# Reviewing Research Participant Payments Through a Diversity Lens

Whether and how a participant is compensated for taking part in a clinical study are two of the decisions an institutional review board (IRB) makes when approving research. The IRB must ensure participants are not unduly influenced to join the research and that the research is just, beneficial, and the participants are respected. Participant payments can include reimbursement of reasonable expenses for travel to and from the research site, fair compensation for the participant's time, effort, burden, and inconvenience, token payments of appreciation, etc. A detailed description and analysis of participant payments was carried out by the Secretary's Advisory Council on Human Research Protections (SACHRP),[1] and this article uses the terms described by SACHRP.

**Protecting Clinical Trial Participants**

IRBs are tasked with protecting the rights and welfare of research participants. IRBs came into being as a result of the Belmont Report.[2] The Belmont Report established three ethical principles: justice, beneficence, and respect for persons. These principles form the basis of the U.S. Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) regulations governing research with human participants. Both agencies publish guidance to help IRBs interpret the regulations. In 2022, the DEPICT Act was passed, requiring applications to the FDA for an investigational use exemption for new drugs and devices "to include information about the demographic diversity of the clinical trial population and addresses related issues."[3]

The three pillars of the Belmont Report are broad concepts. IRBs have further refined respect for persons to focus on the idea of autonomy. This concept undergirds ideas around informed consent and freedom from undue influences. Participant payments have historically been viewed through the lens of undue influence and that has led IRBs to minimise payments in order to allay those concerns.

More recently, scholars[4] and SACHRP have published work supporting the idea that lowering payments does not decrease undue influence. In fact, they report that this approach can negatively impact respect for persons by failing to acknowledge the full context of participants' lives and the sacrifices in time and effort they must make to participate in a research study.

Research should also be just. The burdens and benefits of research should be accrued by all. As outlined in the DEPICT Act, the industry has fallen short of ensuring that research participant populations reflect the general population, and this is a failure of justice as well as science. As IRBs evaluate diversity plans, one area warranting particular attention is participant payment or compensation.

Appropriate payment to research participants is critical for diversifying clinical research participation. When payments and reimbursements to research participants are limited, those who have less free time, less available income, or more burdensome lives are less likely to participate, resulting in a study with a participant population that does not reflect society. Sponsors, sites, and IRBs all play a role in approving participant payment plans, but payment structures are often not transparent, and decisions may be made without a deep understanding of how differences in payments affect participant enrollment and retention.[5]

**Data Analysis of Participant Payment Plans**

To explore how participant payment plans have been structured and described to potential participants, we conducted a systematic review of research payment plans during the past five years. We analysed the participant payment language from more than 7,500 site-level consent forms reviewed by an IRB between 2019 and 2024 in a wide variety of therapeutic areas across the U.S. The analysis was carried out using artificial intelligence (AI) to efficiently summarise this large data set. Trends and patterns in compensation are described, creating a baseline data set.

**Methods**

SACHRP published recommendations on participant payments, including commentary on FDA and OHRP guidance documents, in 2019. Its analysis provides a framework for thinking about undue influence and how different types of payments to participants can be categorised.

Common sense business terms are used in site budgets to describe participant payments. But there is no consistency in how the industry applies terms such as stipend, compensation, and participant payment. The following summary in Table 1 combines the SACHRP recommendations and a sponsor's experience in the space and reflects the concepts featured in the data analysis.[6] This underscores the need for standardisation and consistency in terminology.[7]

We started this study with 14,000 documents, which included extracts of payment information from each site for a given clinical trial that had been reviewed by the IRB. The documents were developed as part of the normal IRB operations to provide the board with a summary of the previously approved payments for a given study. The documents included unique site identifiers and investigator surnames in addition to the specific payment language from the informed consent document. This identifying information has been removed from this analysis, and only aggregate results are reported.

Once this data set was produced, we extracted payment language, terms, and components including payment amounts from the data using ChatGPT4. Average payments per visit were extracted, and they were allocated to various categories such as meals, travel, stipends, etc.

| Payment Term | Definition | Concern about Undue Influence | SACHRP | Common Payment Terms Analysis |
|---|---|---|---|---|
| Payment | Term used to show that research participants may be paid for time, effort. | Maybe | X | X |
| Stipend | A fixed sum of money paid periodically for services or to defray expenses. | Maybe | | X |
| Reimbursement | Reimbursement for out-of-pocket expenses. | No | X | X |
| Meals | | No | | X |
| Travel | | No | | X |
| Caregiver | | No | | X |
| Compensation | Compensation addresses the participant's contribution of time and acceptance of research-related burdens and inconvenience, as distinguished from the out-of-pocket costs addressed through reimbursement. | No | X | X |
| Appreciation | Small payments or gifts that are not intended to meaningfully reimburse or compensate study participants. | No | X | X |
| Incentive Payment | Payments beyond compensation for time and effort intended to encourage study recruitment and retention. | Yes | X | |
| Completion Bonus | Payments beyond compensation for time and effort intended to encourage study recruitment and retention. | Yes | X | X |

*Table 1: "X" represents the inclusion of this payment term in a given analysis.*

Originally, we intended to calculate the total amount of compensation over the course of the trial. After a first refinement of the data, we realised that most payment language was structured as "per visit." To calculate total compensation across the trial, the total number of visits would be needed. Given the wide variety of ways in which study visits were described in other sections of the protocol and informed consent document, we abandoned this effort, and concentrated on per visit compensation. The output from seven training cases was reviewed in detail to confirm that the system was correctly identifying payment terms. It took just over one hour of researcher time to analyse the payment document and accompanying data for the seven training cases using traditional methods.

The documents were then matched to IRB site meta data to create the full data set. Because investigators change over time, we were unable to match all the studies to facility information, and we reduced our list of analysed documents to about 7,500 for analyses involving site location data, i.e., facility type and zip code. Figure 1 is a representation of the process.

Of significant note, before delving into the data analysis, is the uncertainty in terminology usage when describing certain payments. It cannot be discerned how certain sponsors are using the term stipend, while others opt to provide payment for time or effort as compensation. While stipend is commonly used across the industry and appears in the data set, it is not a recommended term because it combines expenses and payment for services. Meanwhile, with the term participant payment it likewise cannot be discerned whether this is a separate payment for time and effort or if it includes reimbursement for expenses.

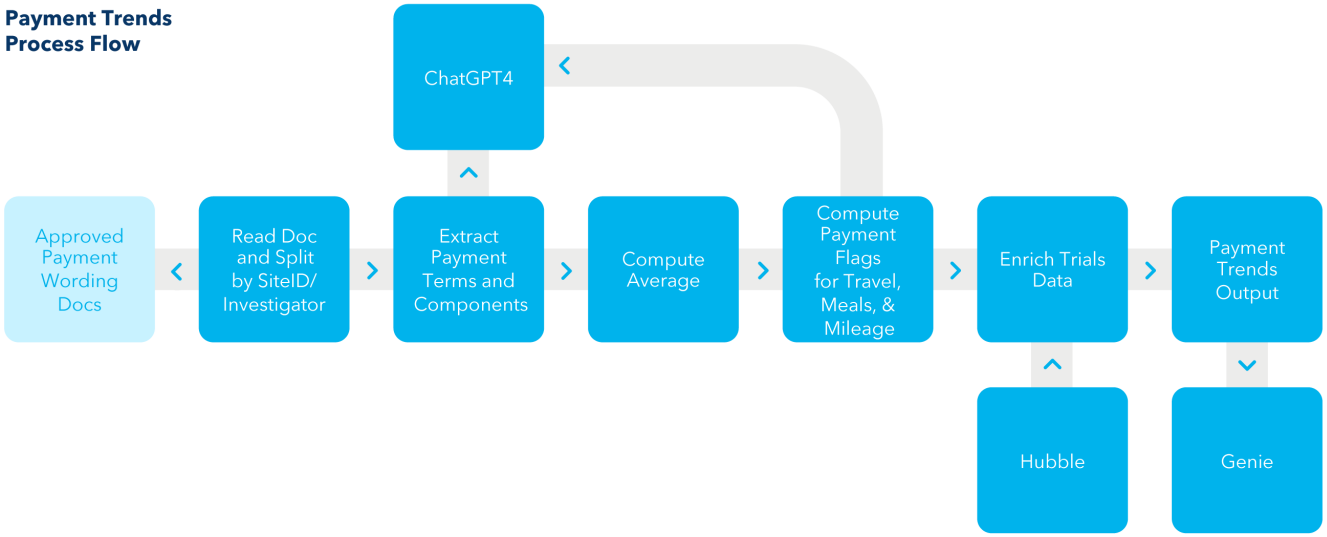


*Figure 1. Hubble is a central internal data repository used to match the results to clinical trial level meta data. Genie[8] is a conversational natural language interface employed to facilitate analysis of the results.*

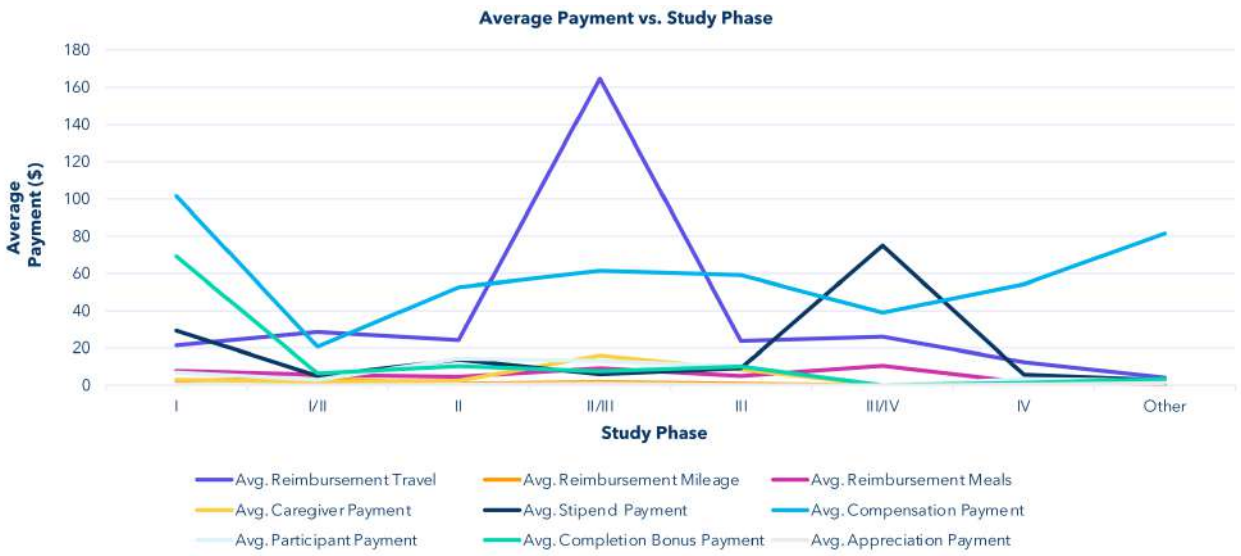


*Figure 2*

As such, the amounts allocated as stipend, compensation, and participant payment may include reimbursement amounts if that is how the language was used in the consent documents. More importantly, separating expense reimbursements from payments for time, effort, burden, and inconvenience (compensation) helps distinguish true income from expenses for tax reporting purposes. This is crucial for participants who may decline to participate for fear of losing SNAP (Supplemental Nutrition Assistance Program) benefits because they may exceed the income threshold.

In summary, this is a call to action for the industry to agree on standards with respect to participant payments by (a) aligning on terminology for payment categories, and (b) separating reimbursements for expenses from compensation for time, effort, burden, or inconvenience. This will help alleviate some impact of the financial burden on research participation.

**Results**

**Prompt A:**

Find the average payment of each payment type based on the phase

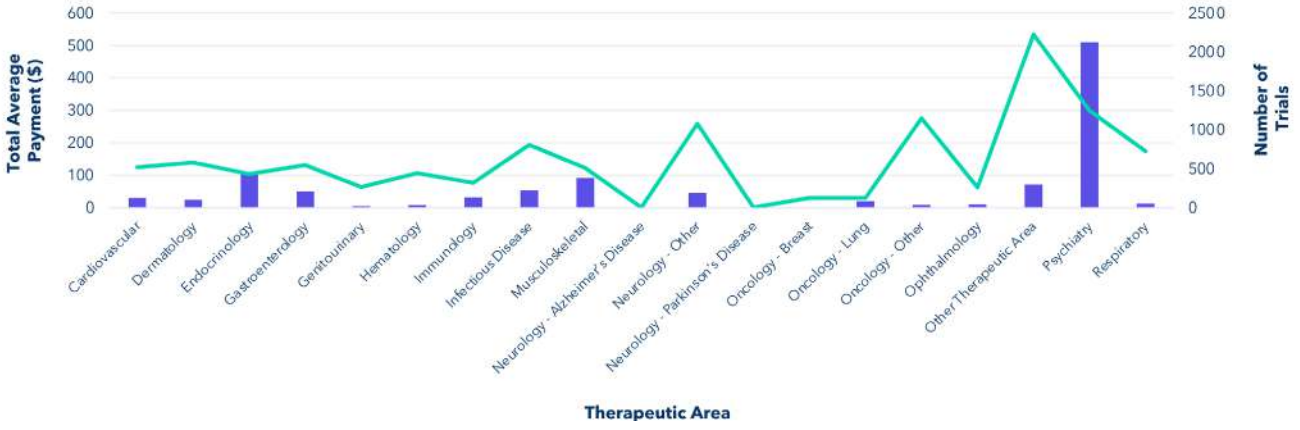


*Figure 3*

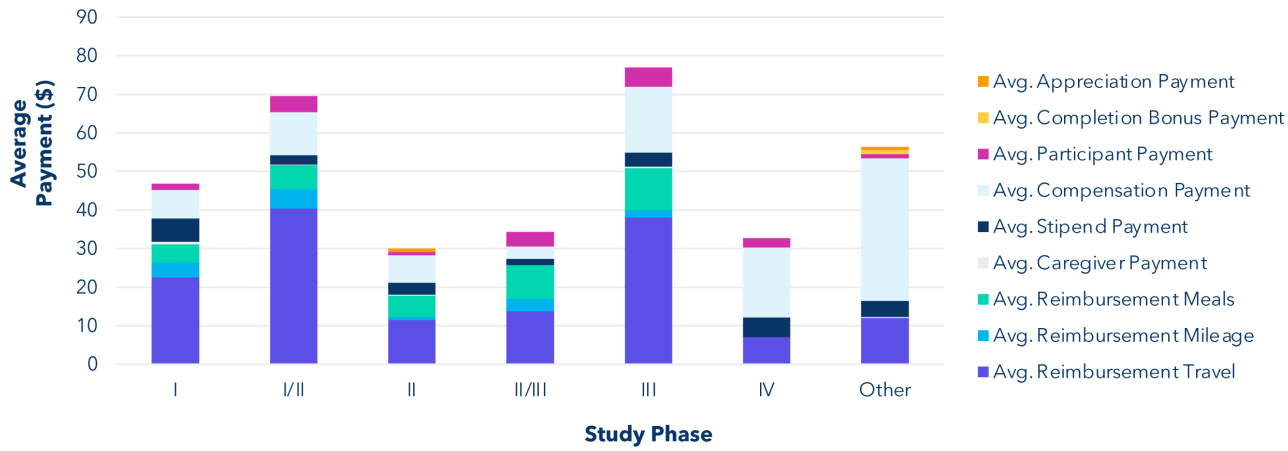


*Figure 4*

of the study. Ignore the rows where phase field contains the string "null." Add a new column to the table showing how many rows have that phase. The phase values in the table should follow the order: I, I/II, II, II/III, III, III/IV, IV, Other.

**Key Insights**

The highest total compensation is clustered around phase I and phase III/IV studies. "Other" studies are primarily composed of a mix of medical device trials, and any other research study that is not a clinical trial involving a drug, and which does not have a phase. The highest total average payment based on aggregate data is for travel reimbursement.

**Prompt B:**

Find the total average payment across different therapeutic areas. Ignore the rows where the therapeutic area field contains the string "null" or "Not Specified." Add a new column to the table showing how many rows have that therapeutic area.

**Key Insights**

There is a wide range of compensation paid per visit for different therapeutic areas. Psychiatry trials represent the high end of this range and breast cancer trials represent the low end. The psychiatry category includes several in-patient, healthy-participant trials with larger than average payments and larger completion bonuses due to the nature of those studies. In future work, we intend to examine trends within therapeutic areas, but we did focus on oncology trials which make up more than 12% of all trials in the data set. Additionally, we have received anecdotal information from both sites and sponsors that they believe IRBs do not approve payments for oncology trials.

**Prompt C:**

Provide average payment for each payment term for various phases of studies where the therapeutic area contains the string "Oncology." Ignore the rows where the phase field contains the string "null." Add a new column to the table showing how many rows have that phase. The phase values in the table should follow the order: I, I/II, II, II/III, III, III/IV, IV, Other.

**Key Insights**

While average payments for oncology trials are on the lower end, we do see several payment categories for oncology participants across all phases of studies. We hope this data serves to dispel the myth that IRBs do not approve payments for oncology trials.

**Conclusions**

Using ChatGPT4, we were able to analyse five years of data from an independent IRB. In 2023, this IRB participated in reviews of more than 90% of drugs approved by the FDA. The full data set involved more than 7,500 records. It allowed us to determine both the types of payments being offered to participants and how they were described in informed consent documents. We also learned how payments varied across study phases and therapeutic areas. We hope to provide access to this baseline data set to help sponsors and sites design trials with just and inclusive payments for participants to better reach underserved populations, increase access, and achieve more diversity in clinical trials.

**REFERENCES**


1. Attachment A – Addressing Ethical Concerns Offers of Payment to Research Participants. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html
2. The Belmont Report. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
3. DEPICT Act. https://www.congress.gov/bill/117th-congress/house-bill/6584
4. Largent EA, Lynch HF. 2017. Paying Research Participants: The Outsized Influence of "Undue Influence." IRB 39(4):1–9. PMID: 29038611; PMCID: PMC5640154
5. Anderson, E. E., & Brown, B. (2021). A Call for Radical Transparency Regarding Research Payments. The American Journal of Bioethics, 21(3), 45–47. https://doi.org/10.1080/15265161.2020.1870763
6. Unpublished work by Donna Libretti Cooke.
7. https://mrctcenter.org/wp-content/uploads/2024/05/Toward-a-National-Action-Plan-for-Achieving-Diversity-Clinical-Trials-240502_FINAL.pdf
8. https://wiki.genie.stanford.edu/en/getting-started/intro-genie



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