personally identifiable health data exist in this country (referred to as the "Data Confidentiality and Security Policy" or "the Policy")? 1. Yes (if written documentation is determined to exist, identify the appropriate staff to answer this module) 2. No, but a policy is in the process of development 3. No, but various informal policies exist 4. No, we do not have any policy or written guidelines	IF "2,""3" OR "4" GO TO QUESTION 15
6	What areas of the data life cycle does the Data Confidentiality and Security Policy cover? (Please select all that apply.) 1. Collection 2. Storage 3. Backup 4. Use 5. Transmission 6. Release 7. Disposal 8. Breach investigation 9. Training	

7	Does the Data Confidentiality and Security Policy define the roles and access levels of all persons with authorized access to personally identifiable health data? 1. Yes 2. No	
8	Does the Data Confidentiality and Security Policy describe which standard procedures or methods will be used when accessing personally identifiable health data? 1. Yes 2. No	
9	Is the Data Confidentiality and Security Policy readily accessible to all staff members who have access to confidential individual-level data? (By "readily accessible," we mean that staff can easily access the policy online or in hard copy while at work.) 1. Yes 2. No	
10	To which stakeholders or organizations has the Data Confidentiality and Security Policy document been distributed? (Please select all that apply.) 1. Ministry to health staff at the national level 2. Health staff at provincial or state facilities 3. District level health facility staff 4. Local health facilities 5. Academic researchers 6. Staff from donor organizations 7. Multilateral institution staff (e.g. The Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank or United Nations organizations) 8. Policy document is not distributed 99. Other (please specify):	
11	In which of the following formats is the Data Confidentiality and Security Policy document available? 1. Printed 2. Electronic, distributed via e-mail 3. Electronic, distributed via CD or other media 4. Electronic, available on the Internet (please specify the URL): 99. Other (please specify):	
12	Which of the following stakeholders were involved in the development of the policy document? (Please select all that apply.) 1. Medical practitioners 2. Nursing practitioners 3. Public health specialists 4. Other health professionals 5. Information technology specialists (e.g. data entry staff, analysts, managers and programmers) 6. Patient advocacy groups 7. Legal expert 8. Human rights advocates 9. Government officials 10. Business representatives 11. Cleaners, security guards and other providers of support services 12. Ethicists 13. Not developed with stakeholders 99. Other (please specify):	

13	Does the policy require periodic review of the policy document? 1. Yes 2. No	IF "2," GOTO QUESTION 15
14	How often is the policy document reviewed? 1. Every year 2. Every 1–2 years 3. Every 3–5 years 4. Every 5–10 years 5. Not reviewed at regular intervals 99. Other (please specify):	

1.3 Governance structure

Purpose – To determine the governance structure that is in place to provide oversight for the appropriate collection, use, and dissemination of data, including regular review of the policy document and security practices.

	ing regular review of the policy document and security pr	actices.
15	Is there is a governance structure (e.g. steering committee or advisory board) in place to provide oversight for the appropriate collection, use and dissemination of data, including the regular review of the policy document and security practices? 1. Yes 2. No 99. Other (please specify):	IF NO, GO TO QUESTION 18
16	The governance structures are present at the following levels (please select all that apply): 1. National level 2. State or provincial level 3. District level 4. Facility level	
17	How often does the steering committee or advisory board meet? 1. Monthly 2. Quarterly 3. Every 6 months 4. Annually 5. Every 2 years 6. No regular meeting schedule	
18	Which uses of personally identifiable health data are covered by the Data Confidentiality and Security Policy? (Please select all that apply.) 1. Individual health care 2. Public health practice (including monitoring and evaluation) 3. Human subject research (with consent) 4. Exceptional statutory purposes 5. Not specified 99. Other (please specify):	
19	Is information security and its management reviewed at regular intervals? 1. Yes 2. No	

1.4 Review of security practices Purpose – To determine the security practice and review as documented in the policy

20	Are security practices reviewed by independent auditors? 1. Yes 2. No	IF "2," GO TO QUESTION 22
21	How often do independent auditors review security practices? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Not specified 99. Other (please specify):	
22	Is the Data Confidentiality and Security Policy regularly updated for technological advancements (such as databases, web servers, e-mail clients, encryption, firewalls, file servers, backup devices and portable storage devices)? 1. Yes 2. No	IF "2," GO TO QUESTION 24
23	How often are software and hardware technologies reviewed? 1. Every year 2. Every 1–2 years 3. Every 3–5 years 4. Not reviewed at regular intervals	

1.6 Responsibilities and training Purpose – To determine the responsibilities and training required as documented in the policy.

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24	Does the Policy state that staff must repeat the review and signing of the confidentiality statement indicating their understanding of the policies and their agreement to implement them? 1. Yes 2. No	IF "2," GO TO QUESTION 26.
25	How often does the Policy state that staff must repeat the review and signing of the confidentiality statement? 1. Every year 2. Every 1–2 years 3. Every 2+ years 4. Never 99. Other (please specify):	
26	Is it a requirement that the Data Confidentiality and Security Policy (or pertinent parts thereof) be shared with patients in facilities that are collecting personally identifiable data? 1. Yes 2. No	IF "2," GO TO QUESTION 28.
27	How is the Data Confidentiality and Security Policy shared with patients? 1. Available on website, but not explicitly shared 2. Provided upon request 3. Provided to all patients as a hard copy or a link to the website as a matter of practice 99. Other (please specify):	

28	Does the policy require organizations to designate an information security manager? 1. Yes 2. No	IF "2," GO TO QUESTION 30.
29	Is there a written description of the information security manager's responsibilities? 1. Yes 2. No	

1.6 Monitoring, detecting and responding to security breaches Purpose – To determine the ability to identify and manage security breaches as documented in the policy.

	1. Yes 2. No	32
31 re 5 6 7 8	The following are included in the policy for responding to security breaches (please select all that apply): 1. Purpose and objectives of the policy 2. Definition of a security breach 3. Consequences of a security breach 4. Organizational structure and delineation of roles, esponsibilities and levels of authority 5. Requirements for reporting security breaches 6. Prioritization or severity ratings of security breaches 7. Performance measures 8. Reporting and contact forms 89. Other (please specify):	

1.7 Conducting risk assessments Purpose – To determine the presence and scheduling of risk assessments documented in the policy.

32	Are risk assessments mandated under the Data Confidentiality and Security Policy? 1. Yes 2. No	IF "2," GO TO QUESTION 34
33	How often are risk assessments mandated as per the Policy? 1. Every year 2. Every 1–2 years 3. Every 2+ 99. Other (please specify):	

1.8 Connectivity to other networks Purpose – To determine the presence of networks and connectivity permissions and methods.

34	Does the Policy have a position on facility and data aggregation point computers being connected to more than one network? 1. Yes 2. No	IF "2," GO TO QUESTION 37
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35	Which of the following methods are permitted for connecting computers in facilities and data aggregation and management points to more than one network? (Please select all that apply across all facilities.) 1. Virtual private network (VPN) 2. Remote desktop software that uses virtual network computing (VNC)/remote frame buffer protocol (RFB) 3. Remote desktop software that uses remote desktop protocol (RDP) 4. Remote desktop software that uses another protocol (AIP, NX, X11 or proprietary) 5. Multiple network interface cards (NIC) 6. Network bridge 99. Other (please specify):	
36	Is built-in encryption mandated by the Data Confidentiality and Security Policy for all methods of connecting to other networks that can be used by facilities and data aggregation and management points? 1. Yes 2. No	
	2. DATA STORAGE	
2.1 Policy Purpose – To determine if there are clear guidelines in terms of data archival within the policy.		
37	Does the Data Confidentiality and Security Policy have clear guidelines/SOPs on archiving data? 1. Yes 2. No	IF "2," GO TO QUESTION 39
38	Which of the following are included in the guidelines/ SOPs on archiving data? (Please select all that apply.) 1. How often data must be archived 2. Approved storage locations of archived data 3. Approved media for archiving data 4. Roles responsible for archiving data 99. Other (please specify):	
2.2 Inventory management Purpose – To determine if there is clear guidance within the policy regarding the migration of data to newer technologies		garding the
39	Does the Data Confidentiality and Security Policy require that data be periodically migrated to newer technologies as they become available? 1. Yes 2. No	

3. AUTHORIZATION AND ACCESS CONTROL

3.1 Policy

Purpose – to determine the existence, accessibility, distribution, development process and review of a written policy document ensuring the confidentiality and security of personally identifiable health data

	and security of personally identifiable health data	
40	Access to data have been defined for following staff members (please select all that apply): 1. Staff access not defined 2. Medical practitioners 3. Nursing practitioners 4. Public health specialists 5. Other health professionals 6. Information technology staff (including data clerks, analysts, managers and programmers) 7. Administrative staff 8. Professional service providers 9. Volunteers 10. Academic or other researchers 11. Cleaners, security guards and other providers of support services 12. Bilateral donor staff 13. Multilateral institution staff (e.g. staff from the Global Fund to Fight AIDS, Tuberculosis and Malaria) 99. Other (please specify):	IF "1," GO TO QUESTION 41
41	Does the Data Confidentiality and Security Policy require that system security controls be independently validated? 1. Yes 2. No	
	3.2 User access	
42	For roles that are defined as having access to data, are levels of access specified for using data for different purposes (e.g. individual health care or public health practice)? 1. Yes 2. No	
3.3 Passwords Purpose – To determine if the policy requires user sessions to be locked after certain periods of inactivity.		
43	Does the Data Confidentiality and Security Policy require user sessions to be locked after a certain specified period of inactivity on software applications that contain personally identifiable health data? 1. Yes	

2. No

4. DATA RELEASE

4.1 Policy

Purpose – To determine if the policy contains a detailed release section.

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44	Does your Data Confidentiality and Security Policy contain a data release section? 1. Yes 2. No	IF "2," GO TO QUESTION 46
45	Which of the following information is included in the data release section? (Please select all that apply.) 1. Class of use for which data may be released (e.g. individual health care or public health practice) 2. Specific data elements by which data may be released 3. Entities or organization to whom data may be released 4. Requirements for how recipients will protect confidentiality of received data 5. Specifications for time limitations on use of released data 6. Data quality standards that must be met prior to data release 7. Clearly defined individual(s) who are authorized to release data 8. Clear procedures for handling data requests that are not covered under the data release policy 99. Other (please specify):	

4.2 Mandatory requirements for data release Purpose – To determine the extent to which the policy covers requirements and conditions in terms of the release of data.

and conditions in terms of the release of data.		
46	According to the Data Confidentiality and Security Policy, for what purpose may personally identifiable health data be released? (Please select all that apply.) 1. Not specified in the Data Confidentiality and Security Policy 2. Individual health care 3. Public health practice (including monitoring and evaluation) 4. Human subject research (with consent) 5. Exceptional statutory purposes 6. Public use 99. Other (please specify):	IF "1," GO TO QUESTION 59. IF "2," GO TO QUESTION 47. IF "3," GO TO QUESTION 50. IF "4," GO TO QUESTION 53. IF "5,"
		GO TO QUESTION 56.
47	When is the release of personally identifiable health data for individual health care permitted? (Please select all that apply). 1. Authorized transfer of patient across facilities 2. Authorized transfer between clinical services 3. Request from patient 4. Not specified 99. Other (please specify):	ANSWER ONLY IF #2 WAS CHOSEN FOR QUESTION 46

48	Which of the following conditions must be met before releasing personally identifiable health data for individual health care? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify that the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	
49	Which of the following conditions must be met by the organization receiving personally identifiable health data in order for data release to be authorized for individual health care? (Please select all that apply.) 1. Signed confidentiality statements from staff at recipient facility 2. Documentation of security training for staff at recipient facility 3. Evidence of security assessment (eg. review of procedural, electronic and physical security controls) 4. Documentation of internal steering group review and approval 5. Agreement by recipient to destroy information after purpose of data release has been fulfilled 6. Undertaking that the minimum amount of data needed to satisfy the purpose is being requested 7. Not specified 99. Other (please specify):	
50	Under what circumstances is the release of personally identifiable health data for public health practice permitted? (Please select all that apply.) 1. Not specified 2. Regulation of public health policy 3. Public health program planning 4. National reporting 99. Other (please specify):	ANSWER ONLY IF #3 WAS CHOSEN FOR QUESTION 46
51	Which of the following conditions must be met before releasing personally identifiable health data for public health practice? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Documentation of the review of a request to verify the minimum amount of data needed to satisfy the purpose is being released 5. Acquisition of formal approval for the data release 6. Not specified 99. Other (please specify):	

52	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for public health practice? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (eg. review of procedural, electronic and physical security controls) 4. Review and approval by internal steering committee 5. Agreement to destroy information after purpose for data release has been fulfilled 6. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 7. Not specified 99. Other (please specify):	
53	Under what circumstances is the release of personally identifiable health data for human subject research permitted? (Please select all that apply.) 1. Ethics committee or IRB review and approval 2. Not specified 99. Other (please specify):	ANSWER ONLY IF #4 WAS CHOSEN FOR QUESTION 46
54	Which of the following conditions must be met before releasing personally identifiable health data for human subject research? (Please select all that apply.) 1. Verification that patient consent was obtained 2. Confirmation that data have been reviewed for accuracy 3. Removal of direct patient identifiers from released records 4. Acquisition of formal approval for the data release 5. Not specified 99. Other (please specify):	
55	What requirements must be met by the organization that is receiving personally identifiable health data in order for data release to be authorized for human subject research? (Please select all that apply.) 1. Signed confidentiality statements 2. Documentation of security training 3. Security assessment (eg. review of procedural, electronic and physical security controls) 4. Proof of ethics or IRB research review and approval 5. Review of a scientific protocol by an internal steering group 6. Agreement to destroy information after the purpose for the data release has been fulfilled 7. Review of request to verify the minimum amount of data needed to satisfy the purpose 8. Not specified 99. Other (please specify):	

56	When is the release of personally identifiable health data for exceptional statutory purposes permitted? (Please select all that apply.) 1. Court order 2. Subpoena 3. Request from law enforcement agency 4. Request from prosecuting attorneys 5. Request from defense attorneys 6. Request from a health-care practitioner providing treatment for a health-care worker or law enforcement officer because of a medically significant exposure to blood or body fluids 7. Not specified 99. Other (please specify):	ANSWER ONLY IF #5 WAS CHOSEN FOR QUESTION 46
57	Which of the following conditions must be met before releasing personally identifiable health data for exceptional statutory purposes? (Please select all that apply.) 1. Review of data for accuracy 2. Removal of direct patient identifiers from released records 3. Acquisition of formal approval for the data release 4. Not specified 99. Other (please specify):	
58	What requirements must be met by the organization that is receiving personally identifiable health the data in order for data release to be authorized for exceptional statutory purposes? (Please select all that apply.) 1. Review and approval of request by legal counsel 2. Review and approval of request by confidentiality and security officer (or equivalent official) 3. Review and approval by internal steering group 4. Signed confidentiality statements from persons receiving data 5. Documentation of security training 6. Medical record release signed by patient 7. Medical record release by patient's attorney 8. Security assessment (eg. review of procedural, electronic and physical security controls) 9. Agreement to destroy information after purpose of data release has been fulfilled 10. Request reviewed to verify the minimum amount of data needed to satisfy the purpose 11. Not specified 99. Other (please specify):	

5. TRANSMISSION SECURITY					
5.1 Routers: Purpose – To determine the extent to which the policy covers router usage.					
59	Does the Data Confidentiality and Security Policy require that facilities and other data compilation and management points install a router that controls the flow of information between the local area network and the Internet or other networks? 1. Yes 2. No				
5.2 Firewalls Purpose – To determine the extent to which the policy covers procedures for protecting data in terms of firewalls.					
60	Does the Data Confidentiality and Security Policy require that systems that are exposed to the Internet have procedures in place for protecting data (firewalls)? 1. Yes 2. No				
5.3 Antivirus on Computers Purpose – To determine the extent to which the policy requires electronic systems containing personally identifiable health data, to use antivirus software.					
61	Does the Data Confidentiality and Security Policy require electronic systems containing personally identifiable health data to use antivirus software? 1. Yes 2. No				
5.4 Antivirus on Servers Purpose – To determine the extent to which the policy requires servers containing personally identifiable health data, to use antivirus software.					
62	Does the Data Confidentiality and Security Policy require servers containing personally identifiable health data to use antivirus software? 1. Yes 2. No				
	6. DATA DISPOSAL				
Purpose	- to determine the extent to which the policy covers second ment and disposal of data.	ure retire-			
64	Is there a written policy on the secure disposal and destruction of paper-based and electronic personally identifiable health data? 1. Yes 2. No				
65	Does the Data Confidentiality and Security Policy require that facilities and data compilation and aggregation points maintain a data retirement schedule for destroying records that are no longer needed? 1. Yes 2. No				

66	Does the Data Confidentiality and Security Policy require that documentation (such as a certification or verification of destruction) be produced for the secure destruction or disposal of paper-based and electronic records that contain personally identifiable health data?	
	1. Yes	
	2. No	



