Contracts for Laboratory Information Systems…
What's included is just as important as what's not

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Disclosures

- No financial disclosures to report

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Disclaimers

- *I am NOT an attorney*

- *Based on my experience*

- *Provided as a convenience*

- *Does NOT represent legal advice*

- *Contracts should be reviewed by an attorney, and any questions about your specific contract should be directed to official counsel.*

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Checklist

- Helpful during contract review process

- 60 copies of sample checklist in back of room

- If you didn't get a copy, please email me at abcart2@emory.edu

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Terms Used

- **SUN**
  - **System Under Negotiation.** This is the system for which you are reviewing and negotiating the contract.

- **Company**
  - This is the company selling the system to you

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Phases of contract review

- Select system

- Do your homework

- Check the items received for review

- Review the contract

- Provide feedback to your attorney

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Homework

- User Licenses
  - Total number of users
  - Concurrent users
    - Number of users on system at same time
    - Usually estimated as 1/3 of total users

- Hosting and support of hardware
  - Locally with local IT support
  - Locally with remote IT support
  - Remotely with remote IT support

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Homework - Interfaces

- Make a list of all other computer systems the SUN needs to communicate with
  - Internal EHR/EMR?
  - External EHR/EMRs?
  - Web portal?
  - Patient portal (if legal)?
  - Internal LISs?
  - External LISs?
  - Instruments?
  - Middleware?

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Homework

- – Does your institution have a backup management system? How are files sent and retrieved from it?

- – Images

  - Does your application need to have image management?

  - How will the images be acquired? Gross photos vs. photomicrographs vs. imported from an instrument (e.g. electropherogram)?

  - How will the images be used?

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Homework

- Data migration and access to old data
  - Do you need data migration?
    - Anatomic Pathology
    - Blood bank
    - HLA and Compatibility Testing
  - Reminder: You do need to have access to the old data per CLIA for a period of time.

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Homework - Who

- Determine ahead of time
  - You?
  - Your LIS team?
  - Subject matter experts for the lab(s) using the system after go-live?
  - The laboratory medical director?
  - Any other IT personnel?
  - Your attorney should ALWAYS review your contracts!

Company

Your attorney

Laboratory (you and others)

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You received the contract

- Check table of contents

- Check for missing parts

- Request missing parts
  - Could be critical!

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Reviewing the contract

- Statements of compliance with…
  - Regulations
    - CLIA
    - HIPAA
    - FDA
  - Standards
    - CAP, TJC
    - ISO, CLSI
    - DICOM, Barcoding symbologies
    - LOINC, SNOMED, ICD-9/10, CPT, etc.

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Scope of Work

- Reality check
  - All sites included
  - Who does what?

- Deadlines
  - What if you don't meet them?
  - What if company doesn't meet them?

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Term and Termination

- Term
  - For what period is the contract in effect?
  - Does it expire if specific actions don't take place?

- Termination
  - By the company
  - By you
  - For cause or without cause
  - Going out of business (you or company)

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Uptime

- Percent uptime should be included

- Is this percent uptime acceptable for the SUN in question?

- What happens if the system isn't up at its expected threshold?

- What exceptions are given for system uptime?
  - Maintenance downtimes
  - End-user tampering/crashing

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Support and Maintenance

- When available?
- What's the turnaround time on support?
  - During unexpected downtime?
- What is supported?
  - Hand-holding
  - Software
  - Hardware
- What type of support?
  - Phone calls, email, on site visits
- Are there extra charges for support if you go above a certain time limit?

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Support and Maintenance

- Updates
  - How frequently are you required to take them?
  - What happens if you don't?
  - Need to balance staying up to date with resource management

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Data migration

- Included?

- Will it be migrated by go-live?
    - If not, when? (Hint: you need a deadline)

- Access to old data included?
    - Need deadlines for this also

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Images

- Included?

- Is specific hardware or instruments required?

- Can it take images from your existing equipment?

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Backups

- Automated backups included?

- Is the mechanism compatible with your institution's requirements, if any?

- Where will the backup files be stored?

- Are they secure?

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Non-disclosure clauses

- What can you NOT disclose about the company?

- What can the company NOT disclose about you or your patients?

  - Business Associate Agreement (BAA)

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Payment

- How and when are you supposed to pay them during implementation?
  - Is this reasonable?
- Price increases?
  - Are they capped?
  - How much notice do you get?

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Comparing systems

- Not usual at this phase

- Always compare five-year costs
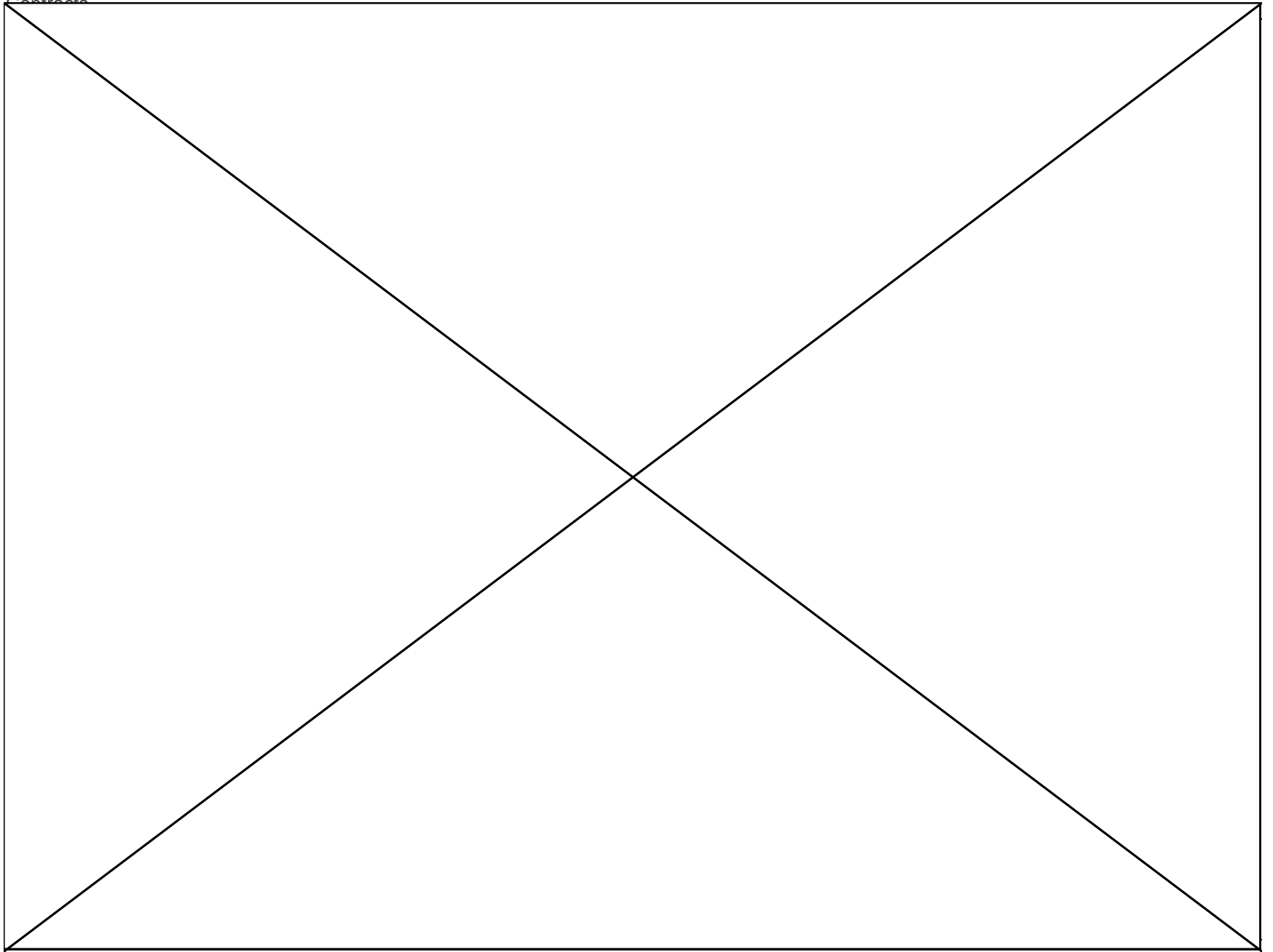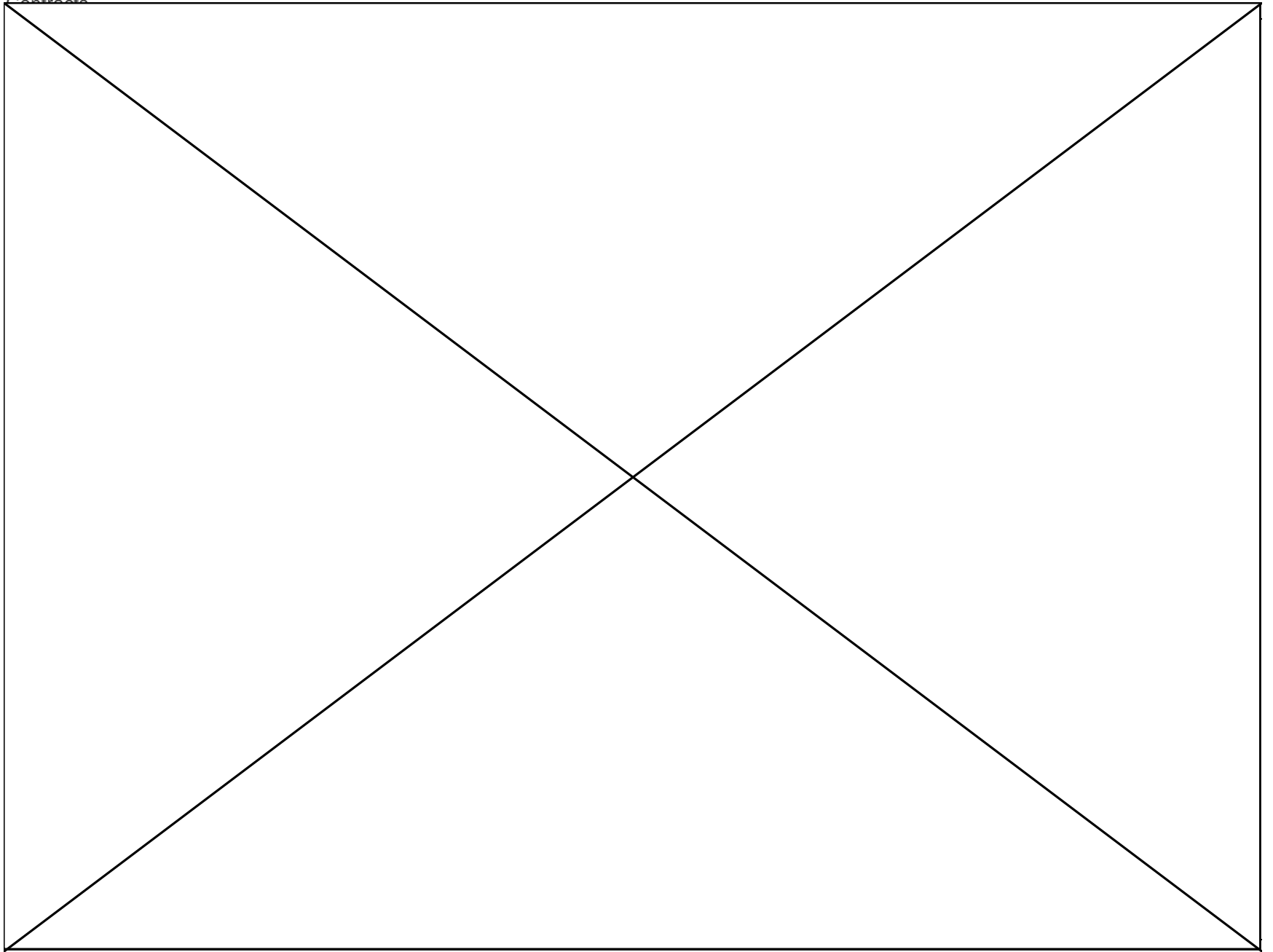 - (see worksheet)

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Conclusion

- Contract review is tedious

- Time in up front saves lots of headache later

- Watch out for changes on multiple iterations

  – Use "compare documents" function to check for attempts at sneakiness!

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QUESTIONS?

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Contracts

Contracts