Inclusion of Court Ordered Patients/Prisoners in Psychiatric Research

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Introduction

- Including prisoners into research studies has been a controversial topic.
- Past exploitation and abuse have contributed to strict regulations and reluctance to involve this vulnerable population as study participants.
- Hence, prisoners are routinely denied the opportunity to participate in research.
- However, many patients now in State psychiatric facilities meet the HHS definition of prisoners and it is often difficult to determine what constitutes prisoner status and what does not.
- This group also represents a population that may be denied the opportunity to participate in clinical research.
- Recent data suggests that prisoners and court ordered psychiatric inpatients have limited access to research participation which may be disadvantageous particularly if the research study is minimal risk and they are excluded from opportunities others may have.
- Data also suggest that the perceived burden of including prisoners is far more prominent in motivating researcher exclusion than due to regulations or ethical concerns.
- It may be time for research to be more accessible to prisoners in line with the principle of equivalence in healthcare.
- We have been successful in recruiting court ordered patients into clinical research and have worked to identify terminology to identify and rationale.

Methods

- We have conducted clinical research with inpatients at a State Psychiatric hospital over the past 30 years and the population has moved from voluntary status to more court ordered status over time.
- This project aims to demystify prisoner research.
- We developed a process to better identify who is and who is not a prisoner in a State hospital affiliated research program.
- Here we present clarification on the prisoner status, detail the regulations and process and report on our experience.

Prisoner Research

Broadly speaking:

Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration **are** considered "prisoners."

Individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, **are not** prisoners.

Prisoner Research Summary

- Regulations state that "prisoner" means any individual involuntarily confined or detained in a penal institution and constitutes a **vulnerable population.**
- The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution*, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).
- The penal institution clarification was added to the definition and 45 CFR in the 2018 regulatory changes.
- Since many patients in State psychiatric facilities locally and across the country are involved with the court system some patient designations would constitute a "prisoner" under the expanded regulations.
- Protocols are required to address all 7 CFR stipulations.
- Protocols are required to be reviewed by an IRB with one prisoner representative present.
- Protocols must be approved by the Office of Human Research Protections (OHRP) if federally funded.
- These are generally sent by the approving IRB to OHRP, but investigator communication with the IRB is important.

Prisoner Research Guidelines

- Research under review represents **one of the categories of research permissible** under 45 CFR 46.306(a)(2).
- Any possible advantages accruing to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are **not of such a magnitude that his/her ability to weigh the risks against the value of such advantages** in the limited choice environment of the prison is impaired.
- **Risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers**.
- Procedures for the selection of subjects within the prison **are fair to all prisoners and immune from arbitrary intervention by prison authorities** or prisoners.
- Random selection.
- Information is presented in **understandable language** for the population.
- Informing participants that parole boards **will not take into account a prisoner's participation in the research in making decisions regarding parole**.
- Where the IRB finds there may be a need **for follow-up/care, adequate provision is made to provide** this, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Categories of Permissible Research

. Possible causes, effects, and processes of incarceration, and of criminal behavior or the study of prisons as institutional structures or of prisoners as incarcerated persons;
. Research on conditions particularly affecting prisoners as a class;
. Research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject;
. Research that describes the prevalence or incidence of a disease by identifying all cases, or potential risk factor associations for a disease.

Results

- Our research team has successfully had 9 protocols approved by the IRB and OHRP for inclusion of patients with "prisoner status."
- We have included 479 prisoner status patients to date.
- We have summarized 11 terms regarding legal status that are typically found in the medical charts: **6 are considered prisoner status under the current regulations**.

Legal Terminology/Designation	Prisoner/OHRP approval required
Voluntary	No
Voluntary Disabled (Guardian of Person)	No
Voluntary Return on Conditional Release	No
Voluntary on Probation	No
Voluntary with Pretrial Conditions	Yes
Voluntary Detainer	Yes
Civil Commitment/ involuntary Admission (IVA)	No
Pretrial	Yes
Incompetent to Stand Trial (IST)	Yes
Not Criminally Responsible (NCR)	Yes
Hospital Warrant (Involuntary Return on Conditional Release)	Yes

Conclusion

- There is confusion regarding the terminology of "prisoners" in research regulations.
- We have attempted to help to clarify terminology and assist with disseminating our successful process of IRB submission.
- We have successfully enrolled hundreds of prisoners into clinical research.
- The sharing of this information is critical to bring more equity and opportunities to this much overlooked and misunderstood research population.

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