

SUBJECT

Subject Name/Initials _____ Date of Birth ____/____/____

Diagnosis _____ Treating Physician _____

Enrolling Site _____ Medical Record Number(s) _____

ENROLLMENT

Sponsor _____ Registered with external sponsor? Yes N/A

To which treatment assignment is this subject being enrolled? _____

Must match the Treatment section in OnCore

ELIGIBILITY

Screening Staff

This subject is [**eligible**/ **ineligible** / **eligible with exception**]. Please check the appropriate boxes below.

| | |
|-------------------------------------|-------|
| Signature: | Date: |
| Printed Name (include credentials): | |

Eligibility Exception (Required only if eligibility exception granted for this subject)

| | |
|---|--|
| OHRs Other Event # for Eligibility Exception | |
| IRB Approval Date for Eligibility Exception | |
| Sponsor Approval Date for Eligibility Exception | |

Enrollment Monitor

The subject's eligibility was verified per DF/HCC REGIST-100 (when applicable).

| | |
|---------------|-------|
| Signature: | Date: |
| Printed Name: | |

| | |
|--------------------|--------------------------------|
| DF/HCC Protocol #: | Date Posted for Use: |
| | Last Revised with OHRs Review: |

3.0 Research Subject Selection

We will recruit 1000 subjects seeking an alternative to the pressures and commercialism of the holiday season. Patients without an alternative holiday to celebrate are still eligible to participate in the study. Patients will be randomized in a 1:1 fashion, stratified by age and BMI.

3.1 Patient Eligibility Criteria

Inclusion Criteria:

- 1. Must have a very high strength-to-weight ratio, as determined by the treating physician.
- 2. Must have expressed a desire to air grievances towards others.
- 3. Must be easily distracted by tinsel.
- 4. Age \geq 18 years
- 5. Willing and able to provide informed consent

Exclusion Criteria:

- 1. Allergy to aluminum.
- 2. Inability to swallow meatloaf served on a bed of lettuce.
- 3. Currently employed by H&H Bagels. Previous employment at H&H Bagels is allowed.
- 4. Eastern Cooperative Oncology Group (ECOG) Performance Status $>$ 2 or other physical limitation that would contraindicate participation in feats of strength.

4.0 Research Subject Entry

The research team will approach customers outside of H&H Bagels and ask a short, verbal series of pre-screening questions. Subjects who meet the pre-screening criteria will sign the IRB-approved informed consent document and be provided with a check for \$20,000 made out to the Human Fund. Subjects will be required to attend a celebratory dinner at a predetermined time and location in New York City.

We are requesting a HIPAA Waiver of Authorization to pre-review subject medical records in order to screen medical charts for strength-to-weight ratios and exclusionary allergies. This waiver is being sought solely to review Protected Health Information as necessary to prepare a research protocol; will not include removing Protected Health