



# Institutional Review Board (IRB) For Human Subject Research (HSR) Protection

FBI CPD 0737D  
DOJ Reg.: 28 C.F.R., Part 46

**NOT AUTHORIZED FOR POSTING ON THE INTERNET**



# HUMAN SUBJECT RESEARCH PROTECTION HISTORY

- In 1991 HHS issues revised, genericized HSR regulations intended to be adopted by all Departments of Government to be known as “**The Common Rule [on Human Subject Research]**”
- 1994 DOJ Adopts its own version of “The Common Rule” embodied in **28 C.F.R., Part 46**.
- 1997 President Clinton issues an HSR Executive Order applying special rules to **CLASSIFIED HSR** after it becomes public that CIA had used LSD in the 1950s as part of a CIA “experimental” employee security interviews process. CIA Senior Scientist Dr. Frank Olson jumped to his death from a hotel room in NYC after such an interview “experiment.”
- 1998, the FBI adopts policy by EC in compliance with the DOJ regulations establishing the first FBI IRB.





# HUMAN SUBJECT RESEARCH PROTECTION HISTORY

.... continued

- 2012 Newly established FBI Office of Integrity & Compliance (OIC) conducts a “red team” on the FBI IRB noting routine delays of 6 – 12 months to approve any FBI HSR. FBI adopts red team mitigation recommendations
- 2012 STB and OIC issue Corporate Policy (CPN) Notice dramatically changing the FBI IRB and the way it operates.
- 2012 OIC recommends that the FBI IRB will be housed temporarily under the control of the STB EAD because OIC does not have the resources to administer the IRB. SL Motta is appointed IRB Chair by STB EAD Martinez.
- 2015 CPN expires and is replaced with Corporate Policy Directive **(CPD) 0737D**. OTD Employee is selected as permanent IRB Administrator.
  - By CPD 0737D, IRB Admin must be no less than 50% of assigned duties.
- 2022 IRB Administrator leaves the FBI.
- 2023 Acting IRB Administrators are appointed.
- 2023 IRB is moved under the Next Generation Technology Lawful Access Section (NGTLAS) of STB FO under the STB EAD.





## FBI CPD 0737D – IRB STRUCTURE & OPERATION

### IMPLIMENTS DOJ REG 28 CFR PART 46

- CPD 0737D implements 28 CFR Part 46 and creates a ten (**10**) voting person FBI IRB.
  - Chairperson appointed by STB EAD – must be SES or SL.
  - IRB answers directly to STB EAD.
  - IRB membership is NOT a collateral duty. PAR must rate IRB duties.
  - IRB Membership: One primary and one secondary member from:
    - Laboratory Division (LD), Critical Incident Response Group (CIRG), Training Division (TD), Office of Equal Employment Opportunity (OEEEO), Human Resources Division (HRD), Employee Assistance Program (EAP), Office of Integrity & Compliance (OIC), Operational Technology Division (OTD) Criminal Justice Information Services Division (CJIS) and One Non-FBI
    - FBI IRB Mets MONTHLY via Skype/MS Teams typically on 2nd Wednesday of the month. Deadline for new submissions is one (1) week before.





## The Scope of FBI IRB Jurisdiction:

- By DOJ Regulation, FBI IRB has jurisdiction over any putative HSR “**conducted**” by (and for) the FBI or “**supported**” by the FBI. - 28 C.F.R. §46.101(a)
- “**Conducted by**” includes:
  - FBI Employee actually doing the research.
  - Contractors, FBI detailees, FBI Task Force Officers doing the research
  - FBI personnel’s personal academic degree research if based upon any non-public FBI topic, non-public FBI specialized knowledge, data, equipment, processes, etc.
  - See FBI CPD 1120, **Sec. 4.8.8.3 & associated approval form**
    - FBI Ethics & Integrity Program Guide
    - Use of Govt Resources For Personal Benefit
    - Requires prior AD certification that the proposed research is in FBI interests and would likely have occurred even if no academic degree of employee was involved.





## The Scope of FBI IRB Jurisdiction:

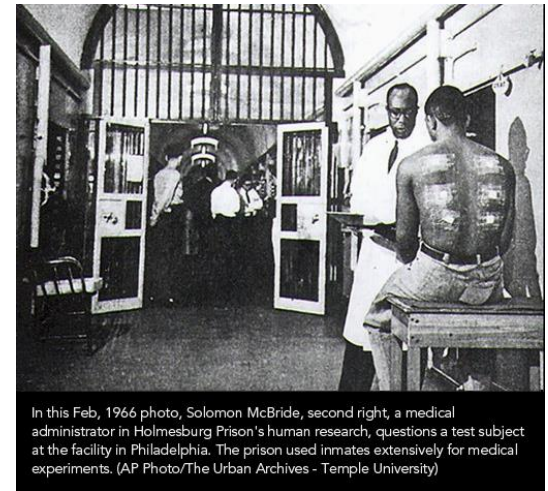
- By DOJ Regulation, FBI IRB has jurisdiction over any putative HSR “conducted” by (and for) the FBI or “**supported**” by the FBI.
- “**Supported by**” includes:
  - With FBI \$\$\$ (including pass through NIPR IC \$\$\$)
  - With FBI resources such as personnel, data (e.g, face galleries, fingerprint exemplars, CHRI, voice exemplars), computing capabilities, insider information, FBI SME quality assurance review).



## The Scope of FBI IRB Jurisdiction:

### ■ DOJ Regulation is **ONLY Part A** of the HHS “Common Rule”

- FBI does **NOT** have authority to study “vulnerable populations”- pregnant women, children, prisoners, mentally incapacitated persons.
  - Common Rule **Part B & D** – Pregnant Women, Children, Neonates, Mentally-incapacitated Persons.
  - Common Rule **Part C** – Prisoners
  - Definition: (45 C.F.R. 46.303) Persons serving a sentence of incarceration, diversion or awaiting arraignment or trial.
- Federal Bureau of Prisons (BOP) has its own HSR Regulations and HSR Officer.
    - DOJ Program Statement implementing then PART B for BOP.



In this Feb, 1966 photo, Solomon McBride, second right, a medical administrator in Holmesburg Prison's human research, questions a test subject at the facility in Philadelphia. The prison used inmates extensively for medical experiments. (AP Photo/The Urban Archives - Temple University)

## The Scope of FBI IRB Jurisdiction:

### Other DOJ Restrictions: Native Americans/Alaskan Natives

- FBI authority to knowingly conduct or support research on or about Native Americans or Alaskan Natives is conditioned upon compliance with President Clinton Executive Order 13175 entitled: “*Consultation and Coordination with Indian Tribal Governments.*”
  - January 26, 2021, President Joseph Biden issued a “*Memorandum on Tribal Consultations and Strengthening Nation-to-Nation Relationships*” reaffirming and expanding upon both the President Clinton Executive Order and the President Obama Memorandum.
  - August 29, 2013, Attorney General Eric Holder issued a DOJ Order and Policy Memorandum implementing President Obama’s November 6, 2000 Memorandum and ExOrd 13175 in the “*Department of Justice Policy on Tribal Consultation*”
    - Requires consultation with DOJ Office of Tribal Justice (OTJ) to determine whether the research first requires “consultation” with Tribal Authorities
    - Tribes run their own IRBs and have established an “Inter-tribal IRB” for some tribes.



## The Scope of FBI IRB Jurisdiction: Exemptions

- IRB Chair, not the researchers, decide what is covered or not by DOJ Regulation and CPD 0737D.
  - See CPD 0737D, Section 6.3.2.2:  
[The IRB Chairperson must:]  
*"Declare research applications and proposals that qualify under DOJ IRB regulations or IRB policies and procedures as exempt from IRB jurisdiction."*
  - **Exemptions by Category vs Exemption by Exclusion:**
    - Exemptions by Category - 28 C.F.R. §46.102(b)
    - Exemption Definitional Exclusion





## The Scope of FBI IRB Jurisdiction: Exemptions by Category

- Exemptions by Category - 28 C.F.R. §46.102(b)
  - (5) “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 information**) in order for obtaining the information to constitute research involving human subjects.”
  - Does “**may readily be ascertained ... or associated with**” require IRB to consider “the rogue FBI employee” who queries FBI databases in violation of policy?
    - Running de-identified fingerprints, faces or DNA in FBI databases?
    - Typically, IRB interprets such databases as not being “readily” available and therefore not an issue in most cases.
    - IRB frequently imposes express stipulations:
      - That the researchers not engage in or assist in engaging in any activity that would lead to the re-identification of human subjects.
      - That HSR data not be enrolled in any **criminal investigatory or national security database** or be used for any criminal, civil or administrative investigatory purpose to the detriment of the contributor.
  - AI is challenging the assumptions of anonymity in big data sets.





## The Scope of FBI IRB Jurisdiction:

What kinds of things may be readily identifiable or ascertainable?

- CONTINUED - OGC Opinion is that there is conceptual overlap between Privacy Act's concept of "Personally Identifiable Information" (PII) and what is readily identifiable for IRB purposes.
- The following biometrics are considered PII and readily identifiable or ascertainable for IRB purposes:
  - Fingerprints;
  - Facial Images
  - DNA [publicly available DNA family ancestry databases complicate this issue]
- This suggests that these biometrics are NOT truly "anonymizable" for IRB purposes and, therefore, exclusion §46.102(b)(5) is NOT applicable.





## The Scope of FBI IRB Jurisdiction:

### Department/Agency Head Authority to Expand Activities Subject to IRB Jurisdiction

- **28 C.F.R. §46.102(d)-Department or Agency Heads May Require IRB Review of Even non-HSR Activities:**
  - **STB EAD mandated that STB Division were not to seek IRB exemptions and that all DNA and Biometric Research was to undergo IRB Review.**





## DOJ REG 28 C.F.R. PART 46 IRB COMPLIANCE IMPLICATIONS

- ❑ **DOJ regulation PROHIBITS** the use of federal funds for HSR that does not conform to the IRB review regulations/policy. See 28 C.F.R. Sec. 46.122
  - *“Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.”*
- ❑ **DOJ Civil Lit:** Failure to obtain prior IRB approval when required can be considered a factor in determining whether a DOJ employee was properly exercising discretionary authority within the scope of their employment for purposes of evaluating Federal Tort Claims Act liability, indemnification and DOJ attorney representation.
  - ❑ Translation: You could, in theory, be on your own if non-IRB-reviewed research creates financial liability.





# The Scope of FBI IRB Jurisdiction: What is a “human subject” Research?

## EXAMPLES OF FBI IRB MONITORED RESEARCH:

- FBI LD Genetics
- FBI HIG “Interrogation Science”
- FBI CT Violent Extremism Studies
- DOJ/CJIS NIJ/USSG Probation/Parole CHRI Recidivism Studies
- FBI OTD/NIST Facial Recognition Studies/ Algorithm Testing
- FBI Forensic Examiner validation studies
- CIRG HRT After Action Response Studies
- CIRG Crisis Management/Leadership Studies





# IRB OPERATIONAL CHALLENGES

- STB Division Request IRB Exemptions More Frequently.
- Combination of COVID and Departure of Permanent IRB Administrator for 8 months dramatically reduced the IRB's Review Capabilities.
  - Pre-COVID IRB reviewed approx. 5-10 new research projects and 15 – 25 annual reviews of ongoing research each month.
  - Post COVID and Post Departure of IRB Admin, IRB now reviewing approx. 1-3 new research projects and 5-15 continuing reviews as of March 2023.





# IRB OPERATIONAL CHALLENGES

- FBI IRB is the largest, busiest IRB in the DOJ
- DOJ relies on FBI IRB to represent it in interagency HSR meetings.
- FBI IRB Chair belongs to an IC IRB Chairperson working group.
- **CLASSIFIED HSR** - FBI IRB is the **ONLY** IRB in the IC which meets the **March 27, 1997 Clinton Executive Order** requirements to conduct “classified research”
  - Tenured University Professor was qualified as the required non-federal classified IRB member.
  - This member serves for free beyond any travel expenses.
  - Some IC classified research is reconfigured to include the FBI because the FBI IRB is authorized to review.
  - **Classified Research cannot be approved by the IRB if the special member does not vote to approve.**



# SIGNIFICANT IRB CHANGES ON THE HORIZON



- **2016 HHS promulgated “NEW COMMON RULE”**
  - Was adopted by all USG Departments except a few.
  - DOJ did NOT adopt it because HHS had not given DOJ Office of Legal Counsel the 90 day advance notice they requested.
- **2018 HHS Further Amended the New Common Rule**
  - DOJ did not join this rulemaking either.
- **2023 DOJ Office of Justice Programs (OJP) has agreed to initiate a new, separate DOJ HSR Rule-making proceeding which combines the 2016 and 2018 HHS “New Common Rule” Changes into one Rule.**
  - FBI IRB Chair has been asked to provide assistance since FBI IRB is the DOJ’s largest and most active IRB.





# SIGNIFICANT IRB CHANGES ON THE HORIZON – NEW 2016/2018 COMMON RULE

- **"ONE IRB" MANDATE-IRBs to collaborate for only one IRB to govern.**
- **CONTINUING REVIEW WAIVER BY IRB UPON MINIMAL RISK FINDING**
  - Final Report still required.
  - IRB can institute a CR at any time if deemed prudent
- **CRIMINAL JUSTICE & NATIONAL SECURITY EXCEPTIONS**
  - 45 C.F.R. Sec. 46.102(L)- Definition of "Research" will exclude:
    - *"(3) 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**."*
    - *"(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other **national security** missions."*
- **5 YEAR ANONYMITY STUDY EXPERT CONSULTANT REQUIREMENT**
  - 45 C.F.R. Sec. 46.102(e)(7) - each department must "reexamine" the meaning of "identifiable private information."



# SIGNIFICANT IRB CHANGES ON THE HORIZON – NEW COMMON RULE



- **ADDITIONAL INFORMED CONSENT REQUIREMENTS:**
  - Foreseeable Future Other Uses must be conspicuously described.
  - Subjects must have the right to “opt out” of future uses.
  - Scope of future uses must be described – can’t be for any and all undescribed uses.
    - FBI IRB is already implementing some of these changes now so as to minimize impact to ongoing research when New Common Rule is adopted by DOJ.





## BASIC IRB STATS:

- Total Docket Numbers to Date is 740.
  - This number does not reflect all Chair Consultations and Exclusions
- From 1999 to 2012 (13 years) there were 254 IRB filings
- From 2012 to 2023 there were an additional 430 IRB filings.
- Prior to COVID, the IRB Docket was increasing by approx. 75 filings a year.
- In 2022, the IRB Docket increased by only 42 filings.
- In 2023 to date, the IRB Docket has increased by 55 filings.
- Top 6 Highest IRB filers are:
  - 1<sup>st</sup>) CIRG/BAU; 2<sup>nd</sup>) CTD/HIG; 3<sup>rd</sup>) Lab Division; 4) TD; 5) CJIS/CHRI; 6) OTD
  - IRB Does NOT have authority to authorize release of FBI controlled data such as CHRI





What is the FBI's Oldest,  
Continuous Human  
Subject Research Project?



## FBI IRB QUIZ:



**IRB Docket No. 003-99 "Serial Homicide Interviews of Incarcerated Offenders" CIRG/BAU-(Silence of the Lambs)**

