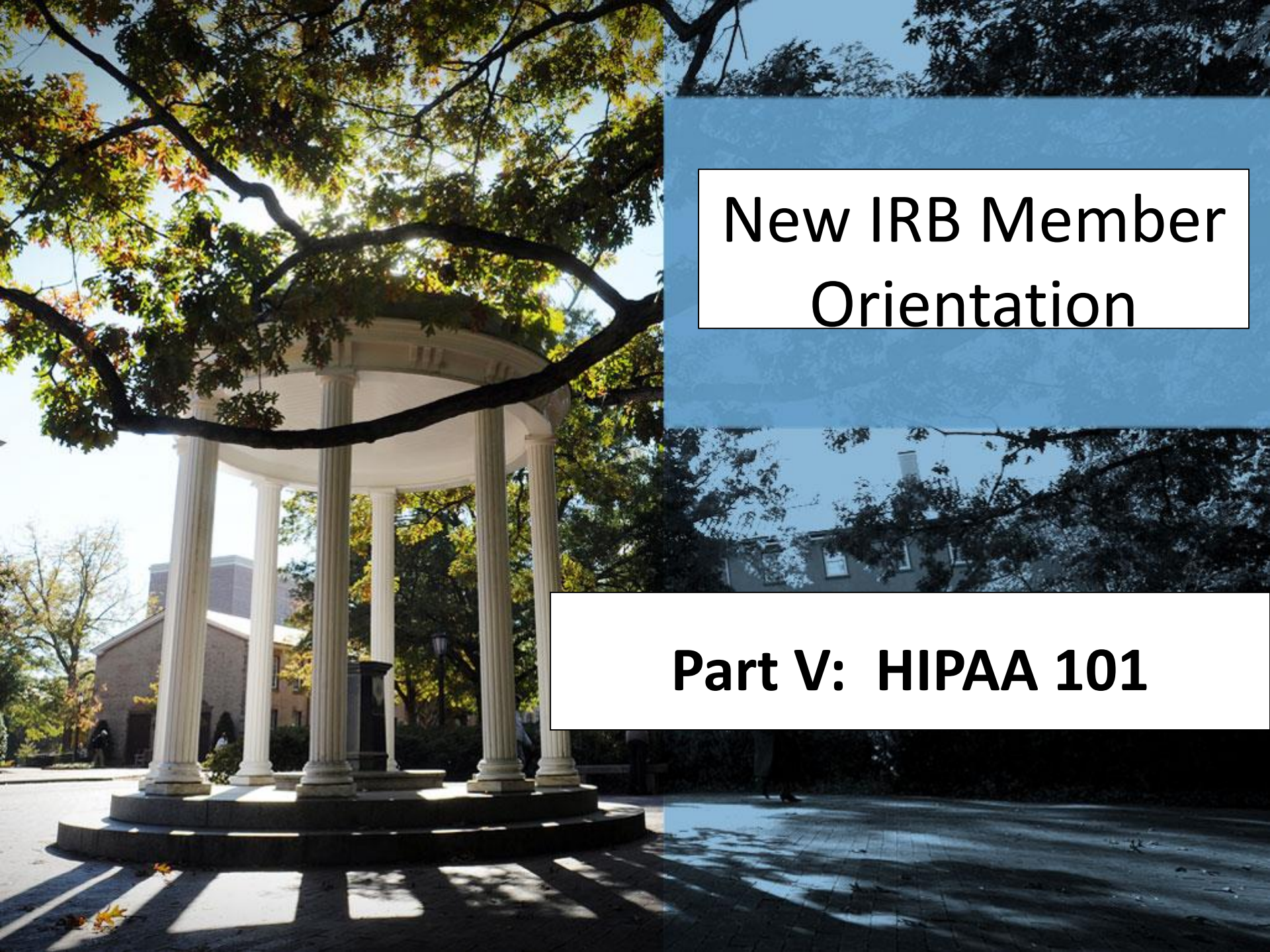

New IRB Member Orientation

Part V: HIPAA 101

HIPAA & Research Authorizations/consents

All of the requirements of 45 CFR 46, PLUS:

- Who may use or disclose the information
- Who may receive the information
- Purpose of the use or disclosure
- Expiration date or event
- Re-disclosures not protected

Common Rule + HIPAA = Extra Protections

1. Pre-enrollment Phase (1st. Contact with PHI)
2. Subjects Become ACTIVE Partner on use of their PHI
3. Minimum Use of PHI & Protect Confidentiality
4. Disclosures Tracked
5. Exception: TPO (treatment/payment/operation)

Clinical Care IS NOT ….

- Clinical Research
- They are subjects not patients
- They are investigational drugs not medicine
- There is no therapy, no treatment

IRB Approval is for a maximum of 1 year

- The year ends at **12:01 AM** on the termination day
- OHRP allows NO extensions, not even 5 seconds!

When You Need an Adult Consent for a Pediatric Study.

- If your pediatric subject turns 18, then you need to re-consent the subject as an adult with an adult consent form.

- You must also remember to retain pediatric data until the pediatric subject becomes 21 &/or 6 years post study whichever is longer.

Data Retention Requirements

- **OHRP: 45 CFR 46.115: 3 years post study**
- **FDA: 21 CFR 56.115: 3 years post study**
  - **2 years following the date of marketing application approval for IND**
- **HIPAA: 6 years**
- **IRB Policy: 3 years or in case of pediatric research till child is 21.**