Scientific Study Blueprint for Licensed Hair Practitioners – Part 1

Use Your Status and Expertise to Advance Science

Week 5

CITI Module 2

Basic Institutional Review Board (IRB) Regulations and Review Process

IRB Role

"An IRB is a review committee established to help protect the rights and welfare of human research subjects. Regulations require IRB review and approval for research involving human subjects if it is funded or regulated by the federal government. Most research organizations, professional organizations, and scholarly journals apply the same requirements to all human research. Although federal regulations refer to IRBs, an organization may have chosen a different name for this committee."

IRB Authority

Federal regulations stipulate that an IRB can:

- Approve research
- Disapprove research
- Modify research
- Conduct continuing reviews
- Observe/verify changes
- Suspend or terminate approval
- Observe the consent process and research procedures

IRB Composition

Federal regulations dictate that the IRB membership will include:

- At least five members
- Member of both sexes
- Members that come from varied professions
- At least one member whose primary concerns are in nonscientific areas
- At least one member whose primary concerns are in scientific areas
- At least one member who is not otherwise affiliated with the organization

IRB Requirements

"Organizations and IRBs vary in the practices that assure they meet the federal regulations and in the details of the standards they apply. What follows are the minimum federal requirements. Organizations and/or IRBs may add additional protections or procedures to these minimum requirements."

Applicant Responsibilities

Minimum Information on an Application for Assessment:

- Risk/anticipated benefit analysis
- Informed consent
- Assent
- Selection of subjects
- Safeguards
- Research plan for collection, storage, and data analysis
- Research design/methods
- Additional info on identification, recruitment, etc.
- Additional items IRBs must review

PI and Research Staff Responsibilities

They are required to:

1. Protect the rights and welfare of human subjects who participate in research.
2. Understand the ethical standards and regulatory requirements governing research activities with human subjects.
3. Personally conduct or supervise the research.
4. Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are informed about the study, regulations governing research, and organizational policies.
5. Ensure that all research activities have IRB approval and other approvals required by the organization before human subjects are involved.

PI and Research Staff Responsibilities cont.

6. Implement the research activity as it was approved by the IRB.
7. Obtain the informed consent of subjects before they are involved in the research and document consent as approved by the IRB.
8. Maintain written records of IRB reviews and decisions, and obtain and keep documented evidence of informed consent of the subjects (or their legally authorized representatives [LARs]).
9. Obtain IRB approval for any proposed change to the research plan prior to its implementation.
10. Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.

PI and Research Staff Responsibilities cont.

11. Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
12. Make provisions for the secured retention of complete research records and all research materials.
13. Ensure the confidentiality and security of all information obtained from and about human subjects.
14. Verify that IRB approval has been obtained from all participating organizations in collaborative activities with other organizations.
15. Notify the IRB regarding the emergency use of an investigational drug or device within five working days (or sooner if required by the IRB's policies) of the test article's administration.

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Consequences of not Following Regulations

- Suspension of research project
- Suspension of all of a PI's research projects
- Inability to use data or publish results
- Notification to sponsors, regulatory agencies, and funding agencies of noncompliance
- Debarment by FDA from using investigational products

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Consequences of not Following Regulations cont.

- Inability to receive funding from federal grants
- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities
- Termination of employment
- Loss of licenses
- Immediate shut-down of all research at an organization

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Types of IRB Review

- Full/Convened Committee Review
- Expedited Review
- Review for Exemption Status

Full/Convened Committee Review

Full committee review or review by the convened IRB is the standard type of review described in the federal regulations. It must be used for the initial review of all studies that are not eligible for expedited review or exemption status. The procedures and conditions for full committee review require that:

- The review must be conducted at a convened meeting of the IRB. A majority of IRB members (a quorum) must be present at the meeting.
- At least one member whose primary concerns are in nonscientific areas must be present at the meeting (in addition, FDA policy recommends that a physician be present).
- In order to approve research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 (and if applicable, 21 CFR 56.111) are satisfied.

Full/Convened Committee Review cont.

- A majority of the members present at the meeting must approve the research.
- IRB members who have a conflict of interest in a research project may provide information to the IRB, but cannot participate in the review of the plan or be present for voting. Members with a conflict do not count toward the quorum for the review of that study.
- The IRB must notify (in writing) researchers and the organization of its decision to approve, modify, or disapprove the research.
- IRBs must keep detailed documentation of meeting activities including attendance, voting on actions, the basis for the actions, and a written summary of the IRB discussion of controverted issues and its resolution.

Expedited Review

"Federal regulations establish nine categories that IRBs may use to invoke the expedited review process. Organizations may adopt some or all of the categories when determining if a research activity can be appropriately reviewed by an expedited review process. Categories 1 through 7 pertain to both the initial and continuing IRB review. Categories 8 and 9 pertain only to continuing review."

Expedited Review cont.

Two Criteria:
The research may not involve more than "minimal risk." Minimal risk means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (Protection of Human Subjects 2009; Institutional Review Boards 2015).
The entire research project must be consistent with one or more of the federally defined categories (OHRP 2003).

****Note:** Some organizations/IRBs have additional requirements. Check with the IRB office to learn how the IRB at your organization handles expedited review.

Categories that Qualify for Expedition

1. Clinical studies on drugs or medical devices for which an investigational new drug (IND) application or investigational device exemption (IDE) is not required. Similarly, a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Categories that Qualify for Expedition cont.

4. Collection of data through noninvasive procedures routinely employed in clinical practice provided that:
   - The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves.
   - Where medical devices are employed, they must be cleared/approved for marketing.

   Note: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.

Categories that Qualify for Expedition cont.

5. Research involving data, documents, records, or specimens that:
   - Have been collected; or
   - Will be collected solely for non-research purposes (such as, for medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior.

Categories that Qualify for Expedition cont.

8. Continuing review of research previously approved by the full/convened IRB where:
   - The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and, the research remains active only for long-term follow-up of subjects;
   - No subjects have been enrolled and no additional risks have been identified; or
   - The remaining research activities are limited to data analysis.
9. Continuing review of research not conducted under an IND application or IDE, and where categories 2 through 8 do not apply, but the IRB has determined and documented at a full/convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Review for Exemption Status

"Federal regulations specifically define six categories of human subjects research that are **exempt** from the other provisions of the regulations. OHRP (2016) guidance indicates that determinations of exempt status should be made by individuals independent of the research who are well-acquainted with interpretation of the regulations governing the conduct of human subjects research. Many organizations grant the authority to make determinations of exempt status to the IRB. Check with the IRB office to find out who has been granted authority to make the exemption determination."

Note: The determination must be made prior to initiation of research or of the activity; it cannot be made retroactively.

Categories that Qualify for Exemption

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   - Research on regular and special education instructional strategies; or
   - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Categories that Qualify for Exemption cont.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
   - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: The federal regulations specify that the exemption for survey or interview procedures do not apply to research with children.

Categories that Qualify for Exemption cont.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of 45 CFR 46.101, if:
    - The human subjects are elected or appointed public officials or candidates for public office; or
    - Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Categories that Qualify for Exemption cont.

4. Research involving the collection or study of freely available de-identified existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Note: According to OHRP, exempt reviewer(s) should define "existing" to mean collected (that is, on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and non-research activities.

Categories that Qualify for Exemption cont.

5. Research and demonstration projects conducted by heads of government departments or agencies, which are designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs
    - Procedures for obtaining benefits or services under those programs
    - Possible changes in or alternatives to those programs or procedures
    - Possible changes in methods or levels of payment for benefits or services under those programs

Categories that Qualify for Exemption cont.

6. Taste and food quality evaluation and consumer acceptance studies.
    - If wholesome foods without additives are consumed; or
    - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

When Review of Exemption is NOT Appropriate

According to 45 CFR 46 (Protection of Human Subjects 2009), research involving the following is not appropriate for exemption:

- Prisoners
- Surveying or interviewing of children
- Observations of public behavior of children when the researcher(s) participates in the activities being observed

HIPAA-Influenced Effects

"In some cases, HIPAA applicability requirements are more stringent than HHS exemption requirements and in other cases less stringent. A research project that is exempt from the human research subject IRB requirements may not be exempt from HIPAA provisions. In addition, a project that is not exempt from IRB review might be exempt from HIPAA."

Criteria for IRB Approval

The board must determine that:

- The risks to subjects are minimized.
- The risks are reasonable in relation to any anticipated benefits to the subject, and to the advancement of knowledge.
- The selection of subjects is equitable.
- Informed consent will be sought.
- Informed consent will be documented.

Criteria for IRB Approval cont.

- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.
- In addition, there are specific requirements regarding the informed consent process. These will be detailed in the CITI Program's *Informed Consent* module.

Types of IRB Submissions

- Application for Initial Review
- Application for Continuing Review
- Amendments or Modifications
- Reports of Unanticipated Problems/Adverse Events/Noncompliance to the IRB

Application for Initial Review

The first request for approval of a specific project is the application for initial review.

The initial review may be either a convened/full committee or an expedited review depending on the type of study, subjects, and level of risk.

Application for Continuing Review

"The IRB must re-review studies at a minimum of once every 365 days. An IRB may require review more frequently depending on the IRB's assessment of the study's risk/benefit ratio. The review may be a full or expedited review."

Amendments and Modifications

"Changes cannot be made to approved studies, including the informed consent document, without prior IRB review and approval. The review may be full or expedited, depending on the magnitude of the change and the effect of the change on the risks/benefits ratio."

Reports of Unanticipated Problems…

The IRB may require reports for:

- Adverse events or unanticipated problems involving risks to subjects or others
- Incidents of noncompliance
- Deviations from an approved study plan and violations of the terms of approval
- Data safety and monitoring report summaries

Examples of Reportable Events

- An unanticipated problem, which may be defined as any unexpected event that affects rights, safety, or welfare of subjects. The event could be physical (such as, an adverse drug experience or adverse device effect) or involve some harm (such as, breach in confidentiality or harm to a subject's reputation).
- Serious adverse event, which may be defined as a death, life-threatening adverse drug or device experience, inpatient hospitalization or prolongation of existing hospitalization, persistent disability/incapacity, or congenital anomaly/birth defect.

Examples of Reportable Events cont.

- Research plan exception, which may be defined as enrollment of a research subject that fails to meet research plan inclusion/exclusion criteria.
- Research plan deviation, which may be defined as a departure from the research plan as approved by the IRB for a single subject.
- Data and safety monitoring plan or board summary reports.
- Complaints concerning subject rights submitted by subjects or concerned parties, family members, or study personnel.

Record Keeping

"The signed informed consent document is one of the most critical research records the researcher needs to obtain and keep. It provides verification that the research was explained to the subject and that the subject understood and voluntarily agreed to participate in the research study. Researchers are responsible for retaining signed consent documents, IRB correspondences, and research records for at least three years after the completion of the research activity (Protection of Human Subjects 2009)."