Protecting Human Research Data:

(Including Some Security Risks You Haven’t Thought Of)

BOSTON UNIVERSITY

BOSTON MEDICAL CENTER

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Presented by

- **Thomas J. Moore, MD**, Associate Provost, BU Medical Campus and Executive Director, Office of Human Research Affairs (OHRA)
- **Arthur W Harvey III, MS, CPHIMS**, VP and Chief Information Officer at BMC
- **David Corbett, JD**, BUMC Information Security Officer

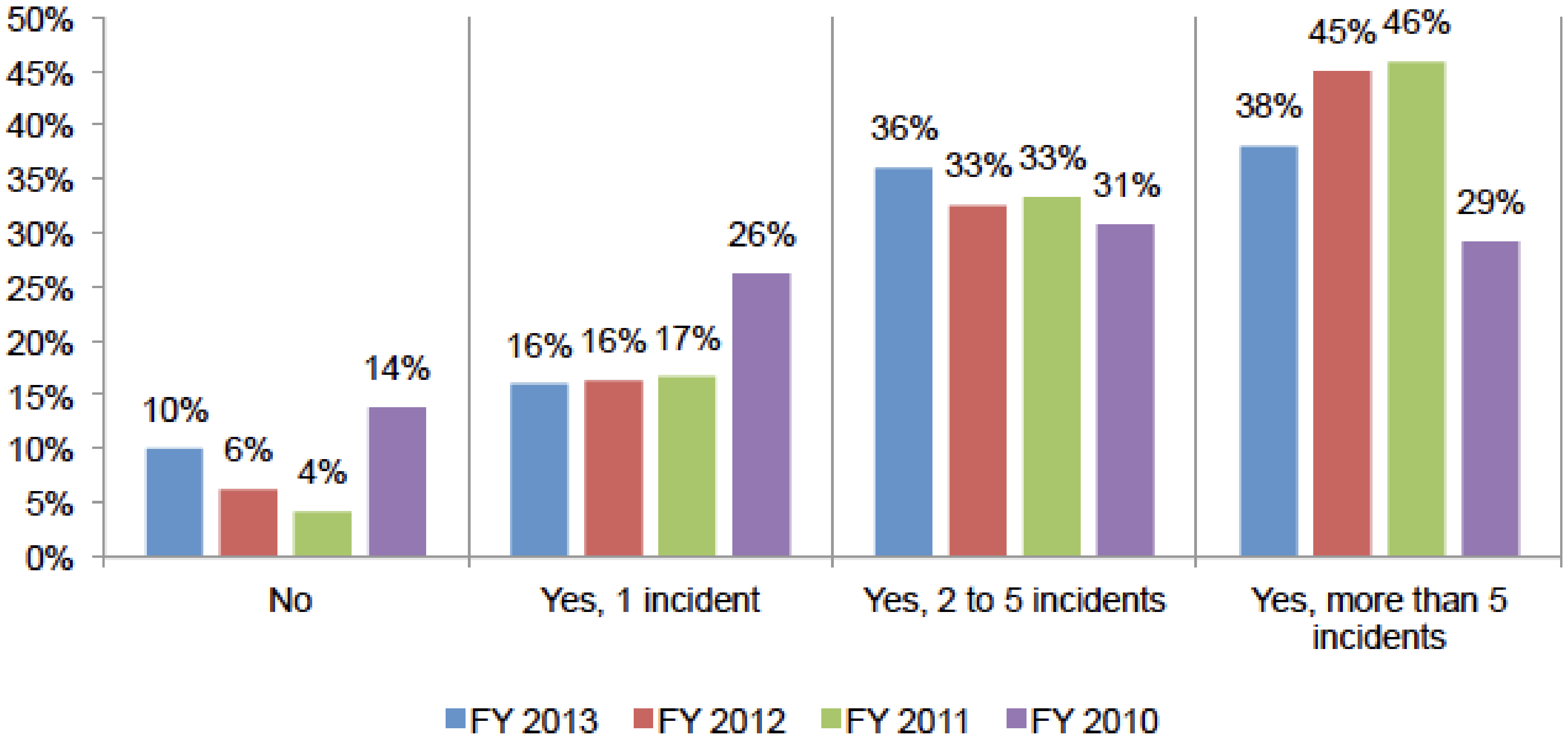
Data Breaches in Medical/Research

- A breach is an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information.

- Identifiable patient/research subject information
- HIPAA identifiers

Healthcare Data Breaches Are Common

Figure 1. Experienced a data breach involving the loss of patient data in the past two years



Data Breaches at Boston Hospitals (involving >500 records)

- 3 at Brigham and Women’s
- 2 at Beth Israel Deaconess
- 2 at Mass General
- 2 at St. Elizabeth’s

- Breaches occurred between Oct. 2009 and Dec. 2016
- *JAMA online April 3, 2017*

How do breaches occur?

Research Data Breaches Here at BUMC

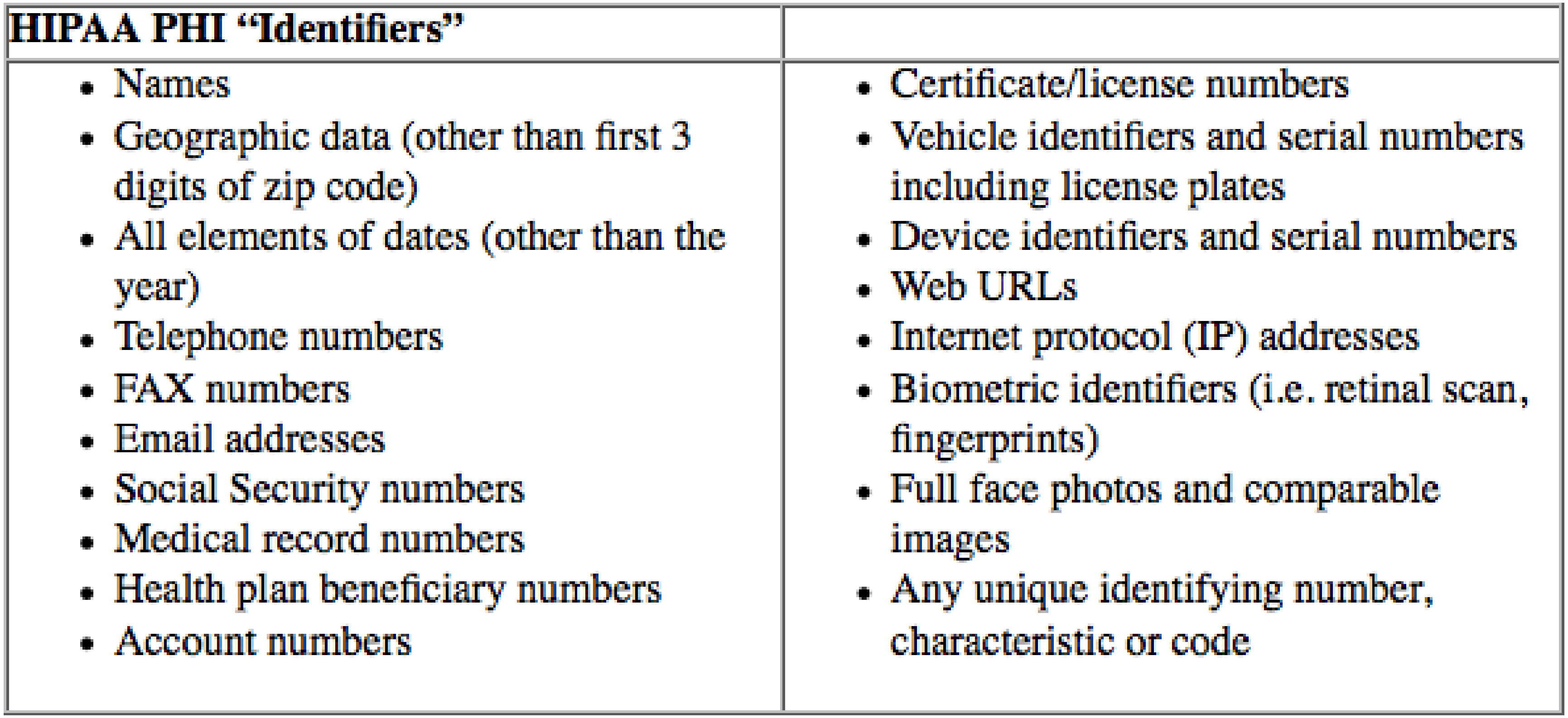
- Hackers accessed older server containing research data
- Hackers accessed server with older security measures
- Hard drive stolen from a lab here at BUMC
- Student laptop stolen from student’s apartment (near miss)
- Utah…..

Preventing Breaches—Your Role

- Collect ‘minimum necessary’ data
- Secure your devices
- Train your people
- Know what resources BU and BMC can offer to help you
    - (Are you BU or BMC?)

What Can You Do to Avoid PHI Loss

- If you don’t need it, don’t collect it.
- Remove HIPAA identifiers



HIPAA PHI “Identifiers”	
• Names • Geographic data (other than first 3 digits of zip code) • All elements of dates (other than the year) • Telephone numbers • FAX numbers • Email addresses • Social Security numbers • Medical record numbers • Health plan beneficiary numbers • Account numbers	• Certificate/license numbers • Vehicle identifiers and serial numbers including license plates • Device identifiers and serial numbers • Web URLs • Internet protocol (IP) addresses • Biometric identifiers (i.e. retinal scan, fingerprints) • Full face photos and comparable images • Any unique identifying number, characteristic or code

Is Your Research Team Compliant?

- Assure that everyone with access to individually identifiable human subjects research data:
  - knows and complies with the security standards
  - accesses data on a secure device

Seek first to understand

- BU Data Protection Standards
  - Classify data (i.e, Public, Internal, Confidential, **Restricted Use**) and specify Minimum Security Standards
  - http://www.bu.edu/policies/information-security-home/data-protection-standards/
- Section 40 on the BMC Policy & Procedure website:
  - http://internal.bmc.org/policy/

Store information securely

- Secure Network Storage for Restricted Use data
- Secure Cloud Storage: BU One Drive
- Special purpose applications
  - Redcap, Freezerpro
- Encryption on your laptop, phone/tablet, USB, CD/DVD
  - Enterprise (McAfee)
  - Personal (Bitlocker, FileVault)
- Personal phones/devices?
  - Must follow Minimum Security Standards

Transmit information securely

- Regular email Is Not Secure
  - Do not send data using BU email
  - Do not forward emails outside BMC
- Encrypt file or use BU SecureMail
  http://www.bu.edu/tech/comm/email/datamotion/
- Connect securely using VPN when off-campus

Secure your devices - Minimum Security Standards

1. Pick a strong password/code - require at startup
2. Enable auto screen lock (5-15 min max)
3. Encrypt your device
4. Set Operating System and applications to automatically update
5. Install Antivirus, set to auto update and scan

Free software and services from BU

- Enterprise encryption for Windows and Mac
  - Crosstown Building (801 Mass Ave), Suite 485
  - bumchelp@bu.edu
- SecureMail
  - http://www.bu.edu/tech/comm/email/datamotion/
- Antivirus
  - http://www.bu.edu/tech/support/desktop/removal/security/mcafee/
- Off campus secure connect
  - https://vpn.bu.edu

BMC Data Security

Security Policies

Can be found on BMC Intranet at:

http://internal.bmc.org/policy/

Cover all aspects of information security

Includes forms to request security assessments

BMC Information Security Team

Can be reached through BMC Service Desk x44500

Can also be contacted through ServiceNow ticket

https://bmc.service-now.com/

Reporting

In the event of a suspect breach timely notification needs to be made to the BMC Privacy Officer Nickie Braxton (Nickie.Braxton@bmc.org, 617-638-7987)

BMC-BU Relationship

Although we are tightly bound organizations, for the purposes of HIPAA security we are separate entities with separate policies

HIPAA Definitions

Covered Entity

- Health plans
- Health care clearinghouses
- Health care providers who conduct certain financial and administrative transactions electronically. These electronic transactions are those for which standards have been adopted by the Secretary under HIPAA, such as electronic billing and fund transfers.

BMC IS a Covered Entity, BU IS NOT a Covered Entity

Source: HHS.GOV

HIPAA Definitions (con’t)

Business Associate

A person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing. Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. However, persons or organizations are not considered business associates if their functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all. A covered entity can be the business associate of another covered entity

Source: HHS.GOV

HIPAA and Research

Researchers are typically NOT Business Associates
To disclose protected health information to a researcher for research purposes, either with patient authorization, pursuant to a waiver under 45 CFR 164.512(i), or as a limited data set pursuant to 45 CFR 164.514(e). Because the researcher is not conducting a function or activity regulated by the Administrative Simplification Rules, such as payment or health care operations, or providing one of the services listed in the definition of “business associate” at 45 CFR 160.103, the researcher is not a business associate of the covered entity, and no business associate agreement is required.

MUST either have patient authorization or be using a limited data set

Source: HHS.GOV

HIPAA and Research (con’t)

But now the tricky bit….

BMC provides a full data set to a researcher who wants to do some initial screening and commits to reducing it to a limited data before it is “used” for research we have an issue. Absent patient authorization BMC is prohibited from releasing this data. If the researcher undertakes to create a limited data set out of the full data set they are providing one of the services specifically listed in the definition of “business associate” at 45 CFR 160.103 and as such become a business associate.

In order to avoid this issue only a limited data set can be provided from BMC which has implications for research.

BMC Security Perimeter

Given the nature of BMC we assume that ALL data in our systems is PHI until proven otherwise

Many different data items from different systems are considered PHI. This data is often communicated through internal systems and shared via internal documents for operational purposes. For those reasons the “security perimeter” at BMC is quite large. The following are examples of systems assumed to contain PHI:

EHR and Clinical Systems
Patient Accounting System
Reimbursement System
Email
Shared file areas
Every desktop, laptop, and USB drive
Text messaging

Within this perimeter all data needs to be encrypted and monitored. No data should exfiltrate this perimeter without appropriate safeguards.

Why do we care?

Breaches are expensive

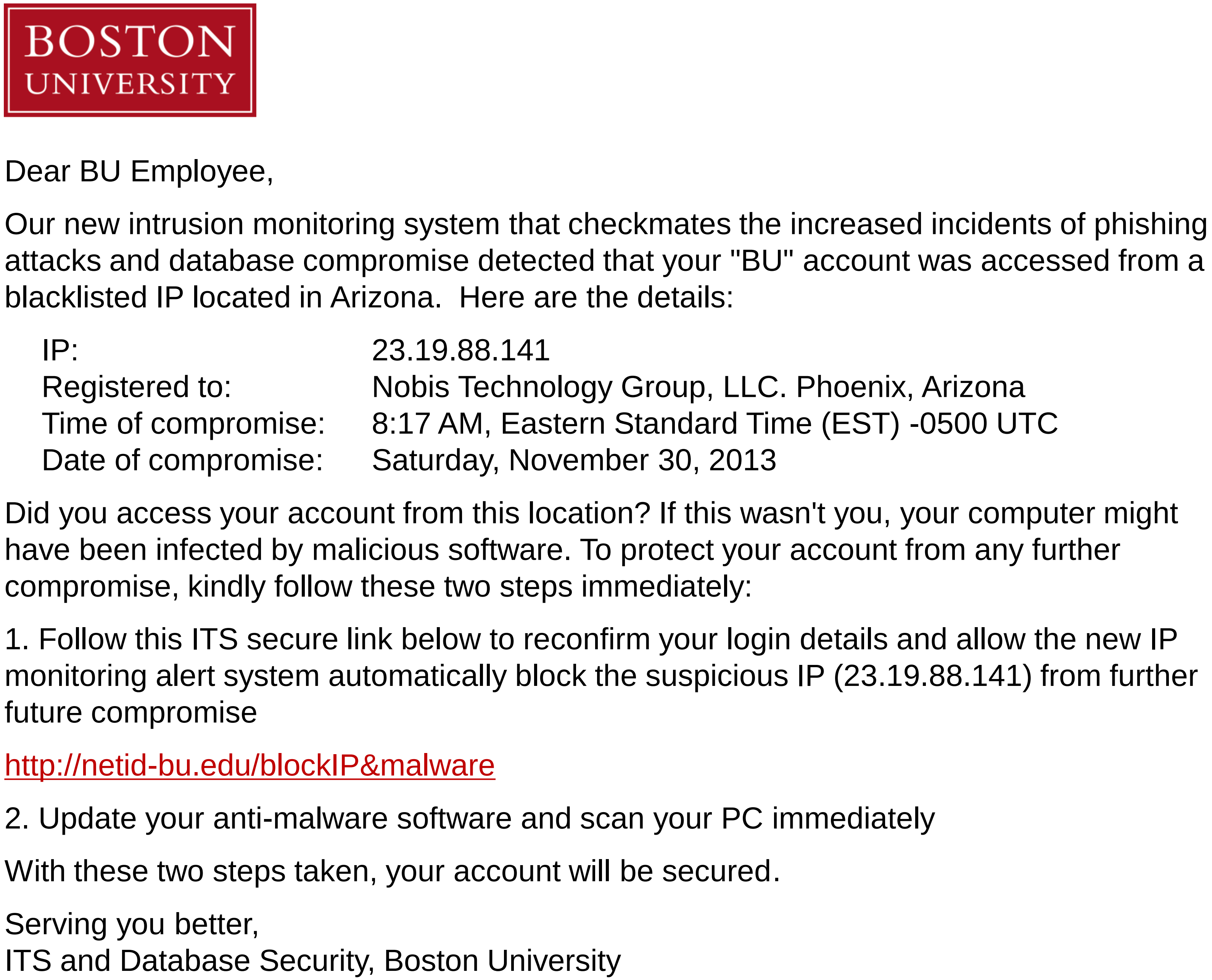
- Fines can run in the millions of dollars (Children’s Medical Center of Dallas - $3.2 million)
- Loss of reputation, most significant breaches involve at least some press coverage
- Opportunity cost, if we are spending time dealing with OCR we are not doing other important work
- It’s the law

Increased activity

- More aggressive enforcement, while not written in the regulation in practice OCR is taking a harder line on investigations and making routine demands for documentation
- Adding new threats, OCR has declared that ransomware attacks are now presumptively a breach and it is up to the covered entity to prove it is not a breach
- More social engineering attacks, PHI is valuable on the black market so there are more attempts to steal it

Q: How do bad guys usually get around security

A: They ask you to do it



BOSTON
UNIVERSITY

Dear BU Employee,

Our new intrusion monitoring system that checkmates the increased incidents of phishing attacks and database compromise detected that your "BU" account was accessed from a blacklisted IP located in Arizona. Here are the details:

IP:	23.19.88.141
Registered to:	Nobis Technology Group, LLC. Phoenix, Arizona
Time of compromise:	8:17 AM, Eastern Standard Time (EST) -0500 UTC
Date of compromise:	Saturday, November 30, 2013

Did you access your account from this location? If this wasn't you, your computer might have been infected by malicious software. To protect your account from any further compromise, kindly follow these two steps immediately:

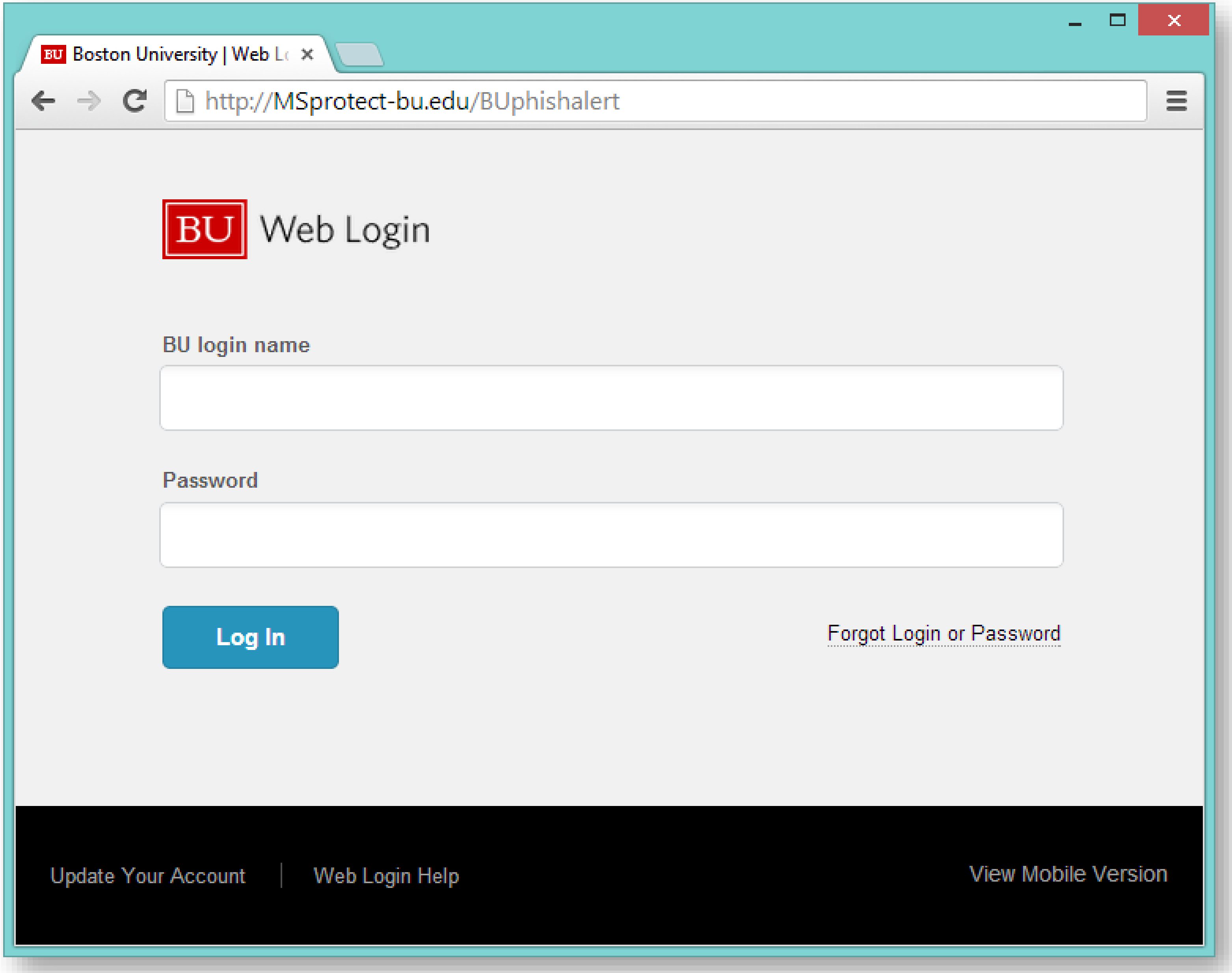
1. Follow this ITS secure link below to reconfirm your login details and allow the new IP monitoring alert system automatically block the suspicious IP (23.19.88.141) from further future compromise

http://netid-bu.edu/blockIP&malware

2. Update your anti-malware software and scan your PC immediately

With these two steps taken, your account will be secured.

Serving you better,
ITS and Database Security, Boston University



Boston University | Web L

http://MSprotect-bu.edu/BUphishalert

BU Web Login

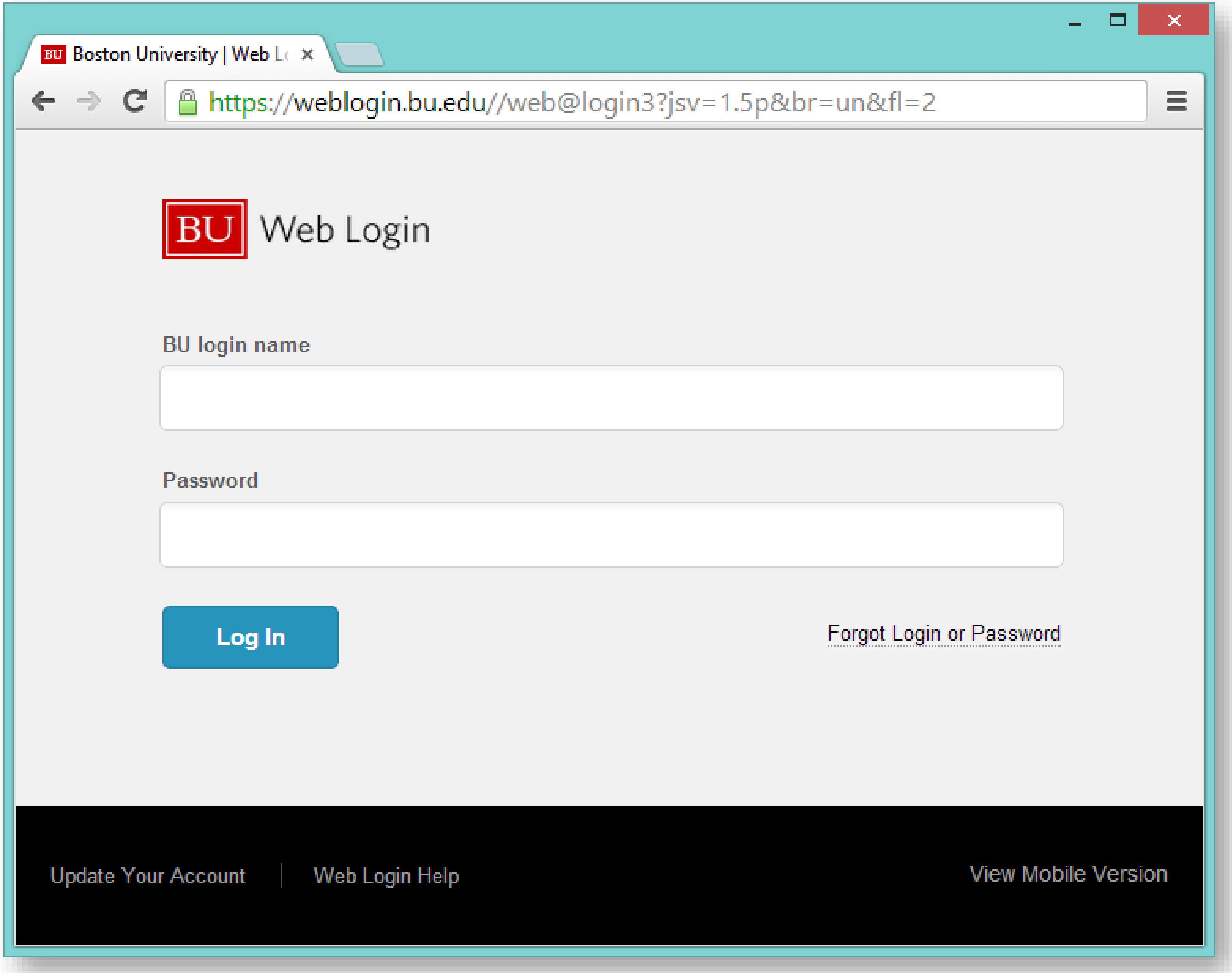
BU login name

Password

Forgot Login or Password

Update Your Account | Web Login Help

View Mobile Version



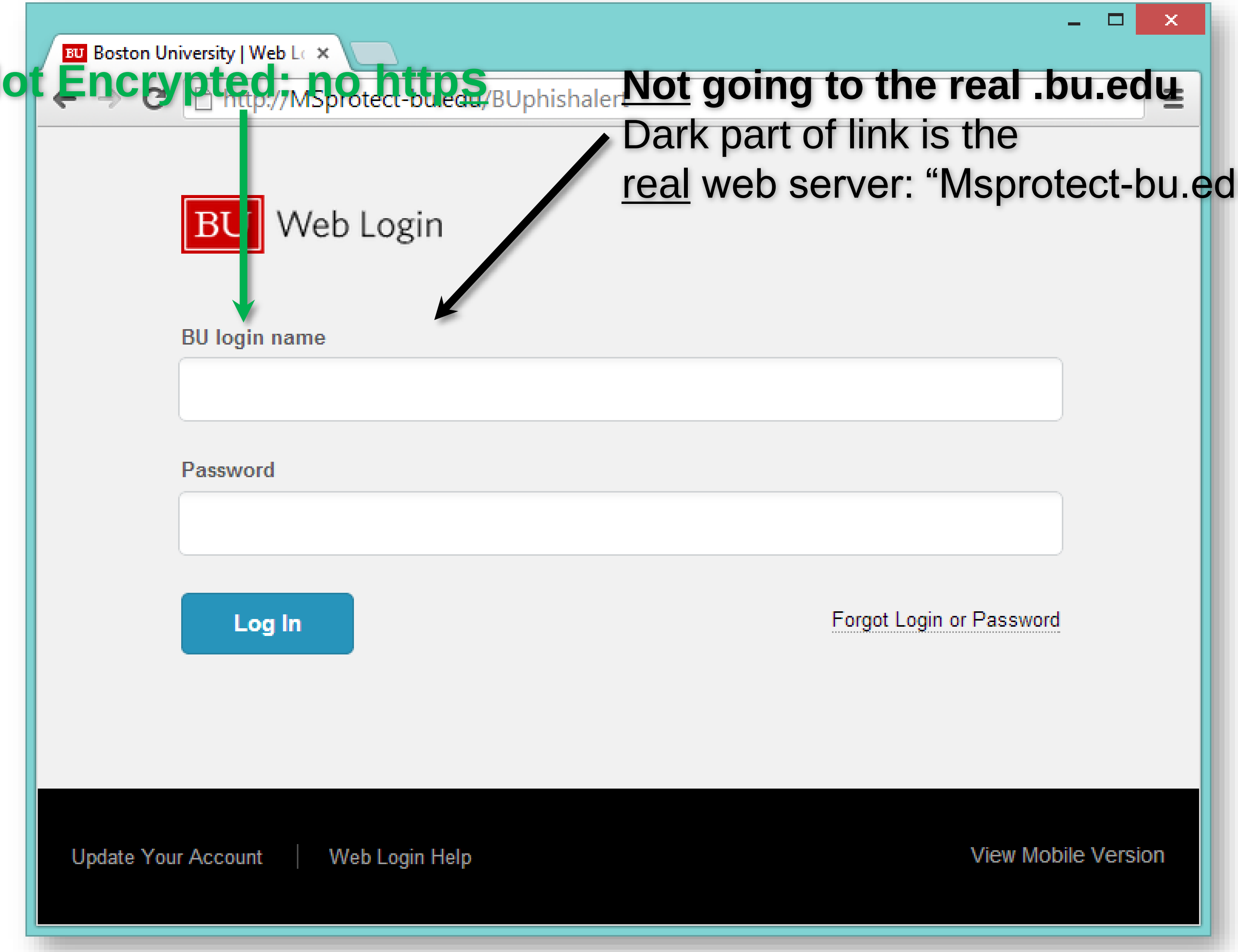
Boston University | Web L

https://weblogin.bu.edu//web@login3?jsv=1.5p&br=un&fl=2

BU Web Login

BU login name

Password



Boston University | Web Lo ×

http://MSprotect-bu.edu/BUphishalert

BU login name

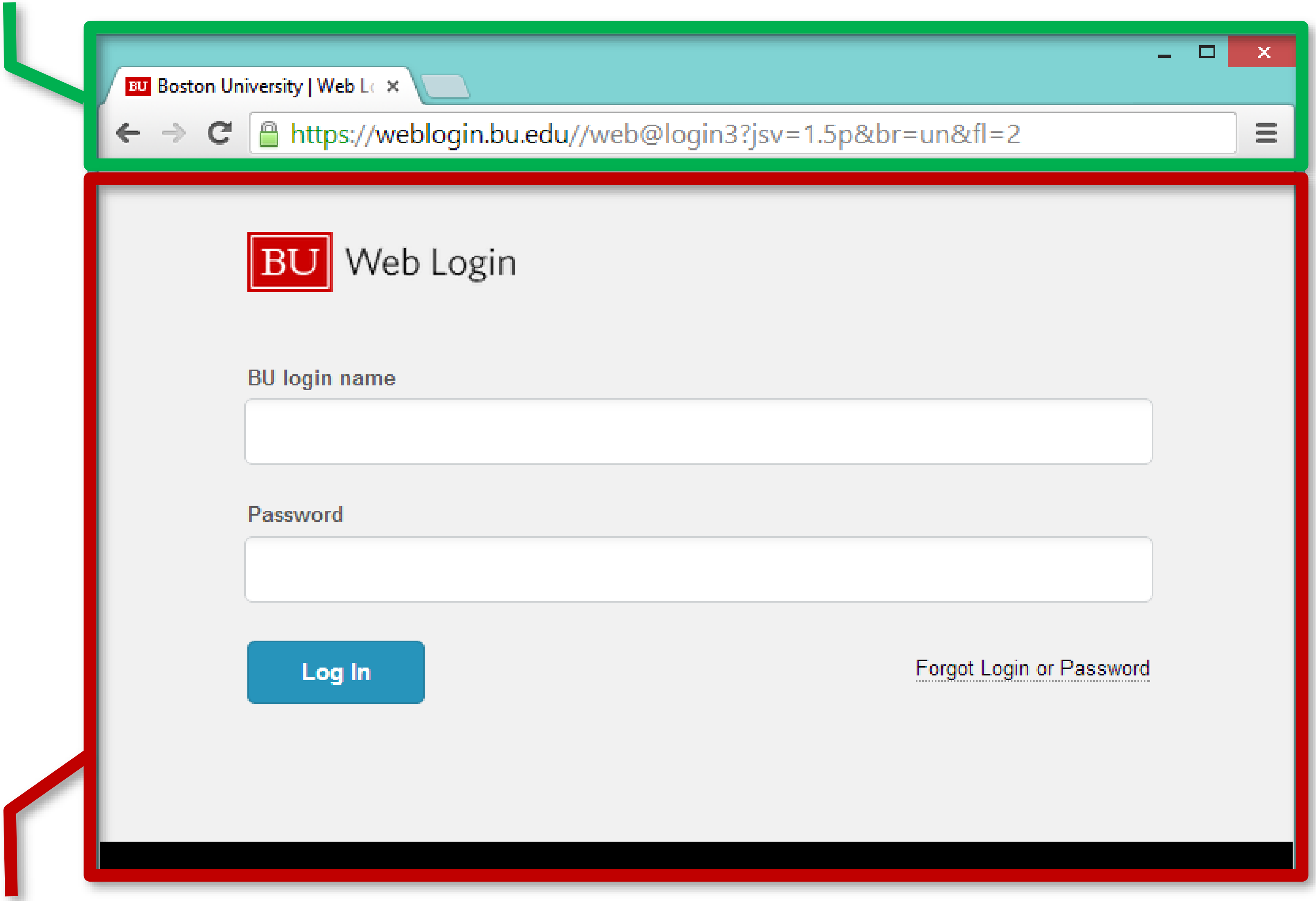
Password

Not Encrypted: no https

Not going to the real .bu.edu

Dark part of link is the real web server: “Msprotect-bu.edu”

The top part is controlled by your computer and the server



Boston University | Web L

https://weblogin.bu.edu//web@login3?jsv=1.5p&br=un&fl=2

BU Web Login

BU login name

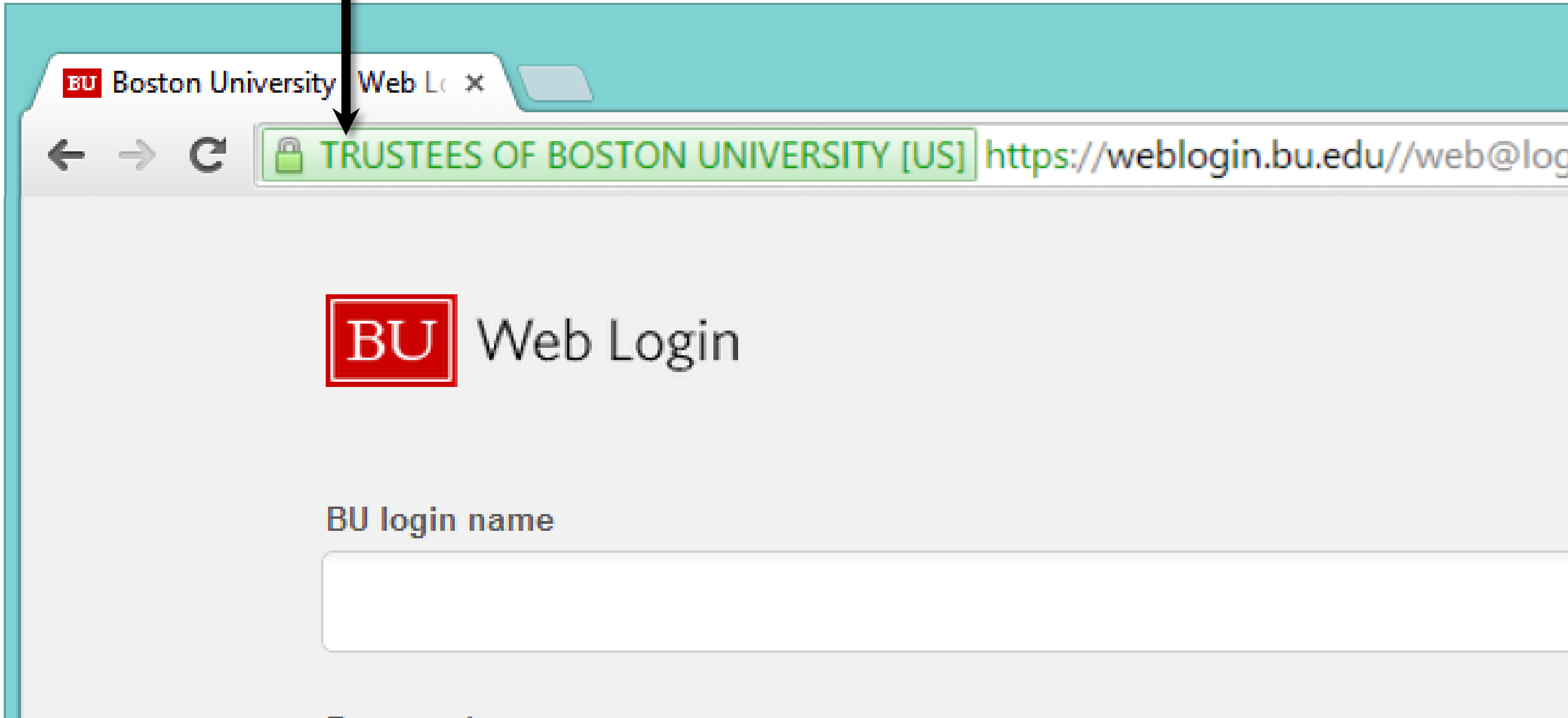
Password

The display window is completely controlled by the page author

What the ***new*** weblogin looks like

Special Certificate shown in Green:

Trustees of Boston University

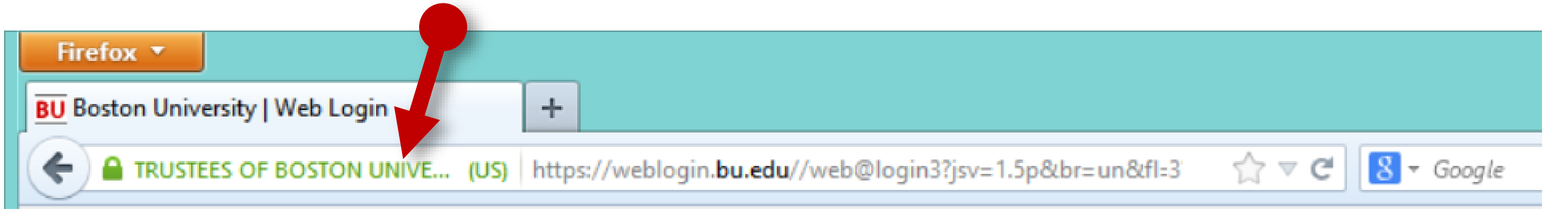


BU Boston University Web Lo ×
TRUSTEES OF BOSTON UNIVERSITY [US] https://weblogin.bu.edu//web@log

BU Web Login

BU login name

Firefox



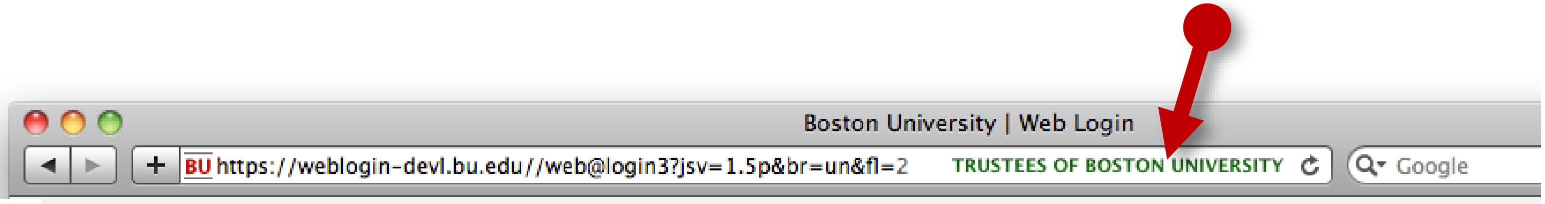
Firefox

BU Boston University | Web Login

TRUSTEES OF BOSTON UNIVE... (US) https://weblogin.bu.edu//web@login3?jsv=1.5p&br=un&fl=3

Google

Safari

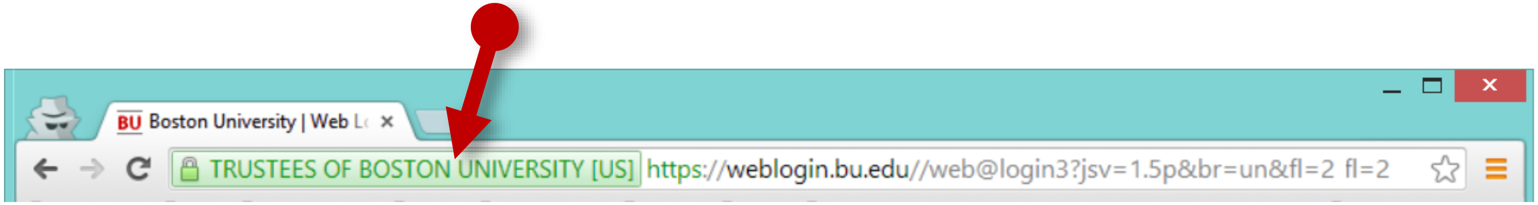


Boston University | Web Login

BU https://weblogin-devl.bu.edu//web@login3?jsv=1.5p&br=un&fl=2 TRUSTEES OF BOSTON UNIVERSITY

Google

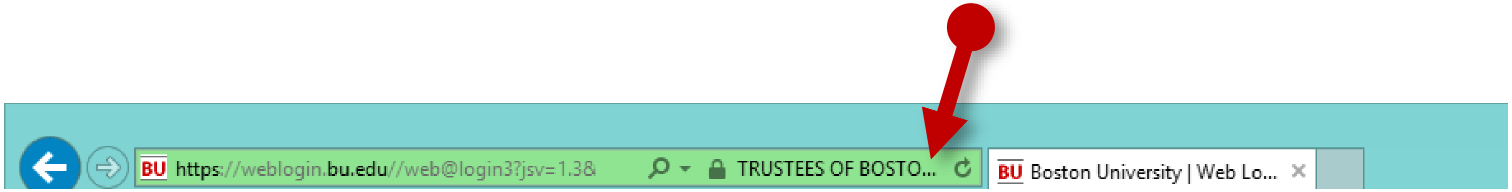
Chrome



BU Boston University | Web L

TRUSTEES OF BOSTON UNIVERSITY [US] https://weblogin.bu.edu//web@login3?jsv=1.5p&br=un&fl=2 fl=2

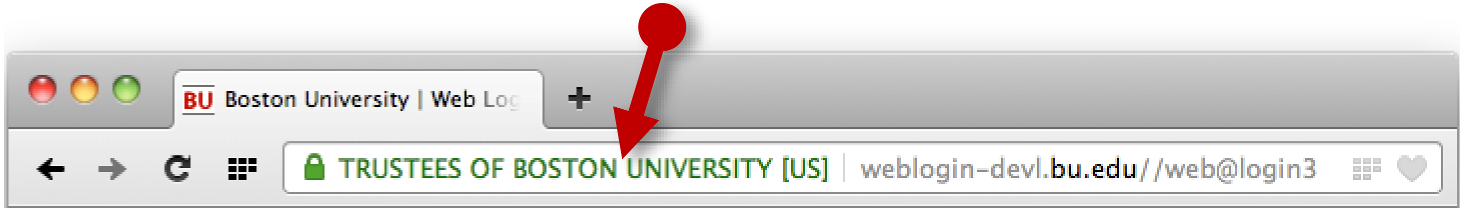
Internet Explorer



BU https://weblogin.bu.edu//web@login3?jsv=1.3& TRUSTEES OF BOSTO...

BU Boston University | Web Lo...

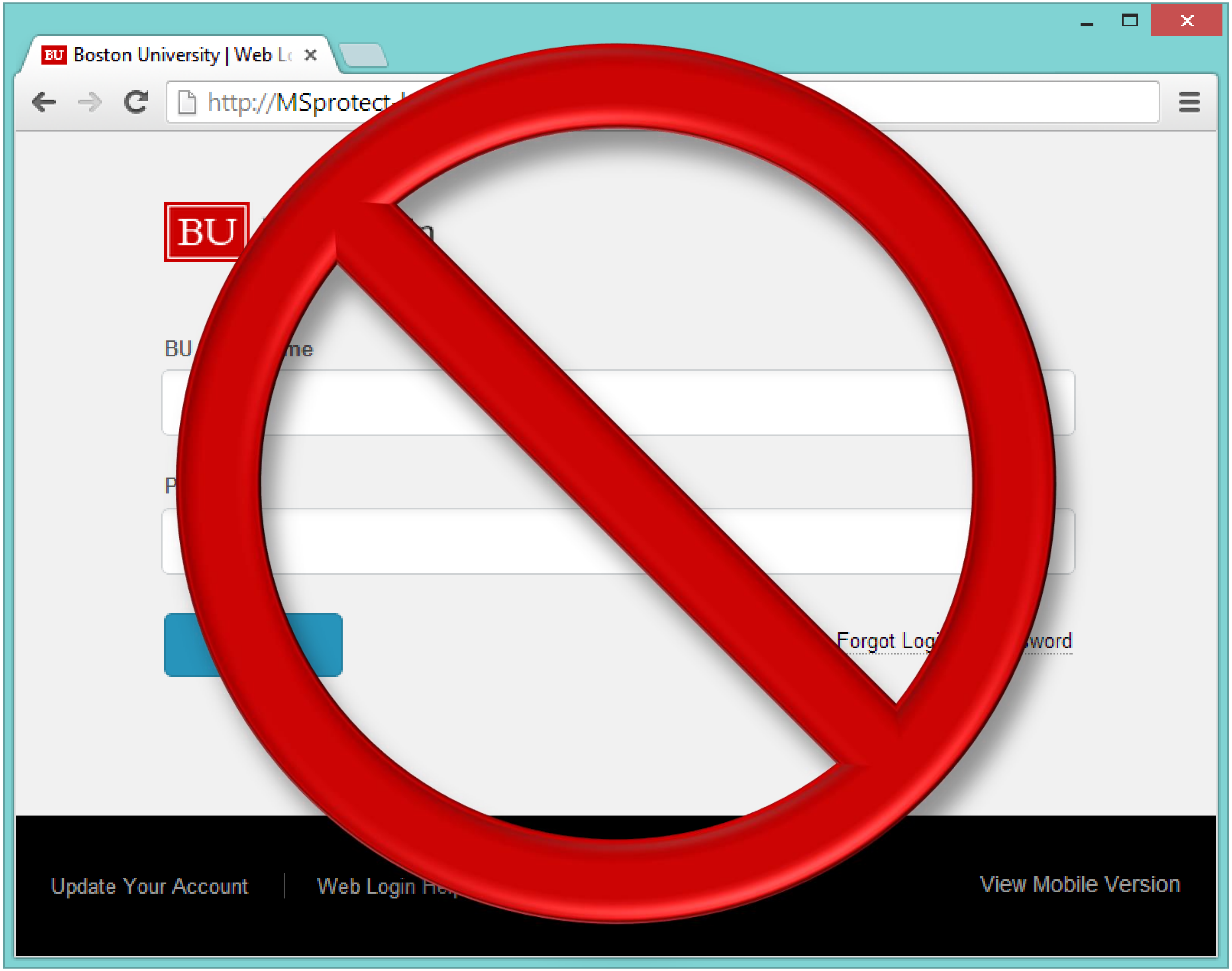
Opera



BU Boston University | Web Log

TRUSTEES OF BOSTON UNIVERSITY [US] weblogin-devl.bu.edu//web@login3

No Green, No Go



Boston University | Web L

http://MSprotect