Researchers can use the internet to conduct research in two ways, as:

⇒ a research tool:
  □ recruit research subjects
  □ collect data via surveys, questionnaires
  □ gather information through online interviews and focus groups
  □ access and collect existing information

⇒ an environment to study human behavior:
  □ observe subjects’ online behavior

Although the federal regulations pre-date Internet-Based Research and Social Media tools, the Common Rule and the Belmont Principles are still applicable.

⇒ Applying the Human Subjects Research definition:
  □ Living Individual: Distinguish whether you are interacting with a live person, an avatar, or a Non-Player Character (NPCs, designed and controlled by a computer through artificial intelligence)
  □ Interacting/Intervening with a living individual: Examples include actively engaging with subjects’ online to collect data, or collecting data by observing the way subjects’ interact or behave online
  □ Access/Obtain Identifiable Private Information: Distinguish what is considered public or private online information, as well as subjects’ expectations of what are considered private online information/behavior

⇒ Applying the Belmont Principle of Respect for Persons (Autonomy):
  □ When conducting Internet-Based Research, consider the informed consent process; an acceptable consenting method is to include an online consent with a “live button” that subjects can click to demonstrate their consent.
  □ Another important point of consideration are children as subjects: determine how will parental permission and child assent be obtained, and consider variations in state (and other countries) laws regarding the age of legal majority.
  □ Also, consider whether your research involves incomplete disclosure/deception (IRB Application Appendix G) and the alteration in the informed consent process (IRB Application Appendix O). For example, an investigator observing a private online chat room may explain to potential subjects that the purpose of the research is focused on job applications; however, the investigator may actually be studying gender discrimination; the consent process would be altered because the true intent of the research was not disclosed as it could change the subjects online behavior and create study bias.

Mitigating Risks in Internet-Based Research and when using Social Media as a research tool: the potential for harm includes violating an individual’s privacy and breaching confidentiality that could damage subjects’ reputations, employability, insurability, or potentially expose them to criminal or civil liability. The protocol narrative and the informed consent process must clearly describe how the subjects’ privacy and confidentiality will be protected.
Comparative Effectiveness Research (CER)

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

Points to consider

⇒ Be sure that potential participants understand:
  □ that they are being asked to participate in research
  □ the nature of the research question being investigated (i.e., improve clinical practice; ensure appropriate use of resources; etc.)
  □ how their care as research participants may differ from care they would receive in the clinical context

⇒ Assure that the protocol makes clear what question(s) are being studied (i.e., comparison of the foreseeable potential harms and benefits; comparison of costs; etc.)

⇒ If randomization will occur, ensure participants understand the process of being randomized to a research group, and whether the study design is single/double-blind

⇒ Include the magnitude of potential risks and benefits associated with the interventions being studied, so that potential participants are provided with all the information necessary to make an informed decision.

Qualitative research performed by anthropologists, ethnographers, sociologists, and others, include observations that are typically conducted outside the laboratory. Sometimes the purpose of qualitative research is to develop hypotheses rather than to test and validate them in controlled studies.

The criteria for IRB review remains the same for qualitative research, as with quantitative research:

⇒ Research that meets the definition of human subjects research requires IRB review

⇒ Research activities that meet the criteria for engagement in human subjects research requires IRB review
**Other Required Reviews**

Before the IRB can review or approve research, there are other prerequisite UCI reviews that may be required. Depending on the research procedures involved, you may require reviews from the following Committees: Protocol Review and Monitoring Committee (PRMC), Clinical Research Finance Assessment (CRFA), Conflict of Interest Oversight Committee (COIOC), Institutional Biosafety Committee (IBC), Radiation Safety Committee Review, Scientific Merit Review, Environmental Health and Safety, and Epidemiology and Infection Prevention Committee (EIP).

**Research Protections Roadmap**

The Research Protections Roadmap is a web-based tool designed to help investigators plan the regulatory and institutional pathway to research initiation. Depending on the proposed activity, the number and type of regulatory committee approvals and/or processes varies. The timing of these approvals and processes is critical. The RP Roadmap takes 5-10 minutes to complete. The user answers a series of yes/no questions about the proposed activity to help determine the applicable regulatory and institutional requirements. At the end, a PDF document listing the required approvals and processes is provided. Traffic signal icons indicate the timing of these requirements relative to three Office of Research committees: the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC) and the Human Stem Cell Research Oversight (hSCRO) committee for stem cell research.

**IRB New Submitters Training online video**

If you are submitting an IRB application for the first time, we highly encourage you to review the *IRB New Submitters Training* online video. The informative 30-minutes video discuss the following topics: application process, pre-submission work, levels of review, resources and forms, non-technical summary, roles and responsibilities, methods and procedures, participants, recruitment, informed consent, risks, data security, the IRB Application, uploading files, submitting, and post-submission process. Viewers may watch the entire video, or skip to specific topics.

**Signing the IRB Application**

Please remember to provide a signed IRB Application. The IRB Application requires signatures from the Lead Researcher, Faculty Sponsor (if applicable), and the Department Chair /Organized Research Unit (ORU) Director. The signed IRB Application can be faxed, emailed, mailed, or hand carried to the Office of Research.

If the Department Chair or ORU Director is on leave, obtain a signature from the delegated authority and provide the delegation of signature authority letter.

If the Department Chair or ORU Director is a part of the research team, the signature must be obtained from the next highest level of authority (i.e., the Dean or Vice Chancellor).
What to do if you forget to obtain research HIPAA Authorization:

The Institutional Review Board (IRB) requires investigators to obtain signed HIPAA Research Authorization from all participants if Protected Health Information (PHI) will be used or disclosed for research purposes, unless a waiver is granted. The HIPAA Research Authorization form is not the Notice of Privacy Practice form used with clinical patients. The template HIPAA Authorization form is available on the Applications and Forms page.

⇒ Be sure to review your IRB approval letter (or the IRB continuing approval letter): Verify whether HIPAA Research Authorization is required.

If you enroll patients in a research study that involves PHI, but did not obtain signed HIPAA Research Authorization, you need to immediately do the following:

⇒ Take Corrective Actions:
  - Obtain signed authorization at the next study visit
  - If authorization cannot be obtained submit an Adverse Events and Unanticipated Problems report within 10 working days