

Automating Risk Assessment

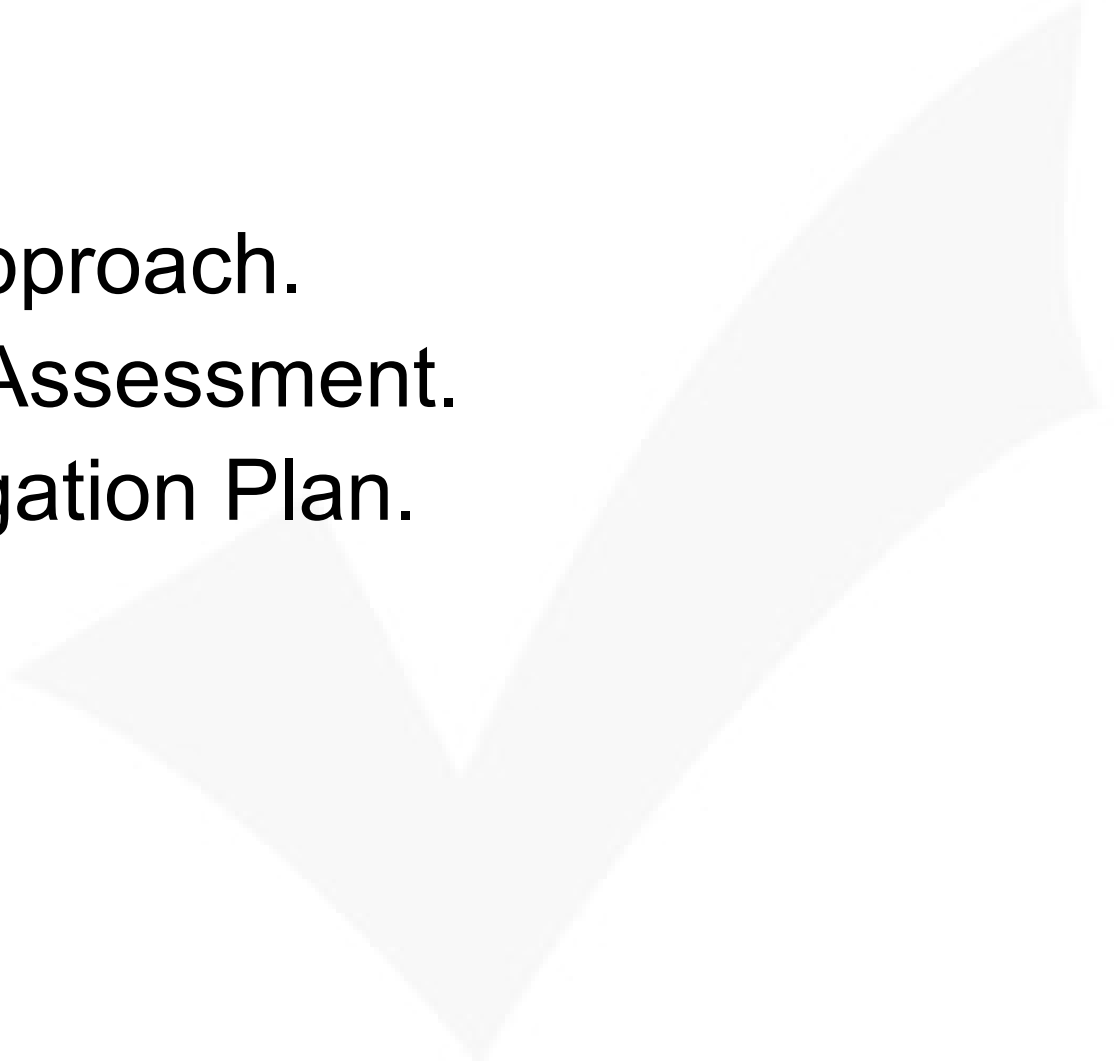
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www.mediregs.com

A Simple Framework

- Set Scope.
- Determine Approach.
- Execute the Assessment.
- Develop Mitigation Plan.
- Monitor.



Set Scope



Determine Approach

Structure

- Trial/Grant
- Departmental
- Process
- Topic

Tools

- Checklists
- 1-1 interviews
- Group interview
- Electronic data gathering/interviews
- What If exercises
- Scenario modeling
- Hazard Assessment

Determine Approach

- Probability
 - High, Medium, Low
 - Imminent, Probable, Possible, Unlikely
 - Scary, Unfortunate, Who Cares
- Impact
 - High, Medium, Low
 - Multivariate
 - Financial, Clinical, Reputational, Political

Determine Approach: Targeting

- Administration
- Researchers
- Vendors
- Partners
- Participants



Execute- General or Program Specific

[Home](#) |
 [RAM](#) |
 [Question Manager](#) |
 [Analysis](#) |
 [Admin](#) |
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Administrative Level: Global Admin |
 Home Page Setting: Dept Head Entity Manager Global Admin
Administrator Name: Ncura Test

Action Plans

- [Dept Head Level](#)

Test Hospital One

View Question Set	Total	Complete	Research	Action
Association for the Accreditation of Human Research Protection Programs	10	10	0	Review all
Assurances	5	5	0	Review all
Blood Borne Pathogens	76	2	0	Resume# 3 Review
Chemical Hygiene Plan	32	7	0	Resume# 8 Review
Clinical Monitoring	24	24	0	Review all
Clinical Trial Prerequisites	10	10	0	Review all
Conflicts of Commitment	10	10	0	Review all
Data Safety Monitoring	4	4	0	Review all
Data and Tissue Banking	6	6	0	Review all
Device Trial Charges	2	2	0	Review all
Emergency Use of an Investigational Drug or Biologic	1	1	0	Review all

Execute: Electronic Interviews

Home

Sign out

Administrator: Ncura Test | Entity: Test Hospital One



Department : Blood Borne Pathogens

[Assignments Home](#) | [Review Answers](#)

Category : Policies and Procedures

Question # : 3 of 76

In creating and maintaining the exposure control plan, did the institution solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls, and is this solicitation documented in the exposure control plan?

[Question Source](#) | [Upload Document](#) |

Yes No Not Applicable Requires Review

Last Review or Update: //



Submit

Supporting Documents Currently Referenced on the Server - Check All that Apply

Enterprise Wide Documents: No Enterprise Wide Documents on file for this Question Set

Local Documents: No Entity Specific Documents on file for this Question Set

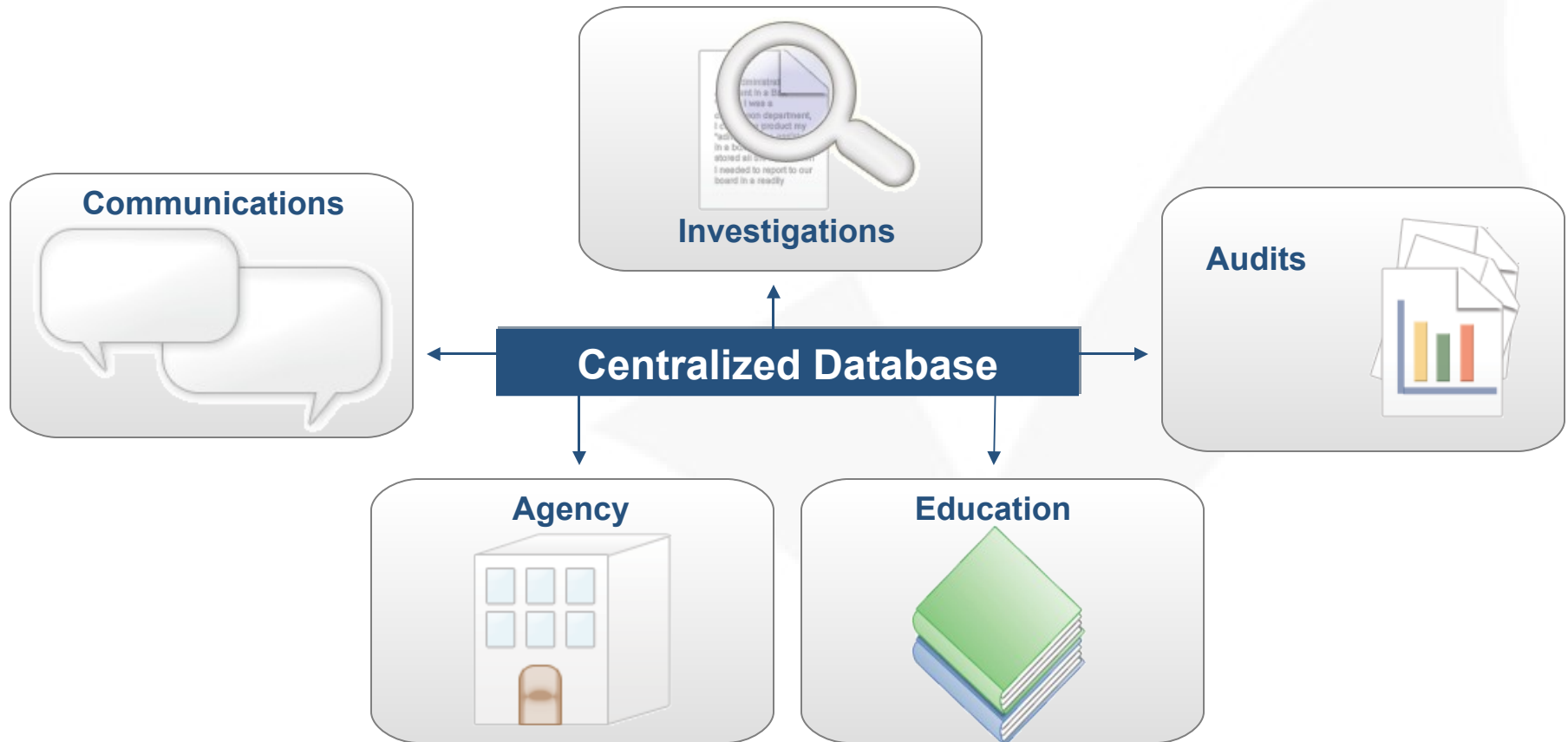
Add Comments (Optional):

Execute: Electronic Scoreboards

Home	RAM	Question Manager	Analysis	Admin	Surveys	Help	Sign out
View Organizations	Manage Entities	Edit Entity-Type Templates	Infrastructure Setup Wizard				
Links to Statistical Recaps as Excel Spread Sheets							
Respondent	Entity	Department	Question				
TOP IORG							
Test Hospital One Entity Manger: Ncura Test							
Ncura Test							
	Action	Satisf	N/A	Review	Skipped	Resolved	Unans
Association for the Accreditation of Human Research Protection Programs	0	10	0	0	0	0	0
Assurances	0	5	0	0	0	0	0
Blood Borne Pathogens	0	2	0	0	0	0	74
Chemical Hygiene Plan	0	7	0	0	0	0	25
Clinical Monitoring	0	24	0	0	0	0	0
Clinical Trial Prerequisites	0	10	0	0	0	0	0
Conflicts of Commitment	0	10	0	0	0	0	0
Data Safety Monitoring	0	4	0	0	0	0	0
Data and Tissue Banking	0	6	0	0	0	0	0
Device Trial Charges	1	1	0	0	0	0	0
Emergency Use of an Investigational Drug or Biologic	1	0	0	0	0	0	0
FDA Electronic Signatures and Records	0	24	0	0	0	0	0
FDA-Specific Conflict of Interest	0	6	0	0	0	0	0
General	0	9	0	0	0	0	0
Good Clinical Practice	0	10	0	0	0	0	0
HIPAA - Human Subjects	0	7	0	0	0	0	0

Execute: Assessing Emergent Risk

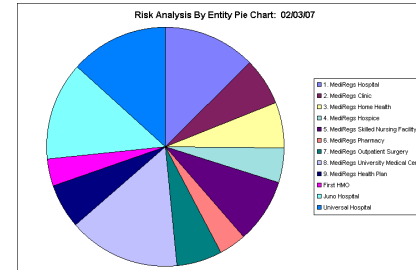
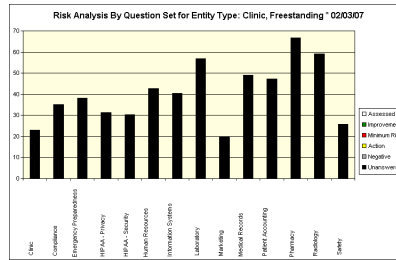
Integrated end to end management of issues, events, incidents and matters.



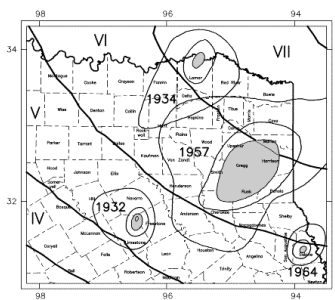
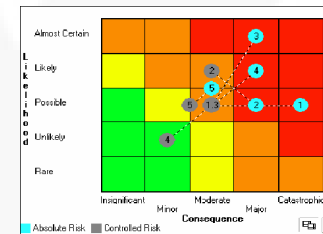
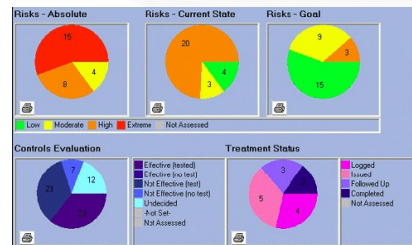
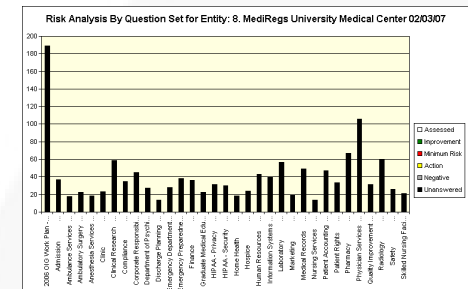
Talking to Management About RA

Say it with pictures

- What is the progress of our assessments?
- What are we assessing and how?
- What are the business risk to our strategies, finances and organization? What are the compliance issues?
- What are our significant risks, scenarios or risk events? How significant are these risks and what is the impact?
- How should we manage these risks?
- How should we monitor these risks



	< 2	2-4	4-6	6-10	10-15	>= 15	ALL
CORP	0	11	8	18	16	12	65
MPT	4	15	7	1	15	40	28
NONE	0	0	0	0	0	0	0
ABS	4	18	29	127	6	30	154
AGCY	5	9	12	10	4	12	52
CMO	0	10	8	75	2	56	151
FPD	0	0	0	0	0	4	4
TSY	1	7	1	11	3	6	29
IRSW	0	0	0	0	0	0	0
ALL	6	2	19	54	10	44	133



Charts Sources: MediRegs and Chief Security Officers.com

Rules of the Road

- Keep it practical but exhaustive
- Be realistic, not idealistic. Look at what actually occurs and exists in the workplace and, ***in particular, include non-routine operations.***
- Identify who is at risk. Include all workers, including visitors, contractors and the public.
- Start with the simple methods, use more systematic methods as necessary.
- Document and have an audit trail