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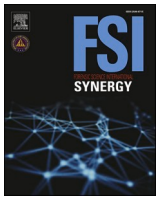

Enhancing research and collaboration in forensic science: A primer on human subjects' research protection

Forensic science is a science of identification and comparison, asking questions such as what or who? For example, attempts to answer the question of "who" commonly draw upon evidence such as DNA profiles, fingerprints, facial or voice recognition data. Research and validation projects help develop powerful investigative methods and these projects routinely require samples or statements from volunteers (human subjects) who play a critical role in the transition of research to real-world applications. The DNA, latent prints, body fluids, face or voice data that are used to test new and emerging methods must be, at one point in the research process, directly collected from individuals. However, the collection of this data from participants may have inherent risks. Some of these data are personally identifiable and jeopardize privacy, such as a fingerprint being publicly revealed, whereas as others may present higher risks such as genetic data being associated with health conditions or bringing to light unexpected familial relationships. Therefore, human subjects research protections are in place to ensure volunteers are aware of risks and to ensure general ethical research practices. This paper is intended to help familiarize forensic science researchers, including those involved with validation, with human subjects' research regulations and considerations during project design.

1. Background

Human subjects research can encompass a broad range of research types, from simple surveys to drug testing and complicated surgeries, all performed in the hope of answering research questions. The "Declaration of Helsinki", adopted by the World Medical Association in 1964, established guidelines for research ethics and "research combined with clinical care" [1,2]. Broadly, the Declaration set forth recommendations that subject research should be based on laboratory and animal research, the protocols should be independently reviewed prior to initiation, informed consent is required, researchers must be medically and scientifically qualified, and risks should not outweigh the benefits. This was revised in 1975, 1983, 1989, and 1996 and is the basis for Good Clinical Practices used today.

Since 1966, the Department of Health, Education and Welfare (DHEW), now the United States Department of Health and Human Services (DHHS), has required the review and approval of all federally funded research using human subjects. As a result of the revelations of the Tuskegee Syphilis Study, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974–1978) and the DHEW, drafted and adopted the Belmont Report to revise and enhance the protections for human subjects entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" published in the Federal Registry in 1979 [3] (Table 1). The Belmont Report established three ethical principles to preserve the rights of human subjects for any research: (1) Respect for persons (informed consent without deception), ensuring that individuals are treated as autonomous persons that are entitled to protection, (2) Beneficence, to prevent harm to subjects and systematically assess the risks and benefits, and (3) Justice, establishing and using fair procedures in the selection of subjects [3,4].

The use of human samples or interactions with human subjects for research purposes is governed by the United States Department of Health and Human Services Office of Human Research Protections where policy is set forth in the Code of Federal Regulations, Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects [8]. This code is referred to as the Common Rule and is applicable to a group of twenty federal agencies including the Department of Homeland Security and Defense, and the National Science Foundation [9,10]. Institutions that are federally funded are required to have a Federal Wide Agreement (FWA) with the government in which the institution pledges to adhere to the Belmont Report [4] and Federal Regulations 45 CFR 46-PartA (Common rule and 2018 Common Rule) when engaging in research with human subjects [8]. Note, the Department of Justice is not a current signatory to the 2018 Common Rule. This is particularly important for the intended audience, as the DOJ is the primary funding agency for forensic science research. Because the DOJ is not a current signatory of the 2018 Common Rule, the DOJ regulations regarding human subjects' protection, 28 CFR Part 46 (pre-2018 Common Rule) [11], remain in effect for DOJ-funded research awards; the provisions of the 2018 Common Rule do not apply. This will change if, and when, the DOJ signs on to the 2018 Common Rule. Additional regulations may apply including federal agency-specific regulations, organizational rules/regulations, state-associated regulations, human-subject vulnerable population-related regulations, and research involving animals or deceased individuals. Due to the complexity of research-related regulations, it is recommended that research scientists seek the knowledge of experts such as Research Directors, Human Subject Protections Directors, IRB Chairs, experienced Principal Investigators, funding organizations and other research professionals.

1.1. Helpful contextual terms to assist reader. The following definitions have been directly obtained from 45 CFR 46 [8] or 28 CFR 46

- *Research*, as defined by 45CFR46.102(I) and 28 CFR 46.102, is defined as a "systematic investigation including research

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Table 1
Seminal events in the evolution and adoption of policy and guidelines related to the ethical engagement in human subjects' research.

Year	Event	Issue	Change	Description
1932	Tuskegee experiments	U.S. Public Health Service and the Tuskegee Institute - a study to record the Natural History of Syphilis. This study recruited black male subjects with syphilis and without who were told that they were being treated for "bad blood". Despite the availability of penicillin to treat the disease, the study participants with syphilis went untreated so the study could continue [5].	1973, study ended, USPHS directed to provide medical care for research subjects. 1979, adopted the Belmont Report to revise and enhance the protections for human subjects [4].	A 1972 press report that led to an official review of the study. The panel concluded that the research was "ethically unjustified and the results were disproportionately meager compared with known risks to human subjects involved" [5].
1945	Post-World War II Nuremberg trial	War criminals who participated in experimentation on concentration camp prisoners	Nuremberg Code of 1948 [6]	Required voluntary participation, informed consent of human subjects, and an emphasis on risk/benefit in research projects involving human subjects [6].
1950s/'60s	Thalidomide scandal	Thalidomide used in 46 countries to treat morning sickness associated with pregnancy without sufficient research on its safety. This resulted in more than 10,000 births with severe deformities.	1962, Kefauver-Harris Amendments were added to the Food, Drug, and Cosmetic Act, strengthening the FDA efficacy requirements [7]	Requires drug manufacturers to prove to the FDA that the drugs are effective prior to approval and set the groundwork for phased clinical trials.

development, testing, and evaluation, designed to develop or contribute to generalized knowledge [9]. Note, the 2018 Common Rule outlines several types of activities that are not considered research, including the "collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes" [9]. This exclusion, however, only applies to a criminal justice agency and does not extend to private or public institutions with an FWA.

- *Human Subject*, as defined by the 45CFR46.102(I), is "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens."; as defined by the 28 CFR 46.102 Human Subject "means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information".
- *Interaction* (45 CFR 46) – direct communication between an investigator and subject.
- *Intervention* – 45 CFR 46 – physical procedures where information or biospecimens are collected; 28 CFR 46 – "includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject."
- *Private information* – 45 CFR 46 – information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record); 28 CFR *46* – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the private information) in order for the information to constitute research involving human subjects.
- *Identifiable private information* (45 CFR 46) – private information where the identity of the subject is either known or can be readily identified or determined by the investigator or is associated with the information being collected.
- *Identifiable biospecimen* (45 CFR 46) – a biospecimen where the identity of the subject is either known or can be determined by the investigator or is associated with the biospecimen.
- *Coded* (45 CFR 46) – identifying information that can lead to the identity of the subject is changed using a naming convention that is free of identifying information (e.g., a number or letter) and a key exists that can be used to trace the naming convention to the subject's identity.
- *Secondary Research* (45 CFR 46) – this research reuses data or biospecimens that were collected as a part of another study or project. For example, the use of samples that were collected from a tissue repository or samples that were collected as part of another research study. This research does not involve an intervention or interaction to collect biospecimens or data from an individual.

2. Institutional Review Board

The Institutional Review Board (IRB) is a review committee established to protect the rights and welfare of human research subjects, and to ensure responsible research practices and compliance with the guidelines established by the Office of Human Research Protections. IRB approval is required if human subjects research is a part of any study that is conducted, supported, or regulated by U.S. federal agencies. Given the importance and sensitivity of human subjects' research, most research organizations choose to apply the review requirements to all research, regardless of the funding source.

An IRB is comprised of at least five members from varied backgrounds and professions. These members will include individuals that have relevant experience and expertise in the areas of research that may involve human subjects research and are knowledgeable in the relevant regulations, laws, and standards of professional practice. Required members include a scientific expert, a non-scientist, and an individual who is unaffiliated with the institution. Additionally, the IRB membership must be diverse in sex, racial and cultural backgrounds [12].

2.1. IRB review process

There are minimum federal requirements of information for IRB review, but an individual IRB may add additional protections or procedures for project approval [9]. The minimal federal requirements for review include:

1. Risk/anticipated benefit analysis, where an assessment of the risks is made, ensuring they are both reasonable and are minimized.
2. Informed consent, requiring a detailed description of the processes and procedures for sample collection and analysis. This includes an

assessment of an informed consent waiver that will be subject to review and acceptance by participants in the study.
3. Assent, where, if the participant is a minor or member of another vulnerable population is to participate in the research, they must have the study—with its risks and benefits—clearly explained and agree to participation in it, despite their inability to provide consent themselves.
4. The selection of subjects is reviewed to ensure it is equitable with respect to race, sex, and ethnicity. The benefits from the research should be distributed evenly across the community. Additional safeguards need to be described for vulnerable populations. If a particular population is excluded from the study, justification needs to be included.
5. Privacy is reviewed to ensure that recruitment does not adversely impact an individual's privacy. This includes an assessment of the study's protocols to ensure the confidentiality of the subjects, the samples collected, and the data produced.
6. A research plan for the collection, storage and analysis of data is created, ensuring the safety of the subjects and describe plans for secure storage of samples and data.
7. Research design and methods must be appropriate, scientifically valid, and do not expose the subjects to unnecessary risk.

The IRB may also require the review of additional information to ensure the protection of human subjects, e.g., protocols/scripts for the identification and recruitment of subjects, the qualifications of the principal investigator and collaborators or compliance with federal/state laws and organizational policies.

2.2. IRB timeline and review categories

The timeline for IRB approval varies based on the practices of the individual board, the complexity of the proposed project, and the skill of the submitter. The time involved in the review can vary greatly depending on the individual application, from weeks to months. The process is initiated when a researcher submits an application that meets the aforementioned criteria. These applications are typically found on the institution's Office of Research website. An initial administrative review ensures all required documentation has been received and is in order. Next, a designated member, or members, of the IRB perform an initial review of the proposal. They may request changes such as additional documentation or that the researcher(s) undergo human subjects research training. During the initial scientific review, the IRB representative will designate the type of IRB review that will be required, such as exempt, expedited, or full.

The type of review is largely dictated by the level of interaction or intervention that is proposed. A full review is required when the proposed study will involve vulnerable populations, procedures that may cause significant physical or emotional harm or discomfort, collection of data about highly sensitive topics or illegal activities and collection of data that—if associated with a participant—may cause serious legal, social, or financial distress. This type of review is evaluated by the full IRB. An expedited review is used when the research poses no more than a minimal risk to subjects and falls into at least one of the following categories: (1) clinical studies of drugs and medical devices for which neither an investigational new drug application nor investigational device exemption are required or the device is cleared and is being used accordance with its approved labeling, (2) collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in particular populations and within certain quantity limits, (3) biological samples that are collected non-invasively for research purposes only, (4) collection of data through non-invasive procedures routinely employed in clinical practice (e.g., external body sensors), excluding procedures involving x-rays or microwaves, (5) data that have been, or will be, collected solely for non-research purposes, (6) data from voice, video, digital, or image recordings made for research purposes, (7) research on characteristics/behavior or research employing surveys, interviews, oral histories, focus groups, program evaluations, human factors evaluations, or quality assurance methodologies, and (8) continuing research previously approved by an IRB with specific conditions [13]. An exempt review, unlike the name implies, does require review by the IRB or research protections office. This type of review is initiated when the interaction or intervention with human subjects poses no more than a minimal risk and satisfy a set of exemption categories that generally consist of research that is performed in common educational settings, information that is collected where the identity of the subject cannot be readily ascertained including secondary research of biospecimens when the samples are publicly available, deidentified samples where the researcher does not have a key available, or data is collected by a federal agency where the data was collected by the government for non-research activities. Additional exemption categories and an expanded description of these can be found in 45 CFR46 Subpart A 46.104 CFR [8]. An exemption, if granted, is not required to have annual continuing review, however other federal, state, local or institutional requirements may also apply. Note, since the DOJ is not yet a signatory of the 2018 Common Rule, exemptions are found in 28 CFR 46 [11].

3. Informed consent

Prospective participants in a research study must be provided with information about the study such that the individual can make an informed decision regarding their participation in the study. This is called informed consent and is a requirement to conduct human subjects research [8]. As defined in 45CFR46.116, basic elements of informed consent include:

a. Information about the study, including the purpose of the research, the duration of the individual's participation, a listing of the procedures, and the identification of any experimental procedures.
b. Any risks or discomforts to the individual.
c. Identifying the benefits of the study.
d. Identifying other appropriate alternative procedures or treatments (if any).
e. The extent of confidentiality that the individual can expect.
f. If the research involves more than minimal risk, identifying potential compensation or covered medical treatments in the event of an adverse event.
g. A designated representative that can answer questions about the study, provide information about the individual's rights as a study participant, and whom to contact in the event of an adverse event.
h. An explanation assuring the ability of the individual to cease participation at any time during the study without penalty or loss of benefits.
i. A statement that indicates if potential future use for biospecimens is permitted.
j. And additional elements covered under 45CFR46.116(c).

There are specific protections for vulnerable populations including:

a. Pregnant women, human fetuses, and neonates (45CFR46 subpart B)
b. Biomedical and behavioral research involving prisoners (45CFR46 subpart C)
c. Children (45CFR46 subpart D)

4. Human subjects and the nexus to forensic science

Human subjects research involves any research activity that collects data on individuals through an interaction or intervention, or obtains, studies, analyzes, or generates private information or biospecimens, whether coded or not. Examples of human subjects' research in forensic science may include a validation where DNA profiles are collected to test a new DNA amplification kit, fingerprints are collected to validate a new

processing method and face or voice recognition. Often, the laboratory personnel carrying out validation projects will seek volunteers from within the laboratory to provide samples. Whereas in other cases the researchers will look externally for participants or purchase or acquire samples from online repositories of data or specimens. See the list below for a list of general project examples where human subjects research regulation may apply.

Forensic Science Research Project Examples:

a. Interlaboratory Studies
b. Error Rate Studies
c. Research projects involving the collection of bodily fluids/biospecimens for testing purposes.
d. Research projects which may involve risk to human subjects.
e. Research projects involving personally identifiable biological information including STR analysis, phenotyping, ethnicity, genetic genealogy, facial and voice recognition.
f. Research projects involving fingerprints for evaluating latent print development techniques.

5. Guidance

Whether the collection is anonymous, or the identities of the volunteers are known, the collection of the samples is considered an intervention or interaction and therefore would constitute human subjects' research and thus would fall under the purview of the human subjects' research regulations. There are means of structuring a study that will not be subject to these regulations such as using non-identifiable data and obtaining data for secondary research purposes. Non-identifiable information/biospecimens are exempt from human subjects' research when the private information or biospecimens cannot be linked to individuals, either directly or indirectly, or they cannot be readily associated to the identifying data by the investigator. For example, in a multi-institutional research project, the institution that collects and codes the information or biospecimens *would* be engaged in human subjects' research. If the coded data or samples were then sent to another institution that did not have access to the key (identifying information), this institution *would not* be engaging in human subjects' research. This exemption is removed if the investigator that received coded data or samples learns the identity of a participant. Many times, laboratories will seek volunteers from their institution to participate in validation or other research activities. Collection of samples from within a lab may not permit an exemption but may qualify for an expedited review. This can be accomplished through the anonymous collection of samples (anonymous to the researchers). For example, researchers may provide instructions to participants to self-collect buccal swabs and label them with a code in a location where the researchers are not present.

Research studies that involve secondary research may be executed without additional IRB approvals, however this should be verified with the appropriate institutional authority. This applies when the data or specimens were collected as a part of another study and are both available for use and coded, so the investigator of the secondary research has no way of connecting the coded sample or data to the identity of the participants. An example of such samples or data are those collected from a public database or tissue repository. Current regulations state that biospecimens can be deidentified and used for secondary research projects without pursuing additional consent [14]. However, this broad consent would still require a waiver of consent to be obtained from an IRB or direct consent to be obtained. The new regulations in combination with the previous, regulations, stress that privacy and confidentiality must be ensured when there is secondary research use of biospecimens [14].

5.1. Exclusions

The 2018 Common Rule has added additional exclusions (not considered research) that may be applicable to the forensic community. Notable exclusions include the collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes [9]. Guidance on the application of this exclusion states that this applies to the collection and processing of fingerprints or DNA samples from victims, suspects, or known offenders and the maintenance of databases [15]. This exclusion and the associated guidance do not address the applicability to validation-related projects, therefore these studies, which are defined as research, may require IRB approval. A second exclusion is related to authorized intelligence operations activities in support of matters of national security. The applicability of this exclusion is subject to approval by the agency authorizing the operations [15]. Although these exclusions exist, local, state, or federal requirements may supersede them and thus it is recommended to verify the exclusion with the appropriate authorized representative, for example, a Research Integrity Office or legal counsel. Another important consideration is that the process of approval of human subjects' research for the primary researcher may be significantly eased or avoided when samples are purchased or acquired through repositories for data or specimens.

5.2. Genetic data

Most research and validation in forensic genetics seek participants that will provide samples for genetic characterization, e.g., single nucleotide polymorphisms (SNPs) or microhaplotypes used for determining identity, ancestry, phenotype, or genealogical/familial relationships, nuclear autosomal STRs, Y-STRs, X-STRs used for individual identification or familial relationships and whole genome, exome or proteome sequencing including mitochondrial sequencing. IRB review and approval of the project will largely focus on the risks that the participants may be exposed to if the data becomes identified or public. These risks are predominately associated with psychological, social, or financial damage. For example, if a person is identified as having a predisposition to a genetic disorder, this could affect the insurance coverage of the individual or the individual's family. Thus, most guidance in the use of genetic data in human subjects' research is focused on the health conditions of the participant or their family. There is a "gray area" when using genetic data in potential human subjects' research in matters outside of the health-based research area, where most forensic genetic research will take place. This type of human subjects' research will typically impart a minimal risk to the participant and therefore the project may qualify for an expedited IRB review. For example, a study where only autosomal STR profiles (fragment or sequence-based) are used would pose a minimal risk because these markers are not significantly associated with any health conditions. Whole genome sequencing, phenotyping, exome or proteome sequencing, or genealogical research in forensics may represent more than minimal risk due to the inclusion of potential health-related genetic markers in the data set. For example, whole genome sequencing projects in forensics may not focus on genes associated with disease states; however, this data is present in the full genomic data set. Similarly, forensic genealogical research may represent more than minimal risk because the data, composed of genetic and non-genetic data that may contain health-related data, will be combined, and associated with an individual and their family members. As the criminal justice community currently debates the idea of privacy as it relates to familial data, so does the human subjects' research arena. IRBs are encouraged to weigh ethical

considerations as to what data is collected and how it will be used in situations where a proband is being recruited. The use of genealogical data is receiving an increased amount of attention and, while studies involve publicly accessible data, studies where data is generated to examine relatedness may be subject to additional recruitment and consent procedures [16].

Government agencies and departments that have committed to the Common Rule and 2018 Common Rule and will be evaluating what is considered identifiable information and identifying analytical methods that may generate identifiable private information or biospecimens. This initial list of technologies will be compiled, and recommendations will be made based on issues relating to consent, privacy, and data protections. This will be a cyclical process with a review at a minimum of every four years [17]. Although guidance is forthcoming, it is recommended that an IRB office is contacted for guidance if there is a question of the applicability of human subjects' research to a specific project. Regardless of the applicability of human subjects research oversight and requirements, it is always recommended that data should be stored in a manner where the individuals cannot be directly identified and data release considerations, such as for publications, must be approved by an IRB (if applicable) and disclosed and agreed to by the participants [16].

5.3. Guidance outside of the U.S

The European Union enacted a law known as the General Data Protection Regulation (GDPR) to establish the protection of privacy and security of personal data in the European Economic Area (EAA) that includes all members of the European Union, Iceland, Liechtenstein and Norway [18]. Under the GDPR, personal data is defined as "information related to or identifiable to a natural person". Examples include names, email addresses, and personal characteristics. Further regulations apply to "special categories of personal data" that include data related to a person's health, genetics, race/ethnicity, and biometrics used for identification purposes. This regulation, unlike the U.S. counterpart, states that coded data is considered to be personal data even if no key exists. However, this is not applicable when data is fully anonymized, where there is no key available to link the data to an individual. This regulation applies to those projects where personal data is physically collected in the EEA and can extend to projects where data is transferred to countries outside of the EEA. Additional information is available and should be reviewed to determine if the GDPR applies to the study in question [18].

6. Final thoughts

Institutional Review Board review is necessary when a study involves human subjects research, as defined by the Common Rule and 2018 Common Rule [9,11]. These regulations will likely apply to many studies that are undertaken in a forensic laboratory, and appropriate consideration must be given to the restrictions, protections and application that may be required in a specific study—exempt, expedited, and full board. Exempt reviews are appropriate for studies that involve minimal risks, however, the determination of the level of risk is decided upon by the IRB. Expedited reviews apply to projects that involve minimal risks and no greater risk than those that would be encountered in daily life. Full board reviews apply to projects to studies where the participants face a heightened risk to themselves, greater than that experienced during daily life when a participant's results or responses, if made public, will be personally damaging or the research involves prisoners or individuals with legal restrictions. The following references may help determine if human subjects research regulations are applicable and identify the relevant review category [19–21]. This paper is only meant to inform the reader of considerations when performing potential human subjects research and is not a substitute for review by the proper authorities. It is always recommended that the study be reviewed by an IRB to determine the applicability of the regulations and protections, regardless of the category to which the study applies.

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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