**Section I:**

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| **Department:** **Principal Investigator:**   Email Address:  Phone Number: **Alternate Contact:**  Email Address:  Phone Number: **Has the PI previously worked with a statistician at the Center for biostatistics:****Are you seeking external Funding:** If yes, please list type of funding & funding organization: If yes, what is the submission deadline for funding :**Preferred Deadline:**  |

**Section II:**

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| **Study Title*:*** *The Role of Buprenorphine Waivers for Infectious Disease Physicians on Hepatitis C treatment***Background and Rationale:**Please provide a brief description of background information and rationale pertaining to this study. Additionally, please provide up to 4 applicable references. *This clinical trial will explore the effect of buprenorphine waivers obtained by infectious disease physicians on the successful treatment of hepatitis C virus.***Objectives (Hypothesis):** Please provide a brief description of the primary & secondary objectives of this study.* **Primary Objective**: *To evaluate the effectiveness of buprenorphine waivers on treating hepatitis C virus (HCV) for the population with injection drug use (IDU)-associated HCV infection.*
* **Secondary Objective:** *To evaluate the effectiveness of buprenorphine waivers on treating opioid use disorder (OUD) problems or IDU-related risk behavior.*

**Endpoints:** It is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. * **Primary endpoint:** *The percentage of hepatitis C patients who are successfully treated in each clinic*
* **Secondary endpoint:** *OUD suppression rate (no indication of OUD in consecutive 12 months) in each clinic; the percentage of patients in each clinic who get OUD treatment medicine; IDU-related risk score.*

**Study Population:** Inclusion and exclusion criteria.*The clinics will be randomly assigned to treatment or control groups by block randomization. Randomization will be stratified by region of the US and clinic size. The study population will be infectious disease physicians who typically treat a patient population with a history of infectious**disease, intravenous drug use, or other risky behavior related to the contraction of infectious disease.***Additional Information (Data):** For example, ICD9/ ICD10 codes for HCUP data**Clinical Trial or Observational Study:** **Study Design:**Please provide a brief description of the study design (i.e. how many arms, is this prospective or retrospective study, observational or randomized, etc.).**Future Direction/Goals:**Please describe the ultimate goal of the study and potential future directions of the work. **Other:**Is there any other information pertaining to the study that may be important? **Is there any patients’ data privacy agreement that we need to fulfill?** |