# Research Protocol for Right to Try Laws

**Prepared by the Center for Public Health Law Research Staff**

**OCTOBER 2016**

# Right to Try Laws

I. **Date of Protocol:** October 1, 2016


II. **Scope:**
   a. Compile state "Right to Try" laws, which state that terminally ill patients can try investigational products that have not yet been approved by the FDA.
   b. This longitudinal dataset includes coding questions on whether the state has a Right to Try law, how "terminal illness" is defined, what the criteria for a patient to be eligible for access to investigational products are, whether manufacturers are required to make investigational products available to eligible patients, whether manufacturers are required to cover the costs associated with investigational products, whether insurers are required to pay for coverage costs, and what coverage or care patients may have to forfeit if they access an investigational product under Right to Try laws.


III. **Project Team:**
   a. **Supervisors:** Nicolas Wilhelm, JD, Lindsay Cloud, JD,

   b. **Researchers:** Amanda Cappelletti, JD candidate, Kaiqi Du, JD candidate, Christopher Manno, JD candidate, Benjamin Segal, JD candidate


IV. **Primary Data Collection**
   a. **Project Dates:** June 1, 2016-October 1, 2016

   b. **Dates Covered in the Dataset:** This dataset is a longitudinal, and covers the time period between January 1, 2014 and October 1, 2016. The effective dates used in this dataset are the actual effective dates listed in the state laws used to code the dataset. If more than one law appears in the legal text, the effective date reflects the date of the most recently amended or enacted law.

   c. **Data Collection Methods:** The researchers began by drafting background memos to explore the legal landscape of the topic. These background memos explored secondary sources such as the Goldwater Institute's website, the FDA website, and academic articles to identify what states have Right to Try laws, and what variables could be studied in the dataset. The researchers then drafted five state memos (three were drafted), to evaluate the Right to Try laws in a total of 15 states, using Westlaw Next and Openstates.org as research tools.
      i. **Databases Used:** Westlaw Next was used to identify relevant laws. The texts of the laws were then collected from state legislative websites.
      ii. **Search Terms Used:**
         1. "Right to Try", "Investigational products", and "Investigational drugs".

2. Keyword searches were supplemented by examining the table of contents of each relevant section of the state law identified for statues or regulations related to Right to Try laws. Researchers also collected effective dates for the most recent version of relevant statutes and regulations.
3. Once all the relevant statutes and regulations were identified for a jurisdiction, a Master Sheet was created that summarized the relevant statute or regulation, included the most recent statutory history for each statute and regulation, and added the effective date for that version of the law.
4. All 30 states (Connecticut law was not yet effective when the research began) with Right to Try laws were 100% redundantly researched to confirm that all relevant law was being collected by the Researchers.
5. When Connecticut's law came into effect, it was redundantly researched to confirm that all relevant law was collected by the researchers.

V. **Coding**
   a. **Development of Coding Questions:** The information collected during the background research phase of the dataset, including the background memos and five state memos, was used to produce a first draft of questions for the dataset. Content expert Lisa Kearns, who is a Research Associate at NYU's Medical Ethics Department, then provided feedback on the questions as they were finalized.

   b. **Coding Rules:**
      i. Generally:
         1. "Investigational product", "Investigational drug", and "Biological device" were treated as the same when coding
      ii. "Does this state have a right to try law"
         1. "Yes" is only coded when the Right to Try law is currently in effect
      iii. "How is 'terminal illness' defined?"
         1. "Death must be imminent" was coded when the law stated that death must occur in the near future, or death must occur in a relatively short amount of time
      iv. "What are the criteria for a patient to be eligible for access to investigational products?"
         1. When the law states that a patient is required to consider clinical trials in their state, researchers coded "Patient is unable to participate in a clinical trial"
      v. Citing affirmative "no" responses
         1. Whenever the law provided an affirmative "no" response to a question being coded, that portion of the law was cited.

VI. **Quality Control**

a. **Quality Control – Background Research:** When collecting laws, all jurisdictions with a Right to Try law currently in effect (31 jurisdictions) were redundantly researched, to ensure accuracy.

b. **Quality Control – Coding:**
   i. Redundant coding: The thirty jurisdictions with Right to Try laws were divided into three batches of ten jurisdictions. After divergences were identified, they were discussed by the project team and resolved.
      1. The first batch (AL, AR, AZ, CO, FL, GA, ID, IL, IN, ND) was redundantly coded at a rate of 100%. A total of 11 records were redundantly coded, and there were 16 divergences out of 176 potential divergences, for a divergence rate of 9.09%.
      2. The second batch (LA, ME, MI, MN, MO, NV, OR, TX, VA, and WV) was redundantly coded at a rate of 100%. A total of 10 records were redundantly coded, and there were 5 divergences out of 160 potential divergences, for a divergence rate of 3.125%.
      3. Because the divergence rate in batch 2 was below 5%, only 20% of records in batch 3 were redundantly coded (MI and NH). These records were randomly selected by a supervisor. There was 1 divergence out of 32 potential divergences, for a divergence rate of 3.125%.
      4. Connecticut was separately coded as its law was made effective on October 1, 2016. The record was redundantly coded, and had 1 divergence out of 16 potential divergences, for a divergence rate of 6.25%
   ii. **Post-production Quality Control:**
      1. To verify the reliability of the data, a sample of 87 unique coding instances were selected and redundantly coded by a researcher who was naïve to the dataset. Of those 87 instances, 43 were checks on coding records in "yes" states with substantive responses. There were 0 divergences in this final check.