Mock Review:
Request for a Full Waiver of HIPAA Research Authorization

You are a group of IRB reviewers tasked with determining whether a request for a full waiver of HIPAA research authorization meets the criteria for approval.

1. Designate a Group Note-taker to record the group’s decision, as well as a Spokesperson who will share the group’s thoughts with the larger audience.
2. Read the description of the study design and aims (below).
3. Evaluate the researchers’ request for a full waiver of HIPAA research authorization (Buck-IRB Screenshots – one per group).
4. Use the Reviewer Checklist to determine whether the criteria for approval have been met.
   a. Jot down reasons why the waiver is approvable or not approvable, as well as what information would help you make your decision.
   b. Each group member will have their own copy of the checklist to take notes.
   c. The Group Note-taker should capture the group’s discussion and final decision on his/her reviewer checklist.

SAMPLE STUDY – REQUEST FOR FULL WAIVER OF HIPAA AUTHORIZATION

- **Study design:** review of existing medical records
- **Study purpose:** to compare survival data from breast cancer patients who received one or two chemotherapy drugs
- **Study population** (inclusion criteria):
  - Female
  - Aged 30 to 75 years
  - Diagnosed with stage III breast cancer
  - Received chemotherapy between January 1, 2012, and January 1, 2018 at the Stefanie Spielman Breast Center