1. PURPOSE

1.1. This policy describes the information recorded in IRB rosters.

2. POLICY

2.1. Note on the IRB roster:
2.1.1. The IRB registration number
2.1.2. The IRB registration name
2.1.3. Any restrictions on the IRB’s scope
2.1.4. Effective date of the roster
2.1.5. If the roster is inactive, the end effective date of the rosters
2.1.6. If the IRB was deactivated, a note to that effect

2.2. For each IRB member record:
2.2.1. Name
2.2.2. Earned Degrees
2.2.3. Gender
2.2.4. Scientific Status
2.2.4.1. Whether the IRB member has primary interests in scientific or non-scientific areas: S (Scientific) or NS (Non-scientific)
2.2.5. Representative Capacity
2.2.5.1. Populations about whom the IRB member is knowledgeable or experienced. (e.g., children, prisoners)
2.2.5.2. If the member represents the general perspective of subjects, note this.
2.2.6. Indications of Experience
2.2.6.1. Brief description that describes the IRB member's chief anticipated contributions to IRB deliberations, such as profession, certifications, licensure, IRB experience, research experience, or life experience.
2.2.7. Affiliation Status
2.2.7.1. Whether the IRB member or an <Immediate Family> member of the IRB member has a relationship with the [Organization]: A (Affiliated) or NA (Non-affiliated)
2.2.7.2. Note that an IRB member may have no relationship to the [Organization], but the IRB member may be affiliated because an <Immediate Family> member may have a relationship with the [Organization].
2.2.7.3. When applicable, a description of the relationship to the [Organization].
2.2.8. Office
2.2.8.1. Whether the IRB member is an IRB chair, IRB vice-chair, or other appointed office.
2.2.9. Membership Status
2.2.9.1. Whether the IRB member is a regular member or an alternate member.
2.2.10. Alternates For
2.2.10.1. If the member is an alternate member, the class of IRB members for whom the member can alternate.

2.2.11. Designated Reviewer

2.2.11.1. Whether the member is a <Designated Reviewer>

3. REFERENCES

3.1. 21 CFR §56.115(a)(5)
3.2. 45 CFR §46.103(b)(3)